Translators of Patient Information Leaflets: Translation experts or expert translators?

A mixed methods study of lay-friendliness

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Table of Contents

Summary 1
Statement of Candidate 3
1. Introduction 5
1.1. Why Patient Information Leaflets? 5
1.2. Aim and scope 6
1.3. Framework 7
1.4. Research question and research design 7
1.5. Contribution of dissertation 9
1.6. Delimitation 10
1.7. Dissertation structure 10
2. Understanding Patient Information Leaflets and motivating the dissertation 13
2.1. Institutional context of PILs 13
2.1.1. The process of PIL production 14
2.1.2. EU initiatives linked to lay-friendliness in PILs 15
2.1.3. EU legislation linked to translation 17
2.1.4. Summing up institutional context 24
2.2. Communicative situation of PILs 26
2.2.1. Summing up communicative situation 27
2.3. Lay-friendliness 28
2.3.1. Questions of nomenclature 28
2.4. Literature review of PILs 29
2.4.1. The importance of PILs 29
2.4.2. Complexity of PILs 30
2.4.3. Conclusion of literature review - research gap 35
3. Translation-theoretical chapter 37
3.1. Translation Studies 38
3.2. Towards a definition of translation? 40
3.3. Different approaches to translation 41
3.3.1. Equivalence-based approaches 41
3.3.2. Functionalist approaches to translation - introduction 42
3.3.3. Other approaches 43
3.4. Different approaches within functionalism 44
3.4.1. Translatorisches Handeln – translatorial action 44

3.4.2. Skopos theory 45
3.4.3. Translation-oriented text analysis and *loyalty* 46
3.5. Main assumptions within functionalist approaches 46
3.5.1. Translator as responsible agent and expert 46
3.5.2. The translation brief 47
3.5.3. *Dethronement* of source text 48
3.5.4. Contingent translation quality 48
3.6. Criticism of functionalism and response 48
3.6.1. Functionalism – realistic or idealistic? 50
3.7. Functionalism and its relevance for PIL translation 51
3.7.1. The skopos of PIL translation 52
3.7.2. Summary of functionalism and its relevance for PIL translation 53
3.8. Conclusion - Two diverging approaches to translation 53
4. Methodology 57
4.1. Research approaches within Translation Studies 58
4.2. Pragmatism - "What works" 59
4.2.1. Pragmatist approaches within Translation Studies 61
4.2.2. Pragmatism and methods 63
4.3. Mixed methods research designs 63
4.3.1. Strengths and weaknesses of mixed methods research 65
4.4. Research design of this dissertation 66
4.4.1. Study 1: Translation competence and Danish PIL translators 68
4.4.2. Study 2: PIL translation choices made by pharmacists and professional translators 69
4.4.3. Study 3: Focus groups with professional translators and pharmacists 70
4.4.4. Part 4: Synthesis of findings 70
5. Translation competence and Danish PIL translators 71
5.1. Translation Competence 71
5.1.1. PACTE's competence model 73
5.2. Research design of study 1 77
5.2.1. Results 78
5.2.2. Profiles of Danish PIL translators 79
5.2.3. Mapping the five sub-competences against the two translator profiles 80
5.2.4. Discussion of mapping against literature review of medical translators 82
5.3.5. Conclusions of mapping 85

5.3. Conclusion....86
6. PIL translation choices made by professional translators and pharmacists....89
6.1. Research design of study 2....90
6.1.1. Experimental vs. naturalistic study....90
6.1.2. Comparative analysis of PIL corpus....92
6.1.3. Analysis method....96
6.1.4. Literature review of methods used to assess textual complexity in PILs....99
6.1.5. Introducing Plain Language as an operationalization of lay-friendliness....104
6.1.6. Towards a lay-friendliness framework....108
6.1.7. Analysis....119
6.2. Results....123
6.2.1. Analytic framework after commencement of analysis....123
6.2.2. Comparing the pharmacist and professional translator corpora....130
6.3. General discussion of study 2....148
6.3.1. Literal translation choices....148
6.3.2. Limitations of study....153
6.3.3. Functionalism revisited....155
6.3.4. Lay-friendliness revisited....156
6.3.5. Contextual constraints....157
6.4. Conclusion of study 2....158
6.5. Transition to next chapter....159
7. Focus groups with professional translators and pharmacists....161
7.1. Research design of study 3....162
7.1.1. The focus group method....162
7.1.2. Planning the focus group....165
7.1.3. Conducting the focus group....169
7.2. Analysis....171
7.2.1. Transcription....171
7.2.2. Analysis procedure....172
7.3. Results....174
7.3.1. Lay-friendliness....174
7.3.2. The approach to translation and the translators' ability to operationalize it....189
7.3.3. Contextual constraints which might influence the translation process....206
7.4. Discussion and conclusions....227

7.4.1. Lay-friendliness 227
7.4.2. Translation 229
7.4.3. Contextual constraints 232
7.4.4. Limitation of focus group study 235
8. Discussion and conclusion 237
8.1. Translation competence 237
8.2. Translation approaches 241
8.3. Contextual constraints 243
8.3.1. PIL templates 243
8.3.2. Status of source text 243
8.3.3. Time constraints 244
8.3.4. Competing skopoi 244
8.3.5. Institutional linguistic usage 245
8.3.6. Extensive amendments 245
8.3.7. Lack of language awareness from client 245
8.3.8. Linguistic review at the Danish Health and Medicines Authority 246
8.4. Expertise and power 246
8.4.1. The translator as expert 246
8.4.2. Power relations in PIL translation 248
8.5. Overall conclusions 251
8.6. Contributions 251
8.6.1. Translation Studies 251
8.6.2. Methodological contributions 253
8.6.3. Professional applicability of the research 254
8.6.4. Social applicability of the research 254
8.6.5. Policy perspectives 255
8.7. Future research perspectives 256
9. Lists of tables and figures 257
9.1. List of tables 257
9.2. List of figures 257
10. References 259
11. List of appendices 275
Appendix 1: Danish PIL template 276
Appendix 2: English PIL template 285

Appendix 3: QRD form 1 293
Appendix 4: QRD form 2 296
Appendix 5: Email to pharmaceutical companies - study 1 299
Appendix 6: Final ethics approval 301
Appendix 7: Ethics amendment approval 306
Appendix 8: Recruitment email - focus group 309
Appendix 9: Background question sheet - translator 311
Appendix 10: Background question sheet - pharmacist 312
Appendix 11: Preparation email for translators 313
Appendix 12: Preparation email for pharmacists 315
Appendix 13: Consent form 317
Appendix 14: Interview guide 319
Appendix 15: Handout with examples for focus group participants 326
Appendix 16: Key word posters 330
Appendix 17: Transcription of focus group – translators 332
Appendix 18: Transcription of focus group - pharmacists 333

Summary

Patient Information Leaflets (PILs) are mandatory texts in the EU accompanying all medication. They must inform users about dosage, side effects, etc. in order to foster informed decision-making and patient empowerment. By its nature, the PIL genre is complex aiming at instructing lay people about complex medical content, i.e. mediation of specialized medical knowledge across a knowledge asymmetry. Legally, PILs must be "written and designed to be clear and understandable" (Article 63(2) of EU Directive 2001/83/EC, European Parliament and of the Council, 2001), here termed "lay-friendly"; however, many studies have shown that PILs are generally difficult to understand for laypeople.

Askehave & Zethsen found in their 2002 study that translated Danish PILs are linguistically more complex than their English source texts. One possible explanation could be that PILs are frequently translated by pharmacists, who do not possess the linguistic tools and translation knowledge necessary for expert-to-layman translation or interlingual translation. This PhD explores this by use of a mixed methods research design involving three empirical studies:

1) The first study identifies Danish PIL translators as professional translators and pharmacists, and it maps these profiles against a model of translation competence and a literature review of research on medical translators. The outcome of this study is the hypothesis that *Pharmacists – compared to professional translators - lack translation competence in relation to lay-friendly PIL translation.*

2) The second study aims to explore the above hypothesis by identifying possible differences in two translation corpora of pharmacists and professional translators in terms of lay-friendliness. The analysis of the two corpora uses a contrastive linguistic framework focussing on elements such as the use of nominalization, compounds nouns and medical terminology. Results show that both corpora contain many instances of literal translation choices to the detriment of lay-friendliness and choices leading to increased complexity. However, in the pharmacist corpus, significantly more Latin-based terms and nominalizations are found than in the professional translator corpus.

3) The third study seeks to gain an understanding of the reasoning behind the translation strategies used in PILs by conducting two focus groups with professional translators and pharmacists, respectively. Results show that the lack of lay-friendliness in PILs is not mainly linked to lack of translation competence or intratextual reasons, but extensively to contextual constraints such as tight deadlines for translation, poor mandatory templates and authoritative bodies and reviewers with limited interlingual and intralingual translation knowledge.

References

Askehave, I., & Zethsen, K. K. (2002). Translating for Laymen. *Perspectives: Studies in Translatology, 10*(1), 15-29.

European Parliament and of the Council. (2001). *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001*.

Statement of Candidate

I certify that the work in this thesis entitled “Translators of Patient Information Leaflets: Translation experts or expert translators? A mixed methods study of lay-friendliness” has not previously been submitted for a degree nor has it been submitted as part of requirements for a degree to any other university or institution other than Macquarie University and Aarhus University - Cotutelle.

I also certify that the thesis is an original piece of research and it has been written by me. Any help and assistance that I have received in my research work and the preparation of the thesis itself have been appropriately acknowledged.

In addition, I certify that all information sources and literature used are indicated in the thesis.

The research presented in this thesis was approved by Macquarie University Ethics Review Committee, reference number: Ref No. 5201200159D on 24 May 2012.

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1. Introduction

This chapter introduces the background of the dissertation in order to briefly situate the unit of analysis, i.e. the Patient Information Leaflet (PIL), in its real-life environment as an important functional genre, and also in its research environment. Against this backdrop, the aim and scope of the dissertation will be introduced as well as the main field within which this study is carried out, i.e. Translation Studies. The main research question is presented and based on this, the approach to research and the overall research design. I briefly introduce the contributions and delimitations of this study before an overview of the eight dissertation chapters is given.

1.1. Why Patient Information Leaflets?

In recent times, there has been an increased focus on the importance of health communication, especially the communication of health matters to lay people, or the general public. Patients want sufficient information to make informed choices whether to go ahead with an operation, take a specific medication etc., and they want the communication of this information to be directed at them, and they want it to be written in an understandable manner. This demand for patient information and communication is not only seen as coming from patients, but there is also a societal push to involve patients in their own health. Consequently, in recent years, the concepts of patient empowerment (e.g. Askehave & Zethsen, 2010; Dixon-Woods, 2001; Holmström & Röing, 2010) and patient-centred communication (Bensing, 2000; Fage-Butler, 2011b; Mead & Bower, 2000) have become increasingly popular. Patient communication and information are often linked to ensuring informed decision-making, but also linked to the idea that informing patients aims at optimising the use of a medicine (Raynor, 2007, p. 60), and ensuring safe, effective and appropriate use when the decision has been made to take it (Raynor & Dickinson, 2009, p. 700). As a result of this demand for patient information and involvement, during the past 15 years, a great amount of legislation has been passed, and many new patient communication genres have come into existence. One of these genres is the Patient Information Leaflet (PIL) which came into existence as a legal genre in 1992 (fully adopted in 1999) (Council of the European Communities, 1992). The PIL is said to be the most important source of information about a medication for the patient (Bjerrum & Foged, 2003, p. 58), and most patients read PILs (Askehave & Zethsen, 2000b, forthcoming; Horwitz, Reuther, & Andersen, 2009). Despite its legal requirement to be “written and designed to be clear, understandable and enable the users to act appropriately” (Article 63(2) of EU Directive 2001/83/EC, European Parliament and of the Council, 2001), a growing mass

of research shows that a large amount of PILs are still today linguistically complex and difficult to understand for lay people (Askehave & Zethsen, 2000a, 2000b, 2002, 2003; Clerehan & Buchbinder, 2006; Consumers' Association, 2000; Dickinson, Raynor, & Duman, 2001; Harwood & Harrison, 2004; Horwitz, et al., 2009; Lægemiddelstyrelsen, 2004; Pander Maat & Lentz, 2010; Raynor, 2007; Zethsen & Askehave, 2010), which is of course in direct contrast to the function and purpose of the genre.

Research focus has almost exclusively been on the English-language PIL. However, a complication that can further challenge linguistic complexity in PILs is translation. A study conducted by Askehave & Zethsen, based on textual analysis, has shown that Danish PILs translated from English are more complex than their source texts (Askehave & Zethsen, 2002). Askehave & Zethsen analysed the nature of the increased complexity and offer several explanations for this phenomenon, for example the fact that the PIL is a mandatory, and therefore extremely regulated, genre (Askehave & Zethsen, 2003), and also that there might be competing interests between (1) providing correct and lay-friendly patient information and (2) ensuring a fast and smooth approval procedure by staying close to the source text (Askehave & Zethsen, 2002, p. 28). Perhaps the most important explanation, according to Askehave & Zethsen, is that many PILs are translated by pharmacists, who may not have the necessary translation skills, and they venture the hypothesis that these pharmacist-cum-translators revert to the expert register they know, even when the English source text does not use such register (Askehave & Zethsen, 2002, p. 28). In the study by Askehave & Zethsen, it was not systematically investigated to what extent Danish pharmaceutical companies use pharmacists for their translation of PILs, and therefore, no empirical research has been conducted into the translation choices and competence of pharmacists versus professional translators in relation to linguistic complexity in translated PILs.

1.2. Aim and scope

This dissertation thus aspires to research the translation phase of the PIL production with a special focus on investigating who the translators of PILs are and whether the profiles and the competences of these PIL translators[1] could be linked to the increase in complexity that occurs during the translation phase. Overall, this dissertation aspires to investigate whether the lack of easy-to-understand language in translated PILs could be linked to the nature of the

[1] In this dissertation, *PIL translators* refers to any kind of (de facto) translator who translates PIL. When the PIL translators are identified as *pharmacists* and *professional translators*, these labels will be used when taking about the separate types of translators.

PIL translators as it has been assumed that PILs are generally translated by pharmacists with no language or translation skills (Askehave & Zethsen, 2002, p. 24) as opposed to professional translators. This aim is linked to a motivation to work towards PILs becoming easier to understand for lay people in the future, i.e. making them more *lay-friendly*; an aim that can only be achieved if the reasons why they are not presently optimal from a comprehensibility point of view are uncovered.

1.3. Framework

This dissertation is written within the main discipline of Translation Studies, but as will become apparent, with inspiration from other fields such as Health Communication, Linguistics and Plain Language. Translation Studies encompasses several approaches, and before it is possible to carry out an analysis to determine whether translator background has an impact on the complexity of the translations, the approach to translation needs to be discussed. Communication is here viewed as a dynamic, contextually bound process, which means that the receiver plays an important part. This overall approach to communication fits well with the functionalist approach to translation where translation is viewed as a functional activity and focus is on the receiver of the communication and the purpose of the translation. The functionalist approaches to translation will be further presented later in the thesis.

Furthermore, this dissertation places itself within the *patient-centred* approach to health communication. Patient-centredness is an established way of considering the practice of health communication, and grew out of a frustration with and as a counterpart to the biomedical paradigm as a default communicative paradigm within health communication (Bensing, 2000; Mead & Bower, 2000). Patient-centeredness is a communicative and ethical movement in health communication theory aiming to respecting the patient and his/her knowledge, experiences and emotions (e.g. de Haes, 2006; Duggan, Geller, Cooper, & Beach, 2006). Thus, instead of investigating PILs and their complexity from the point of view of the biomedical paradigm where the main goal is often compliance, PIL complexity is investigated for the purpose of ensuring better informed and satisfied patients, by providing them with material to support decision-making.

1.4. Research question and research design

To fulfil the aims stated above, the dissertation has the following overall research question:

> *Does the profile and translation competence of PIL translators influence the linguistic complexity of translated PILs?*

As will be seen below, this dissertation follows a pragmatic approach using a sequential mixed methods design with three studies, and therefore, the research questions will continually evolve and become more specific based on the findings in each of the three studies as these three studies build on each other (see below).

This thesis is placed within the pragmatist research paradigm, which "sidesteps the contentious issues of truth and reality, accepts, philosophically, that there are singular and multiple realities that are open to empirical inquiry and orients itself toward solving practical problems in the ''real world'"" (Feilzer, 2010, p. 8). Pragmatism thus focuses on the research interest and chooses research questions, framework and methods that best investigate this interest with a focus on practical consequences. A mixed methods design was chosen because neither a quantitative nor a qualitative approach in itself is adequate to understand my research problem as both explanatory and exploratory approaches are needed. Mixed methods research is accepted within empirical Translation Studies and even encouraged (Hansen, 2005a, 2005b, 2008a). Being a young and multidisciplinary discipline, Translation Studies does not have a fixed set of methods readily available to the researcher; instead many different quantitative and qualitative methods are used depending on the nature and area of the research, which is also in line with the pragmatist approach. The research design follows an iterative sequential design, which is a sequential study with more than two phases, in this case, three phases (Teddlie & Tashakkori, 2009, p. 274). The pragmatic worldview, the mixed methods approach and the research design will be further presented and discussed in Chapter 4, but for the reader to get an overview of the dissertation, the overview of the three studies conducted is briefly outlined below in Table 1.

Study 1: Translation competence and Danish PIL translators
Objective: To investigate who the Danish PIL translators are and to map these translator profiles against a model of translation competence.
Study 2: PIL translation choices made by professional translators and pharmacists
Objective: To investigate the hypothesized competences from study 1, and investigate whether there are any differences in the PIL translation products translated by the two types of translators in relation to lay-friendliness.
Study 3: Focus groups with professional translators and pharmacists
Objective: To investigate the reasons behind the choices found in study 2. To gain an understanding of how the PIL translators view their translation choices and process and argue for them. To investigate how the PIL translators view their expertise and their roles as PIL translators.

Table 1: Overview of the three empirical studies.

1.5. Contribution of dissertation

The study builds on and contributes to Patient Information Leaflet research by exploring a new angle on the complexity of PILs. Although previous studies have examined the linguistic complexity in PILs, there has not been a study of the influence the translator has on the translation product. This is important in the light of the previous research findings that patients read PILs, and that the PIL is often the only source available when the patient actually takes the medicine (Raynor, Savage, Knapp, & Henley, 2004, p. 172). A UK study shows that up to 50% of people on long-term medicines do not take them as prescribed, one explanation being linked to the misunderstanding of prescription instructions and limited education about the medication (Haynes, Ackloo, Sahota, McDonald, & Yao, 2008, p. 18). Another recent UK study found that one in three adults over the age of 65 had difficulty understanding basic written health information. This poor understanding was associated with a higher risk of death over five years, even after accounting for socioeconomic circumstances and baseline health (Bostock & Steptoe, 2012, p. 6). Therefore, there is an ethical element in finding out why PILs are not optimal for patients from a linguistic point of view for the

purpose of drug safety. Ensuring informed decision-making and patient empowerment needs to develop from easily accessible information (Raynor & Knapp, 2000, p. 270).

In addition to this societal importance, the focus on translation competence in relation to non-professional de facto translators makes a new contribution to the field of Translation Studies. Although many studies have identified the translation sub-competences possessed by professional translators and novice translators, little attention has been paid to de facto translators, such as pharmacists, who are professionals in another field, but who perform translation.

1.6. Delimitation

Patient Information Leaflet in this study refers to leaflets found inside medication packages and not leaflets for example given at the doctor's office that include information about a specific disease or procedure. Various countries now use PILs in their medication, and some countries have regulations that state that this is a legal requisite; however, in this study, only EU PILs are included, and therefore, only the EU legal framework will be taken into consideration even though it is known that other countries have different regulations for the production and dissemination of the PIL genre. This study only looks at Danish PILs translated as part of the European Union Centralised Procedure. In addition, this study exclusively looks at complexity in PILs from a linguistic perspective meaning that layout is not included even though it is appreciated that layout is of course part of the overall understanding of PILs. Finally, it should be emphasized that this is not a translation process study for reasons which will be explained at a later stage.

1.7. Dissertation structure

Chapter 2: Understanding Patient Information Leaflets and motivating the dissertation

This chapter introduces the contextual environment of PILs and has the purpose of presenting the legal, contextual factors which affect the PIL genre and hence its translation, i.e. the external constraints that translators face. Based on the legal requirements of PILs, the concept of lay-friendliness in PILs is introduced. Chapter 2 also contains a literature review of previous studies of PILs and their complexity with a view to situating this study, and showing how this study aspires to fill a gap in the research field. In this section, the interdisciplinary nature of the study will become apparent as the literature review will focus on both studies conducted within Health Communication, Linguistics and Translation Studies.

Chapter 3: Translation-theoretical chapter

This chapter first introduces the main research field within which this dissertation is carried out, i.e. the field of Translation Studies. The chapter will give a brief introduction to the history and unique characteristics of the field, the research carried out in this field, and the approaches used. Before it is possible to carry out an analysis to determine whether translator profile has an impact on the complexity of the translations, the approach to translation needs to be established as "the perception and evaluation of an error as a translation 'error' depends on the theoretical approach to translation" (Hansen, 2010, p. 385). It will be argued that for PILs, a functionalist skopos-theoretical approach is useful because of its focus on the function of the target text, the contextual environment surrounding this mandatory genre, and especially the target text receivers, who need to be able to understand the pharmaceutical information. Furthermore, this approach also frames the translator as a responsible agent. Finally, the chapter compares this translation-theoretical approach with the apparent approach to translation of the European Medicines Agency, the authoritative body in charge of the legislation concerning PILs and PIL translation seen in Chapter 2.

Chapter 4: Methodology

This fourth chapter presents the approach to research taken in this dissertation, i.e. the pragmatist approach by arguing for its suitability for Translation Studies in general and for my studies in particular. A mixed methods approach is presented as the approach suitable for answering the overall aim of this dissertation and the research questions. Based on a theoretical introduction to mixed methods, the iterative sequential design is argued for, and the three studies of this thesis are mapped out in more detail.

Chapters 5-7: Three empirical studies

These three chapters contain the empirical studies presented above in Table 1 (and further presented in Chapter 4). Because of the iterative sequential design, this dissertation is structured somewhat untraditionally in the sense that the relevant literature reviews are presented in the chapters where they belong. For example, the literature reviews of translation competence and medical translators are presented in Chapter 5 with study 1 and the literature review of Plain Language as an operationalization of linguistic complexity is carried out in Chapter 6 for study 2.

Chapter 8: Discussion and conclusion

This last chapter of the dissertation synthesizes and discusses the accrued results of all three studies. On the basis of this, the overall contributions of the dissertation are presented both in

relation to the theoretical and methodological contributions as well as societal and policy contributions. The thesis concludes with future perspectives.

2. Understanding Patient Information Leaflets and motivating the dissertation

The purpose of this chapter is threefold: First, as the PIL genre is heavily legally regulated, before any research can be carried out, it is important to understand its institutional context within the EU as this context strongly influences the production process and final product of English-language PILs as well as the translation process and the final translation product of the Danish PIL. Second, based on the situational context, the legal requirement that PILs must be easy to understand is conceptualised as *lay-friendliness*, and this concept is explained and explored. Third, this chapter locates the PIL within its research context by reviewing existing research on PILs in order to situate the studies conducted in this dissertation. PILs have been studied using various approaches, but as this thesis is interested in the problems of linguistic complexity in PILs, especially in translated PILs, only existing research which sheds light on this issue is included in the literature review. By doing so, this chapter will investigate the main findings achieved so far in PIL research so as to show the research gap that this dissertation aspires to fill.

2.1. Institutional context of PILs

This section introduces and situates the PIL within its contextual, real-life environment. This section thus sheds light on contextual factors which affect the PIL genre and hence its translation. PILs were introduced in 1992 by EU law with Council Directive 92/27/EEC and became fully implemented as mandatory in 1999 (Council of the European Communities, 1992). A PIL must accompany all medication, and it contains information to patients about dosage, side effects etc. The EU has made it an explicit requirement that PILs are easy to understand for lay people as seen by Article 63(2) of EU Directive 2001/83/EC, which stipulates that the PIL "must be written and designed to be clear, understandable and enable the users to act appropriately" (European Parliament and of the Council, 2001) here termed *lay-friendly* (see more on this below in section *2.3. Lay-friendliness*). EU PILs are therefore so-called mandatory genres, i.e. heavily, legally regulated genres (Askehave & Zethsen, 2003) governed by legislative regulations. Thus, in the EU, when a pharmaceutical company wants to sell a pharmaceutical product, it must adhere to strict rules concerning the pharmaceutical product itself, but also concerning the informational material that goes with it, including the PIL. When a pharmaceutical company wants to market a medication all over the EU, one of the options is for the pharmaceutical company to apply for marketing authorisation through

the European Medicines Agency (EMA). The company produces all the accompanying material in English, and then has to translate it into all Member State languages.

Against this background, the aim of this section is to explain the emergence and the environment of the PIL (both the original English PILs and the translated Danish PILs), and the role it plays in the EU. To fully understand the genre, the relevant legal requirements linked to PIL production are introduced in the following and discussed in relation to lay-friendliness. In addition to legal acts, EMA has produced other kinds of information to guide and regulate the production process of PILs; these include a readability guideline and English and Danish PIL templates, which will also be presented.

PILs are, however, not only a complex genre because of the legal environment and its status as a mandatory genre. The communicative situation is also complex as it is characterised by the fact that PILs are mass communicated, there is knowledge asymmetry between producer and receiver and PILs communicate complex information.

In summary, this section serves the purpose of first introducing the PIL from a legislative perspective and then describing what this results in from a linguistic and translation perspective. Furthermore, this section describes the communicative situation of PILs and discusses the consequences the contextual environment has for the production of PILs as they cannot be analysed without reference to their broader contextual environment.

2.1.1. The process of PIL production

In order to be granted marketing authorisation of a pharmaceutical product, a pharmaceutical company must among other things provide a PIL[2] (European Parliament and of the Council, 2001). Thus, the production of PILs is a mandatory part of the granting of marketing authorisation. The EU has four different procedures for the marketing authorisation of pharmaceutical products (European Commission, 2005), but for this thesis, only PILs authorised through the Centralised Procedure are included. Through this procedure, marketing authorisation is granted in all Member States at once, and the application is filed with EMA. The reason for including only these PILs is that they have to be translated into all EU languages, because these pharmaceutical products are authorised to be sold all over the EU.

Directive 2001/83/EC also states what must be included in the PIL and in which order, which means that both the content and the order of the content are legally regulated (Article 59(1)). Some of the main information which must be included the PIL is:

[2] In EMA terminology, the *Patient Information Leaflet* is called the *Package Leaflet*. I have opted for *Patient Information Leaflet* as this term refers to the function and the receivers of the leaflet, and not merely its location in the medication package.

- name of the medicinal product
- strength and pharmaceutical form
- lists of contra-indications
- appropriate precautions for use
- forms of interaction with other medicinal products
- special warnings
- necessary and usual instructions for proper use
- dosage
- route of administration,
- how often the medication should be taken,
- duration of treatment etc.

As can be seen above, the information which must be included by law is quite extensive, which makes it even more important that the information is written using language, which is easy to comprehend.

2.1.2. EU initiatives linked to lay-friendliness in PILs

Since the introduction of PILs in 1992, EMA seems to have become increasingly aware of the importance of the language used in PILs, and the challenges linked to producing PILs that are easy to understand for lay people, witnessed by the several initiatives which are relevant for the production and translation of easy-to-understand PILs. These initiatives, which can be seen in Figure 1, include a readability guideline, templates in all EU languages (both implemented in 1998), and user-testing of the PIL (implemented in 2005).

1992	1998	2005
• All medicines must have PIL • Required to be in "clear and understandable terms for the patient"	• Readability Guideline • Templates	• User testing

Figure 1: Legislative measures related to the production of PILs.

In the following, the measures implemented in 1998 and 2005 will be presented and discussed.

Readability guideline

As seen above, in Figure 1, one of the first legislative measures in connection with the production of PILs is the readability guideline issued by the EU in 1998 (European Commission, 1998), and last revised in January 2009 (European Commission, 2009). The purpose of the guideline is "to provide guidance on how to ensure that the information on the labelling and package leaflet is accessible to and can be understood by those who receive it, so that they can use their medicine safely and appropriately" (European Commission, 2009, p. 5). Also, the purpose of the guideline is to maximise the use of PILs: "If the package leaflet is well designed and clearly worded, this maximizes the number of people who can use the information, including older children and adolescents, those with poor literacy skills and those with some degree of sight loss" (European Commission, 2009, p. 7). The guideline includes information to PIL producers on the use of font, headings, syntax, layout, style etc., and it is meant as a help for applicants when drawing up a PIL as it provides guidance on presentation of the content, design and layout concepts and user-testing (user-testing will be covered below in a separate section below). The guideline is said to be based on experience showing that following these techniques will optimise usability, however, no references to research or studies are provided.

PIL templates

As seen in Figure 1, along with the introduction of the readability guideline in 1998, PIL templates were produced in all Member State languages to ensure consistency across different medicines and across different languages (European Commission, 2009, p. 11; see Appendix 1 for Danish template and 2 for English template). The template is said to be guidance for PIL producers, i.e. the pharmaceutical companies, but the template stipulates headings, and the wording of specific sections, and alternative headings and wording can only be used in exceptional cases, and must be justified by the producers. It could therefore be assumed that pharmaceutical companies would stick very closely to the template to ensure quick marketing authorisation. Research has shown that PIL users have some problems understanding the leaflets based on the template (Dickinson, et al., 2001, p. 156), and the template has been criticized as it was produced by EMA without having been tested (Pander Maat & Lentz, 2010, p. 113; Raynor, 2008b, p. 11) and for solely focussing on content and not on language (Askehave & Zethsen, 2008, p. 187). However, even though both the form and the content of the PILs are heavily regulated, Pander Maat & Lentz found that it is still possible to improve the quality of the PIL while staying within the guidelines (2010, p. 19). In addition to the

templates, annotated templates have also been produced in each EU language with guidance on how to complete each section. Because the pharmaceutical companies must only deviate from the template in exceptional cases, it would seem likely that they would stay very close to the template even though it has not been tested with PIL users; this thus makes the genre even more rigid without much room for creativity.

User-testing

When Directive 2001/83/EC was amended by Directive 2004/27/EC, mandatory user-testing of PILs was implemented for all marketing authorisations granted after 30 October 2005. The purpose of the testing with target patient groups is according to the amended Article 59(3) to "ensure that it [the PIL] is legible, clear and easy to use", which is also expressed as "to demonstrate the readability and usefulness of the package leaflet to patients" (European Commission, 2006, p. 2). It is not prescribed by EMA what type of user-testing has to be conducted; therefore, both user-testing, which is explained, quite vaguely, as testing "the readability of a specimen with a group of selected test subjects" as well as other forms of consultations are permitted as long as the outcome of the consultations is that "the information is legible, clear and easy to use". However, user-testing with a group of test subjects seems to be the preferred method as all other methods must be justified by the applicant and are assessed on a case-by-case basis (European Commission, 2006, p. 3). In the readability guideline, an example of user-testing is included. The described user-test is based on one-to-one, face-to-face, structured sets of interviews, involving at least 20 participants. The participants are supposed to reflect the population for whom the medicine is intended (European Commission, 2009, p. 24).

2.1.3. EU legislation linked to translation

English-language PILs constitute only a fraction of the EU PILs as through the Centralised Procedure, all PILs must be available in all EU languages, which means that all leaflets must be translated into 23 languages[3]. The legal requirements related to the production process of translations are presented below.

[3] The EU has 23 official languages including English. One of them, Irish, is not translated into, but PILs are also translated into the non-EU languages of Icelandic and Norwegian, so it all adds up to 23 translations.

The time of production of the English PIL

As can be seen in Figure 2[4], at the time of submission of the marketing application, the pharmaceutical company submits a dossier which includes the draft Summary of Product Characteristics, labelling and most importantly for our purposes, a PIL in English. This is an English mock-up[5] of the outer and inner packaging for each pharmaceutical form of the medicinal product. EMA then has 210 days to decide whether marketing authorisation should be granted, the so-called *CHMP (The Committee for Medicinal Products for Human Use) opinion*. As far as the quality checks of the English PILs are concerned, in this period of pre-opinion, several parties are involved in assessing the application, and during this time, the English PIL will be subject to checks both by EMA and patients' and consumers' organisations, and subsequently revised by the pharmaceutical companies.

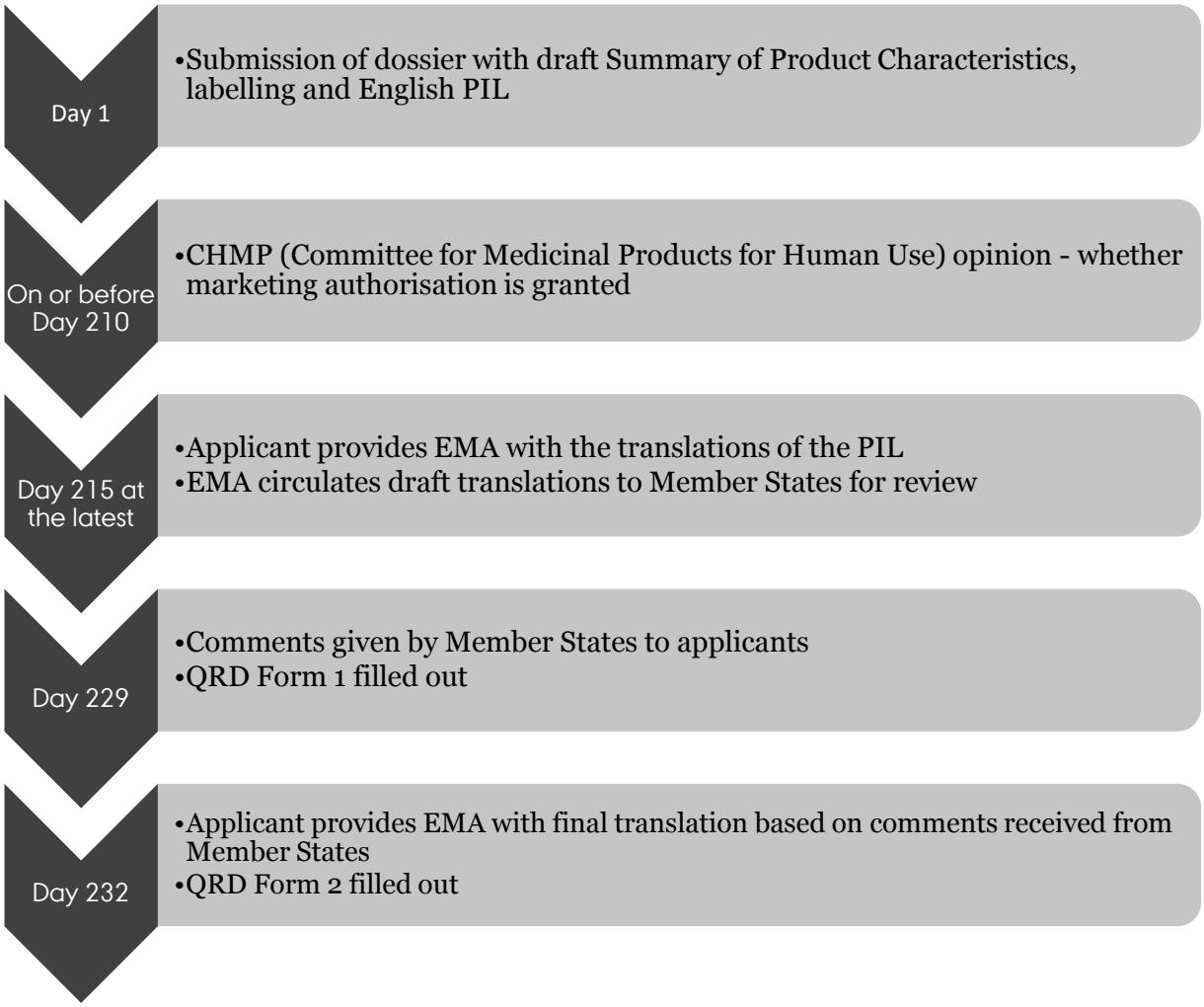

Figure 2: Marketing application through the Centralised Procedure, with steps relevant for the production and translation of PILs.

[4] Information in Figure 2 as well as in this section is taken from European Commission (2006) unless otherwise stated.

[5] This is a copy of the flat artwork design (computer generated) in full colour.

Timeline of PIL translations

When investigating the relevant steps for marketing authorisation through the Centralised Procedure in Figure 2, it becomes evident that very limited time and importance are given to the translation and checking of translations of PILs – the last three arrows in Figure 2. Figure 3 below shows these three steps involving the order of the production process from English to Danish PIL and the deadlines which the translators and the reviewers of the translations have.

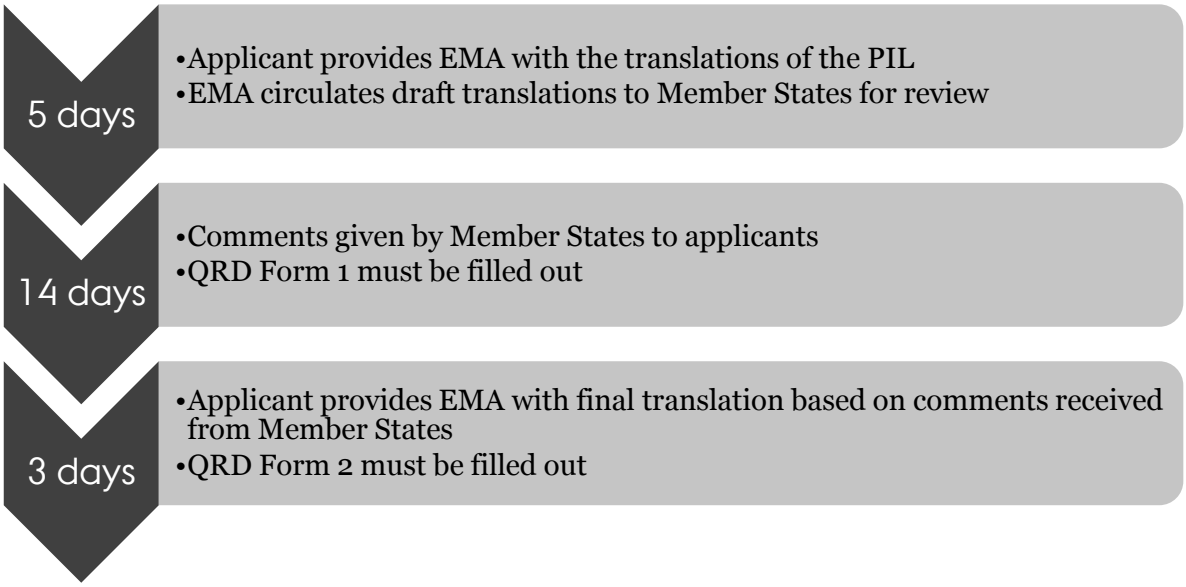

Figure 3: Time for translation part of PIL production.

Within five days after the CHMP opinion, the applicant provides EMA with the translations of several documents including PILs in all EU languages. This means that the pharmaceutical companies only have five days to provide all 23 translations. EMA therefore advises that the translation process is started well in advance, e.g. after Day 165 (European Medicines Agency, 2011, p. 3) even though it is not known at that time whether marketing authorisation will be granted. It is interesting to note that the translations from English into all other languages are made after the CHMP opinion, i.e. *after* EMA has granted the marketing authorization. This means that it is the source text which is the approved version.

Very limited time is given to the translation part of the PIL production process. Therefore, it is reasonable to assume that PIL translators are under time pressure to produce the translations as these must be produced and approved before the company can start selling the medication. Therefore, the aim of clear and understandable language might not be the only, or even the most important, when producing the PIL translations. Askehave & Zethsen (2002) argue that "the translation assignment also comprised another more or less implicit

skopos [function], namely that the package insert should be approved as smoothly and fast as possible" (p. 24). The aim of clear and understandable language thus conflicts with the aim of quick marketing authorization (Askehave & Zethsen, 2002, p. 24).

The quality checks of the translations

The translations are checked; however, very little time is granted for this, i.e. only 14 days as the Member States only have from Day 215 to 229 to give a so-called detailed linguistic review of all translations. For the Danish PILs, this is done by Quality Review of Documents (QRD) members at the Danish Health and Medicines Authority (DHMA). The QRD members then send their comments directly to the pharmaceutical company and EMA at the latest by Day 229 together with the QRD Form 1 (see Appendix 3), which includes overall feedback on the quality of the translations. On day 232 at the latest, the applicant provides EMA with final translations of all documents including PILs in all EU languages. From this overview, it can be seen that the national medicines agencies, such as the DHMA, only have two weeks to check the translations, and then subsequently, the applicant has a maximum of three days to implement the DHMA's comments and corrections before having to resubmit to EMA. After this, EMA checks if all comments have been implemented, and then sends the final translations to the Commission.

Translation of the PIL[6]

All non-English language EU PILs are translations as the English-language PIL is always the language version included in the initial dossier. As seen from the above timeline, the translations from English into all other languages are finalized after EMA has granted the marketing authorization. As will be seen in the literature review below, many studies have concluded that a large number of PILs are linguistically complex and difficult for lay people to understand, but many of these studies use only the English versions (i.e. the source texts). There is very little specific information or instruction from the EU concerning the important process from approved and tested English PIL to 23 language versions of this source text. The little information available can be found in the readability guideline (European Commission, 2009). On page 22 of the readability guideline, the EU Commission states the following three main points concerning translation:

1. The quality of translation should be the focus of a thorough review by the applicant/marketing authorization holder once the original package leaflet has been

[6] The content of this section has also been treated in Nisbeth Jensen & Zethsen (2012).

properly tested and modified. It is important that the outcome of the user consultation is then correctly translated into the other languages.

2. During the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way.
3. Following the grant of the marketing authorisation, the responsibility for the production of faithful translations will rest with the marketing authorisation holder in consultation with the Member States/European Medicines Agency. Strict literal translations from the original language may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand. Therefore, different language versions of the same package leaflet should be 'faithful' translations allowing for regional translation flexibility, whilst maintaining the same core meaning.

Re 1: Quality checks of translations

Following the grant of the marketing authorisation, the responsibility for the production of translations rests with the marketing authorisation holder. These translations are checked by the Member States, who have 14 days to check them using QRD Form 1 (see Appendix 3). It is, however, not very explicitly described exactly how this check should be carried out. The national medicines agencies have to rate the overall quality of translation on a scale of Very Good, Good, Acceptable or Unacceptable, but the categories are not further defined or explained. Furthermore, according to the QRD Form 1, it should be rated whether there are Many, Several or Few:

- Missing words or sentences
- Scientific [sic] incorrect translations (e.g. terminology)
- Inaccuracies (incorrect translations – incl. spelling, punctuation, grammatical mistakes)
- Editorial, stylistic changes (e.g. rephrasing)

These four categories show a sole emphasis on content, correctness and accuracy. None of the categories are linked to difficulty of the language or to whether the translation has been adjusted to the receivers. This is problematic as the translations are not user-tested, which means that this check by the Member States is the only control mechanism supposed to ensure that PIL receivers are provided with lay-friendly texts.

The DHMA is responsible for checking the quality of the Danish translation, and therefore, it is also relevant to see the requirements put forward by the DHMA in relation to translation as these might be more explicit and more focused on lay language. According to the DHMA, the translations of the product information are checked based on the expectation that they fulfil the following standards (Lægemiddelstyrelsen, 2008):

- The standard headings and standard texts on EMA's website have been used
- The content in the PIL is consistent with the Summary of Product Characteristics (SPC)
- The Danish translation reproduces the content of the original text correctly
- Choice of words and use of terminology are consistent
- PILs must be in correct Danish
- Phrasing and choice of words are adapted to the user, PILs are always written using readable language
- In the PIL, technical terms are only used when they are known by the user

The first five points are similar to the guidelines put forward by EMA in that they focus exclusively on accuracy and content; however, the last two points are clearly related to lay language and they are interesting as they seem to give quite explicit advice to the translators. The question is, however, to what extent this is enforced in the actual translations. Research shows that some Danish PILs do not live up to the requirement that terms should only be used when they are known by the user (Askehave & Zethsen, 2000b). Furthermore, the PIL translators and the reviewers might not be fully aware of what terms are likely to be known by the user.

After the translations have been checked and sent back to the pharmaceutical company, the company must fill in QRD Form 2 (see Appendix 4) for each language, and state whether all comments have been implemented or not. If not, the reasons for this must be justified, and should be discussed with the Member State (e.g. the DHMA) before the final translation is submitted to EMA. EMA states that "poor quality translations or a poor implementation of Member States' comments or absence of a completed QRD Form 2 may lead to a delay in transmission to the Commission" (European Medicines Agency, 2011, p. 4), so it seems that *good translations* are valued in principle; however, it is not stated what a good translation entails.

Re 1: User-testing of one language version

In relation to user-testing, it is noteworthy that even though the PIL must be "legible, clear and easy to read in all EEA languages", it is sufficient to undertake patient consultations in one EU language (Raynor, 2008b). The pharmaceutical company can decide which language version to test; however, as the English PIL must be submitted much earlier in the application process (see above), and the questions asked, the results etc. of the user-testing must be presented in English, it could be assumed that most often, the English PIL would be the one tested. It seems to be assumed that it is enough to test one language version, but this does not guarantee that all the translations are equally understandable: "A leaflet that has gloriously passed a readability test in one language may be poorly translated into any or all. The content will probably be there (so the translation is technically correct), but it is often the wording that decides if a leaflet is readable or not" (Andriesen, 2006, p. 44). So the fact that the translations are not user-tested seems to signal that EMA thinks that an understandable source text can be translated into an understandable target text without the use of further user-tests. This layman notion of translation (Askehave & Zethsen, 2002, p. 27), and the lack of understanding of the intricacies involved in translation is also seen in the requirement that solutions to the problems identified during testing of the English version must be applied to the 23 other EU languages by the pharmaceutical companies without consideration of the variability of the different linguistics constraints. If EMA's assumption is correct, all the Danish PILs which are translated versions of a good, easy-to-understand English PILs would be equally good and easy-to-understand.

The European Federation of Pharmaceutical Industries and Associations argues in a similar way that testing in multiple languages is not likely to add new evidence on the usability of the PIL, but would only test the quality of the translation (EFPIA, 2003, p. 4), thus assuming that these two are different matters that can be distinguished. Because of the fact that user-testing was implemented in the first place, it must have been assumed that the medical professionals were not able to assess the quality of a PIL in relation to the end user. As argued by Dolk, a similar problem is not seen in relation to the same medical professionals checking the translated PILs (Dolk, 2009, p. 11).

Re 2: Drafting of original

During the drafting of the original PIL, every effort should be made to ensure that it can be translated from the original to the various national languages in a clear and understandable way. It is not clear what exactly is meant with this requirement, and consequently, how it is to be fulfilled by the pharmacists producing the PIL, apart from ensuring that the original source text is as clear and easy to understand as possible. Each language pair will undoubtedly pose

its own, individual challenges to the translation due to language system differences, cultural differences, etc., which a pharmacist drafting the original English PIL has no control over. One suggestion would be a translation guide explaining the conscious choices made in the original with lay language in mind, e.g. reminding the translators by means of specific examples that the active voice, personal pronouns, lay terms etc. are deliberate choices and should not be changed back to expert register. Such a guide could be very valuable, but it is unlikely that this is how the requirement is interpreted and that such guides are in fact produced.

Re 3: Faithful translation

According to the legal requirements, it is the responsibility of the marketing authorisation holder to make *faithful translations*. EMA warns against strict literal translation from the source language as it "may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand" (European Commission, 2009, p. 22). This shows that EMA seems to understand that literal translation is not ideal, as it can lead to unnatural phrases; instead they want *faithful translation* as they call it, which is explained as "allowing for regional translation flexibility, whilst maintaining the same core meaning". This is not further explained or defined, and does not seem to be very helpful advice for translators as it is not further described what *regional translation flexibility* is or entails, or what *core meaning* is and how to maintain it in 23 languages.

The term *faithful translation* is quite problematic as in Translation Studies, it connotes focus on and faithfulness to the source text, and the translator thus does not have much freedom to change the text according to the new target text receiver (e.g. Hönig, 1998b, p. 15). The argument for faithful translation could reflect that the medical and pharmaceutical information in the PIL is crucial, but the trained translator may be a bit confused by the use of the concept of *faithful* translation which is normally contrasted with *free* or *communicative* translation in Translation Studies (Hönig, 1998b, p. 15). When referring to preserving the *core meaning* and allowing for *regional flexibility*, the concept of free translation is evoked. This contrast may create confusion, and it is difficult to tell from the recommendation how much flexibility is allowed in reality.

2.1.4. Summing up institutional context

From the above overview of the regulations surrounding the PIL, it becomes evident that it is an extremely regulated genre, sometimes referred to as a mandatory genre (Askehave & Zethsen, 2003, 2008). Mandatory genres, like the PIL, are introduced into the community by

regulatory *force*, and their communicative purpose, content, and form are formally discussed and defined by legislators prior to being released (Askehave & Zethsen, 2008, p. 170). This has some consequences for these genres, i.e. that they have not had the "gradual evolvement and constant development of 'ordinary' genres" (Askehave & Zethsen, 2008, p. 170), and therefore, they are also rigid without room for "creativity, innovation, or significant departures from the template" (Askehave & Zethsen, 2008, p. 170). This of course influences the translation process and the product as the source text producers and the translators do not have a great degree of freedom. The above overview also shows EMA's approach to translation: first of all, the translations have to be made, reviewed and revised within very short time frames, which could show a lack of understanding of the intricacies of the translation process. Second, even though EU legislation states that PILs must be easy to understand for receivers, none of the quality checks performed really investigate this parameter. Instead the main purpose of the translation review seems to be an accuracy check. Third, the requirement of only user-testing one language version shows an assumption that user-testing results from one language can easily be implemented into other language versions.

Due to the challenges linked to the legal requirements discussed above, such as the templates which must be followed and the strict deadlines for translation, producing an optimally lay-friendly target text can be difficult. Another issue is EMA's view on translation and the translation process. Only one language version needs to be user-tested, which is most often the English version, and there seems to be a view that all other language versions would then be equally lay-friendly. PIL producers are asked to produce a so-called *faithful translation*; however, not much guidance is given as to how to achieve this. Also, for trained translators, the wording *faithful translation* might give the wrong connotations. Even though the translations are checked by the Member States, emphasis when assessing the PIL is on correctness and accuracy; yet, accuracy is not the same as using language which can be understood by receivers, and it could be detrimental to the language to transfer source text items very directly. There does seem to be some awareness of some of the problems in connection with lay language as the DHMA states that phrasing and word choice must be adapted to the receiver, but the problem might instead be whether the pharmaceutical companies follow these suggestions.

Not only the legal, institutional environment of PILs influences the genre; also the broader communicative situation presented below is relevant for the understanding of PILs.

2.2. Communicative situation of PILs

It is clear that the contextual environment of PILs linked to the legal EU setting strongly influences the production of lay-friendly PILs. However, it is not only the legal environment that makes PILs a complex genre. PILs are also complex, because:

- they are instances of mass communication with an extremely broad receiver group and no feedback mechanisms
- there is an asymmetrical relationship between sender and receiver
- they convey information of a complex nature

Re 1: PILs as mass communication with broad receiver group

The receivers of PILs can potentially be the entire population of a country, and PILs must thus address an extremely large, heterogeneous audience. Some researchers have found that patients prefer patient information written more directly for them (Raynor et al., 2007, p. 27); however, PILs are mass produced with one PIL for each medication. This means that a person might be taking medication for hepatitis, but this medication might also be prescribed for HIV, which means that the PIL will contain information irrelevant for the receiver. Some would say that the receiver group of some medications is quite clear, which could be said to be true about medications such as for osteoporosis being for elderly people; it is, however, not possible to characterise the receiver more thoroughly, and also, there could be exceptions where the medication is used by a younger person.

Because PILs constitute a written, mass-communicated genre, there is no feedback mechanism. The genre is sender-controlled (Askehave & Zethsen, 2003, p. 25), but the PIL senders are not able to know whether their receivers have actually understood the information. You could say that for English PILs, there is a preliminary feedback mechanism, because these PILs are user-tested; however, for the Danish ones, there is no way of knowing whether the PILs are actually understood by Danish lay receivers as they have only been checked by people who are subject matter experts themselves, i.e. experts at the DHMA and EMA.

Several suggestions have been proposed as to how to write PILs for such a large receiver group. One is visualizing an audience and writing to that; however, communication research shows a tendency to create a secondary audience consisting of friends and colleagues (Windahl, Signitzer, & Olson, 2009, p. 165), and as PIL producers are likely to be highly educated experts, they are also likely to have friends and colleagues who might not be

representative of the population (Askehave & Zethsen, 2003, p. 26). There is thus an asymmetrical relationship, which will be discussed below.

Re 2: Asymmetrical relationship

The sender of the English PIL source text is the individual pharmaceutical company and more specifically, typically a pharmacist, i.e. an expert in pharmaceuticals. The receiver group of PILs is, depending on the medication, potentially the entire population of a country, and thus includes many non-experts in pharmaceuticals. This traditional knowledge asymmetry is then exacerbated by the introduction of the translator who sits in the middle of the communicative situation – a translator who might also be a pharmacist with subject-matter expertise or a trained translator with linguistic and translation expertise. Or it might even be someone in the middle of the scale from subject matter expert to linguistic expert.

The PIL producers and translators may be influenced by their own expertise, and thus may struggle to distinguish between their own knowledge and that of the receiver – a phenomenon previously coined *the curse of expertise* (Hinds, 1999, p. 205). Also Gal & Prigat found that expert PIL producers overestimate PIL receivers (2005, p. 489).

Re 3: Complex information

Last, but not least, even though PIL receivers are lay people, PILs must communicative potentially quite complex information concerning pharmaceuticals. Because the human is such a complex being and medicine such a complicated field, the information to be presented in this context is often complex. Furthermore, there is a widespread use of scientific and medical jargon, which might be incomprehensible by lay persons because of unfamiliar terms. PILs must not only explain how to take a medication, but also the way in which the medication works as well as the risks involved in taking the medication, i.e. the potential contraindications and side effects. Furthermore, some patients find that PILs are product liability documents (Consumers' Association, 2000, p. 12), which means that the content included does not function as to inform the patient, but rather to limit the responsibility of the company and authorities. Therefore, the main purpose might not be to write a PIL, which is easy to understand.

2.2.1. Summing up communicative situation

Because PILs were introduced by legal mandate, and are thus mandatory genres, the production process and the final product are very regulated leaving limited room for freedom for the translators. Furthermore, PILs are an instance of mass communication with an

extremely large receiver group and no possibility of feedback. The complexities of the PIL production and translations are not only linked to the legal requirements, they are also emphasized by the knowledge asymmetry between the sender, a medical expert, and the receiver, a lay person. The already complex problems of the communication process and the knowledge asymmetry between the sender and receiver are compounded by the introduction of the translator who sits between the expert text producer and the lay text receiver. Finally, PILs must convey complex expert information in a lay-friendly way; a difficult feat.

2.3. Lay-friendliness

Following Article 63(2) of Directive 2001/83/EC, PILs must be "written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals". This requirement of minimal linguistic complexity in the PILs is termed *lay-friendliness* in this dissertation for the reasons provided below.

2.3.1. Questions of nomenclature

There are several reasons for using the term *lay-friendliness* instead of another term such as *readability* or *user-friendliness*. The reason that the term *readability* is not used is its association with readability formulas and quantitative approaches, which, as will be seen below, only offer a simplified view of the intricacies of text comprehension. Moreover, the term readability suggests that it is an inherent text quality that can be assessed by looking at the document without taking into consideration who the receiver is. This would fit better with the traditional, mechanistic, transmissionist one-way communication models, but not with the approach to communication taken in this dissertation – as a dynamic process in which the receivers are in the centre (see Chapter 3 for more on this).

User-friendliness is a term which has been used within linguistic and translational approaches to PILs (Askehave & Zethsen, 2000a, 2002, 2003, 2008); however, this term can be seen as vague because the notion of *users* is vague. This could potentially be all kinds of receivers, i.e. also including health professionals (e.g. for vaccines that are injected). *Lay-friendliness*, on the other hand, clearly shows that the text must be friendly or easy to understand for lay people, i.e. non-experts who do not have specialised knowledge.

It should be noted that various disciplines and studies investigate PILs and their complexity with different goals in mind. Within the biomedical paradigm, the goal is often compliance whereas in other paradigms such as patient-centredness, the goal is to ensure better informed and satisfied patients by providing them with material to support decision-making. This dissertation follows the latter paradigm (as stated in the Introduction); however,

for the below literature review, the purpose for assessing PIL complexity is seen as irrelevant. The following section contains a literature review of existing PIL research with a view to situating this dissertation, and showing how it aspires to fill a research gap.

2.4. Literature review of PILs

Before embarking on this literature review, it should be clarified that the term Patient Information Leaflet is used with different meanings in research. Like this dissertation, some scholars use the term when referring to the leaflet found inside medication providing information on dosage and side effects; however, other scholars use the term referring to the written material, often of an educational nature, which can for example be found in doctor's surgeries on various diseases and conditions. Research on this kind of PIL is only included if relevant for the context of this study. Furthermore, it should be noted that research on PILs in the sense used in this thesis is undertaken in many different national and international legal environments. The consequence of this is that PILs have different institutional contexts, which influence both the content and structure of the PILs. Even though EU PILs are the unit of study in this dissertation, research on PILs in other institutional contexts is also included in this literature review where relevant results are found. Finally, PILs are also sometimes referred to as Patient Package Inserts (PPIs) and in Australia and New Zealand, the term Consumer Medicines Information (CMI) is used. I have opted for Patient Information Leaflet as this term refers to the function and the receivers of the leaflet, and not merely its location.

The literature review will focus on three factors relevant to PILs: 1) the importance of PILs, 2) the complexity of PILs and 3) the causes of complexity in PILs.

2.4.1. The importance of PILs

Research has shown that the PIL is the most important source of information about a medication for the patient (Bjerrum & Foged, 2003, p. 58), and most patients read the PIL (Askehave & Zethsen, 2000b, forthcoming; Horwitz, et al., 2009), which shows that patients value the PIL. Today, the time pressure in the doctor's consultation is quite high, and the tendency people have to forget oral information underlines the importance of the comprehension of the PIL (Pander Maat & Lentz, 1994, p. 139). It is extraordinarily important that patients are able to understand this information, because it is essential for informed decision-making and for the correct use of medication. In the event that the communication is not understood by the receiver, it could have catastrophic consequences leading to wrong dosage, failure to report serious side effects, which in turn can lead to hospitalization or death (Stableford & Mettger, 2007, p. 85). A UK study showed that up to

50% of people on long-term medicines do not take them as prescribed (Haynes, et al., 2008), two of the explanations being misunderstanding of prescription instructions and limited education about the medication (Haynes, et al., 2008, p. 19). A long the same line, a recent study by Bostock & Steptoe (2012) found not only that a third of older adults in England have difficulties reading and understanding basic health related written information, and that this poorer understanding is associated with higher mortality.

2.4.2. Complexity of PILs

Despite the importance of providing patients with good quality, easy-to-understand information, patients complain that the PIL is difficult to understand and too linguistically complex (e.g. Blanck & Nyblom, 2012), and research tells a similar story, i.e. that a large amount of PILs are still today complex and difficult to understand for lay people (Askehave & Zethsen, 2000a, 2000b, 2002, 2003; Clerehan & Buchbinder, 2006; Consumers' Association, 2000; Dickinson, et al., 2001; Harwood & Harrison, 2004; Horwitz, et al., 2009; Lægemiddelstyrelsen, 2004; Pander Maat & Lentz, 2010; Raynor, 2007), which is of course in direct contrast to the function and purpose of the genre. Several reasons have been discussed in the literature as to why PILs are linguistically complex; these will be presented below.

PILs – a mandatory genre

According to Pander Maat & Lentz (2010), the EU's extensive legal requirements introduced above have produced some problematic constraints such as the information requirements which lead to leaflets that may be longer than 2000 words, and the pressure on the agencies testing the lay-friendliness of the PILs to deliver successful texts, with the danger of them asking easy questions to educated participants (Pander Maat & Lentz, 2010, p. 113). Another issue is the template, which specifies headings, sub-headings and text structure, but which has never been tested (Pander Maat & Lentz, 2010, p. 113; 2011, p. 199), and which gives readers problems in locating information (Pander Maat & Lentz, 2011, p. 214). Moreover, there is a conflict between the template and what is found in user testing (Andriesen, 2006, p. 44) and a conflict between the template and document design principles (van der Waarde, 2008, p. 220). Some argue that because of its mandatory nature, the PIL will never be able to meet all needs of patients as patients want information about medicines but have different individual needs. This is not possible as PILs must be general and standardized (Raynor, Knapp, Moody, & Young, 2005, pp. 610-611). However, in their study, Pander Matt & Lentz found that it is

possible to improve PILs while staying within the legal guidelines (Pander Maat & Lentz, 2010, p. 118).

As seen above, the complexity of PILs is not only linked to the legal requirements, it is also intensified by the knowledge asymmetry between the sender, a medical expert, and the receiver, a lay person. The receiver side of the communication process is very complex for PILs as the potential receiver group consists of a large, heterogeneous group, sometimes the entire population (Askehave & Zethsen, 2006, p. 647), who, in the reception situation, might feel anxious, stressed or insecure (Albin, 1998, p. 118).

PIL producers

The literature has also indicated the producers of PILs as problematic in relation to the complexity of the text. According to Gal & Prigat's work on PILs (in their case, these were printed health education materials) (2005), one of the problems lies in the fact that some of the producers are overconfident in their ability to create PILs that live up to their communicative requirements. The PIL producers in their study relied primarily on reactions and advice from co-workers or specialists. Therefore, Gal & Prigat argue that the complexity of the PILs may be caused by producers who are in charge of production, but who lack sufficient experience in developing PILs. Lack of experience is not the only issue; also, PILs become more difficult when these producers are unable to balance the requests or pressures of decision makers, experts or partners to add or modify materials. The participants in the study for example described common situations in which "experts or others insist on including additional complex texts, or add technical details or clauses and caveats, presumably to improve medical accuracy" (Gal & Prigat, 2005, p. 489). This quote shows that there might be disagreements between different experts, which might effect the complexity of the PILs negatively.

This knowledge asymmetry between the expert sender and the lay receiver is thus seen as one of the reasons why PILs are complex and difficult to understand. However, there is another reason often ignored in monolingual contexts:

> While most studies assert that the scarcity of user-friendly inserts is due to experts' difficulties in adjusting their language for the benefit of non-experts (i.e. they are incapable of writing plain English), the studies overlook another important reason why inserts are hard to understand, namely that in non-English-speaking countries which import medical and pharmaceutical products

> from the Anglophone world, many inserts are translated from one language (English) into another one. (Askehave & Zethsen, 2002, p. 16)

Translation thus plays an important factor in relation to the final PIL products, at least in the EU context. Both interlingual and intralingual translation is relevant for the production of PILs. These factors will be discussed below.

The problems with PILs – enter translation

Most PIL research has been conducted within a monolingual framework (Clerehan & Buchbinder, 2006; Clerehan, Buchbinder, & Moodie, 2004; Clerehan, Hirsh, & Buchbinder, 2009; Dickinson, Raynor, Kennedy, Bonaccorso, & Sturchio, 2003; Dickinson, et al., 2001; Fage-Butler, 2011b; Kenny et al., 1998; Knapp, Raynor, Silcock, & Parkinson, 2009; Koo, Krass, & Aslani, 2003; Mottram & Reed, 1997; Raynor, et al., 2007; Ross, Potter, & Armstrong, 2004). Many studies on the complexity of PILs have been carried out within the field of Health Communication, but many of these do not take into consideration that many PILs are translations. To my knowledge, only few studies have examined translated PILs (e.g. Askehave & Zethsen, 2000b, 2002, 2011; Cacchiani, 2006). The translation perspective cannot be ignored because of the multilingual environment in the EU, which means that PILs must be available in all 24 EU languages. As seen above, the English version is produced first as it must be submitted first in the marketing authorisation process; hence the majority of PILs are translations of the English source text.

Before the PIL is translated from English into other EU languages (interlingual translation, translation proper), it is first translated intralingually: A PIL must be drawn up in accordance with the Summary of Product Characteristics (SPC), a process which could be termed *intralingual translation*, i.e. translation within the same national language (Jakobson, 1959/2000; see also Zethsen, 2007; Zethsen, 2009) as it comprises a change in receiver group from expert to lay person, and thus in communicative purpose. As seen be seen in Figure 4 below, non-English language PILs are thus products of both an intralingual and an interlingual translation process.

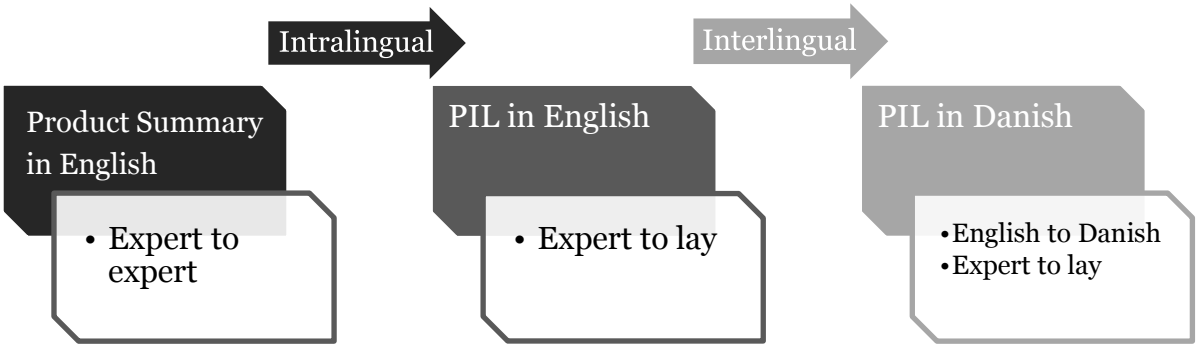

Figure 4: The production process of a Danish PIL (Askehave & Zethsen, 2011).

From a Translation Studies point of view and with an understanding of the complexities involved in the act of translation, it is clear that complications might occur when these English PILs then have to be translated into all other EU languages. The translation perspective becomes even more important in view of the findings of the study by Askehave & Zethsen (2002), which demonstrated that even when the English versions are relatively lay-friendly, in many cases, their Danish translations were more linguistically complex and thus less understandable for patients: "on the basis of our contrastive analyses we were able to conclude that without exception the Danish PPIs were more formal and dominated by expert syntax and terms than the English originals" (Askehave & Zethsen, 2003, p. 40). So why is this? Several reasons have been presented in the literature. According to Askehave & Zethsen (2008), one possible reason is EMA's translational assumption which states that if the English version is lay-friendly, the Danish translation will automatically be equally lay-friendly. This is an unrealistic conclusion taking the complexities of translation into account. Furthermore, the translations are checked by pharmaceutical professionals who primarily focus on the faithfulness of the translation to the original leaflet rather than on the comprehensibility of the translated version (Dolk, 2009, p. 11). This means that PIL translations are carefully checked to guarantee their degree of literalness, not necessarily their lay-friendliness, in line with the conclusions of the section above concerning the quality checks of the translations. We saw above that it has been suggested that the expert status of the original PIL producer and their lack of language competence might influence the complexity of the PIL negatively because of the knowledge asymmetry between the expert sender and the lay receiver. A similar potential explanation has been presented as to why the translations are more complex than their source texts, i.e. the expert background of the PIL translators. As can be seen in Figure 5 below, the

knowledge asymmetry is further exacerbated by the introduction of a translator – either a medical professional or a trained translator – between the expert sender and the lay receiver. Research on PIL translators will be further introduced below.

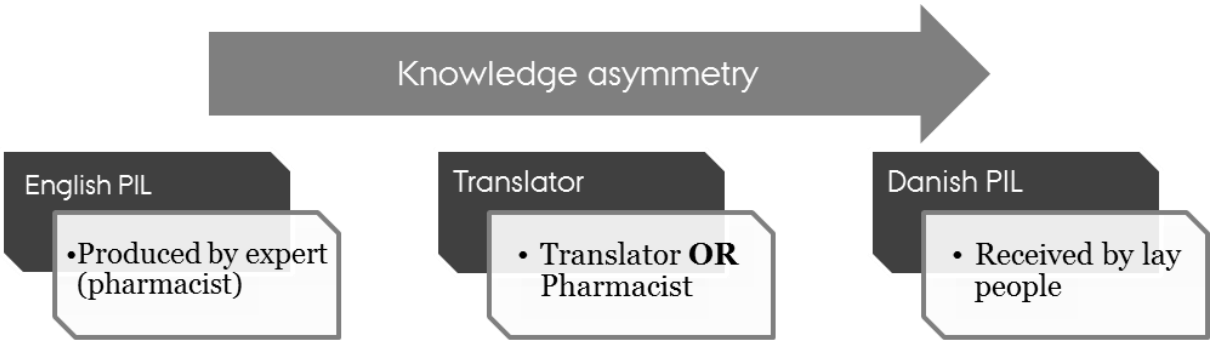

Figure 5: The communicative situation of translated PILs.

PIL translators

It has been suggested that medical companies located in Denmark often use pharmacists to translate PILs into Danish (Askehave & Zethsen, 2000a, p. 68), and because they are not trained translators, but instead have a medical background, this could be one of the reasons that Danish PILs are more complex than their English source texts. It is argued that these pharmacists resort to their expert language in their translations (Askehave & Zethsen, 2002, p. 28) because they lack knowledge of English and Danish and translation theory and methods (Askehave & Zethsen, 2002, p. 24). The expert status of the PIL translator thus affects the lay-friendliness of the translated PIL: "The medical expert status of those making the PPIs […] is the most harmful factor in relation to the user-friendliness of the package insert" (Askehave & Zethsen, 2003, p. 39).

According to functionalist approaches within Translation Studies (more about this in Chapter 3), the role of PIL translators would be to "act as linguistic experts who should intervene and improve the text according to the new skopos [function] necessitated by the fact that the audience are now Danish consumers" (Askehave & Zethsen, 2002, p. 23). Askehave & Zethsen argue that skilled translators do so, but that pharmacist-cum-translators are not able to do so because they have not been trained in the rhetorical ways and means of language and consequently would not know, for example, how to raise or lower the level of formality in a text (Askehave & Zethsen, 2003, p. 39).

2.4.3. Conclusion of literature review - research gap

Because of the lack of focus on the fact that most PILs are translations, many PIL studies have primarily focused on the PIL texts themselves, i.e. the translation products, not on the translation process and the translator. Shifting the main focus away from the translation product and instead focusing on the translation process allows us to investigate whether the increase in complexity in the translation could be linked to the contextual circumstances such as the background of the translators and their translation competences. Even though it has been suggested that the expert status of many PIL translators influences the lay-friendliness of translated PILs negatively, it has never been systematically, empirically investigated who actual PIL translators are, and whether this might affect the translation process and hence the product. This is where this thesis aspires to provide new insights by exploring the translators of PILs and investigating whether the translation competences and profiles of these translators could be linked to the difficulties found in PILs. Within translation approaches that take these extratextual factors into consideration (such as functionalism), translation is viewed as a complex communicative activity that requires expert competences (PACTE, 2003, p. 44). We can therefore assume that the competences of the translators might also influence the translation product. Based on this literature review, the following research questions have been elaborated:

- Who are the translators of PILs in the Danish context?
- Does the profile of the PIL translator influence the final PIL translation product in relation to lay-friendliness?

The above overview of the institutional context and the literature review of existing PIL research thus show that translation plays a significant role for PILs and PIL lay-friendliness. Before these research questions are empirically investigated, the field of Translation Studies and the theoretical approach to translation need presentation. Therefore, the following chapter contains an overview of the field of Translation Studies as well as a discussion of the concept of translation and the approach taken in this dissertation to translation and the translator.

3. Translation-theoretical chapter

This chapter serves to introduce the disciplinary context of the dissertation, i.e. Translation Studies and the theoretical approach to translation taken. According to Morgan, the kind of research conducted, and thus the choice of questions asked and the methods used by a researcher are all linked to the dominant paradigm within the researcher's discipline "where researchers have preexisting commitments to other systems of beliefs and practices" (Morgan, 2007, p. 49). Therefore, to understand the context within which this thesis is placed, this chapter firstly introduces the field of Translation Studies (TS). The TS field is a unique field for several reasons, and it will be seen that there is no *one* dominant paradigm within TS for several reasons. First of all, compared to other, neighbouring disciplines, such as Linguistics, TS is a very young field of research; it became a fully-fledged academic discipline in the 1970s. Secondly, it was born out of other research disciplines, and continues to borrow research models, theories and methods from other disciplines. Thirdly, the phenomenon it studies – translation – is a complex phenomenon. These three dimensions will be further explored in this chapter.

Furthermore, before it is possible to conduct research into translation, the approach to translation in the context of this dissertation must be made explicit. This chapter thus contains the translation-theoretical basis of the thesis. As will be seen, the phenomenon of translation can be approached from many different angles; approaches which will be briefly outlined before placing this dissertation within a functionalist approach to translation, and explaining the consequences for research of such an approach. This chapter also emphasizes the role of the translator in functionalist approaches as a responsible agent and expert of translation and how this view is relevant in this study.

After a discussion of functionalism, the chapter will link this approach to PIL translation. To be able to perform translation analysis within a functionalist paradigm, the translation function must be known and must be the principal factor in such analysis. Thus, the establishment of the translation function is essential to every translation task, which means that for the purpose of this thesis, the functions of accuracy and lay-friendliness need to be established before the study is carried out. As a conclusion to this chapter, the functionalist approach to translation is compared to the approach to translation of the European Medicines Agency introduced in Chapter 2.

3.1. Translation Studies

Translation Studies (TS) is a very young academic discipline, becoming an academic discipline in its own right in the 1970s (Munday, 2012, p. 10), and is often referred to as an interdiscipline for example illustrated by the title of the edited volume *Translation Studies: An Interdiscipline* (Snell-Hornby, Pöchhacker, & Kaindl, 1994), and this label is used "in the sense that the complex phenomenon [i.e. translation] consists of inseparably connected aspects from different disciplines" (Ferreira Duarte, Assis Rosa, & Seruya, 2006, p. 2) such as Linguistics, Pragmatics, Literary Theory, Anthropology, Sociology, Cultural Studies, History, Philosophy, Cognitive Psychology etc. Translation is thus a multifaceted phenomenon, but its interdisciplinarity is also connected to the fact that TS was born out of other, already established, research disciplines, such as Linguistics and Comparative Literature (Munday, 2012, p. 14). TS continues to maintain links with theories and methods from other disciplines, adapted to be applied to the analysis of translation as a product, process or function (Ferreira Duarte, et al., 2006, p. 2). This means that in TS, these various other disciplines are always relevant, and they are thus an inherent part of the research conducted within the field. Both as a cause and a result of this interdisciplinarity, TS scholars come from many different backgrounds; they are "disciplinary immigrants" (Gile, 2008, para 1) ranging from "literary theory to computer science, from English studies to experimental psychology, to mention but a few" (Jääskeläinen, 2005, para 4) as well as psychology or neurophysiology (Gile, 2005, para 2), leading to a pell-mell of different academic disciplines with researchers who bring different worldviews, procedures of inquiry and methods to the table. Despite this interdisciplinarity, TS today must be viewed as a discipline in itself, because only by being one, interdisciplinarity becomes possible. That TS is a discipline in its own right is witnessed by the many TS departments, TS curricula and pure TS researchers that exist today. TS has also started developing its own research models, theories and methods.

This interdisciplinarity is usually not seen as a hindrance, but rather as an advantage, because it means that research issues can be investigated from different angles, using knowledge and methods from different paradigms and disciplines, which at first glance might not seem to have many commonalities with translation (Hansen, 2005c, para 4). However, such diversity can also be perceived as a lack of disciplinary identity, and thus, in recent times, there has been a push for greater unity, and *shared ground* (Chesterman & Arrojo, 2000) or *disciplinary togetherness* (Martín Ruano, 2006, p. 44).

Another important element when introducing TS is the complexity of translation. According to Pöchhacker, by definition, interpreting[7] cannot be contained in one single, uniform research model because of the complexity of the phenomenon which can be seen as

> a function between socio-cultural entities *and* a distinct professional profile *and* a service rendered in an institutional context *and* a set of interactional behavior *and* a text comprehension and production task *and* a cognitive processing skill *and* a unique pattern of neurophysiological activity. (Pöchhacker, 2011, p. 9)

Of course, the last characteristic might be unique to interpreting; however, the other factors are relevant for the study of translation. Another way to demonstrate the multiplicity of the concept of translation is by use of Holmes' famous map of Translation Studies (Figure 6) which visually shows the extent of the discipline:

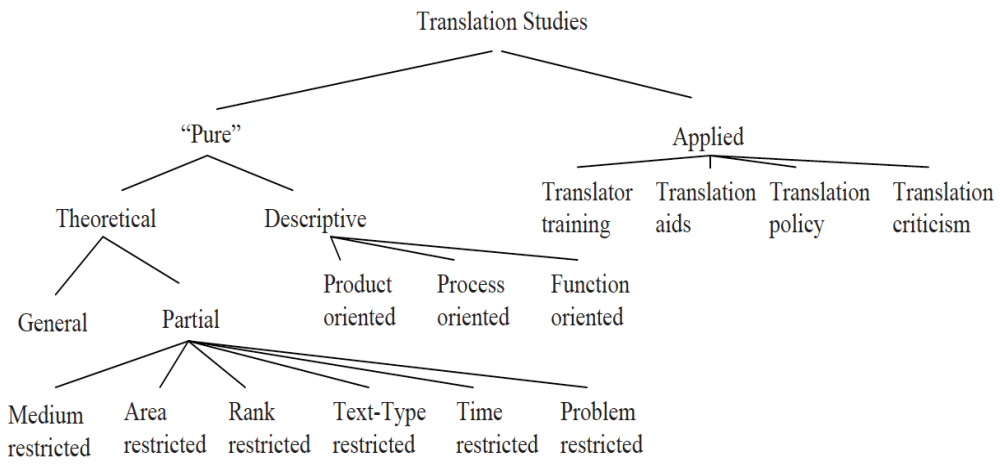

Figure 6: Holmes' map (based on Holmes (1988 (reprinted 2000))), borrowed from Chesterman (2009)[8].

The map shows the extent and multiplicity of the discipline encompassing both a pure branch (divided into theoretical studies and descriptive studies) and an applied branch (related to the practice of translation). The map thus shows that translation can be approached from a product-, process- and function-oriented approach, a theoretical approach and partial elements of translation are studied such as text type, medium etc.

[7] In my view, interpreting is part of the overall discipline of Translation Studies.

[8] The published version of Holmes' original article (1988 (reprinted 2000)) does not contain the map in diagram form. Therefore, I have borrowed the visual presentation of the map from Chesterman (2009). The map has since Holmes (1988 (reprinted 2000)) been further developed, e.g. by van Doorslaer (2007). Holmes' map has been problematized and criticized; however, it is not relevant here to introduce this criticism as the map only serves to give an overview of the multiplicity of TS. For an overview of criticism of the map, see Munday (2012, pp. 19-22) and Chesterman (2009, p. 15).

Translation is not only unique because of its complexity; it is also seen as fundamental to human communication. The ubiquitousness of translation is e.g. claimed by George Steiner, who argues that all communication equals translation (Steiner, 1998, p. 274): "translation is formally and pragmatically implicit in *every* act of communication, in the emission and reception of each and every mode of meaning, be it in the widest semiotic sense or in more specifically verbal exchanges" (Steiner, 1998, p. xii). Translation thus becomes fundamental to all disciplines and all human activity related to language and communication.

This section has introduced TS as a young, interdisciplinary field which studies a complex phenomenon, i.e. translation. But what is translation and how is it defined? These questions will be discussed in the following section.

3.2. Towards a definition of translation?

This section presents some different definitions of translation from different times and approaches. As such, these definitions cannot be compared, and they should by no means be seen as comprehensive of the field, but they function to give an idea of the different approaches.

Translation has been defined in various ways at different points in time and from different perspectives. Some definitions are quite narrow such as Catford's definition: "translation may be defined as follows: the replacement of textual material in one language (SL) by equivalent textual material in another language (TL)" (Catford, 1965, p. 20) showing a very textual and equivalence-focused approach to translation. Other definitions are quite broad like Toury's definition of translation as "any target language text which is presented or regarded as such within the target system itself, on whatever grounds" (Toury, 1982, p. 27). Other definitions approach translation from a wider perspective also taking the agents into consideration like Vandepitte:

> the translation activity is applied by a human agent to an object, the source text or source discourse, and the result is a new product, i.e., the target text or target discourse. This activity takes place in certain circumstances: with certain means in a certain place at a certain time. (2008, p. 570)

This could be perceived as a quite broad definition of the translation activity. Do we need to get closer to a definition? Some argue yes, which can be seen by Tymozcko's quote: "scholars in the field have been preoccupied in diverse ways with the task of defining translation" (Tymoczko, 2005, p. 1083). The need for a specific definition has also been fuelled by the desire to unify the field of TS. To explain this, I point to the discussion in TS about *shared*

ground, seen most explicitly, by the discussion with the same name in the TS journal Target in 2000. These discussions seem to have their root in a desire to unite the TS field, to find out which elements and definitions and models we share in TS. This could be seen as a push toward the need for a clear definition of translation.

Others argue that a strict definition of translation is irrelevant and unnecessarily restrictive limiting the field and the research conducted within it. A definition thus always leads to exclusion in some way. Tymoczko argues that it is not even possible to define translation "because translation, like the concept *game*, discussed by Wittgenstein, is an open concept" (Tymoczko, 2005, p. 1085). But does this mean that anything goes? No, because as according to Tymoczko, "the very openness of translation studies implies that every project must have its own research requirements and research design" (Tymoczko, 2005, p. 1095). This thus means that scholars need to be explicit about their approach to translation in each research study of translation.

In this dissertation, translation is viewed quite broadly. Here, the concept of translation encompasses all three of Jakobson's forms of translation, i.e. intralingual, interlingual and intersemiotic (Jakobson, 1959/2000; see also Chapter 2 for the relevance of intralingual translation for PILs). Below, I present the understanding of translation within some of the main paradigms of TS before I argue for the most suitable approach for my purposes.

3.3. Different approaches to translation

3.3.1. Equivalence-based approaches

Prior to the 1970s and 1980s, the discipline now known as Translation Studies was mainly a sub-discipline of Applied Linguistics, which "adopted methods of exact sciences in particular mathematics and formal logic" (Snell-Hornby, 1988, p. 14). This dominance by linguistic approaches to translation, which mainly viewed translating as a code-switching operation, led to a heavy focus on the importance of the source text and on preserving its features in the target text (Nord, 1997b, p. 7). Translation research was thus mainly dominated by an equivalence-based approach to translation, i.e. transferring all source text elements accurately into the target text: "The central problem of translation practice is that of finding TL [target language] translation equivalents. A central task of translation theory is that of defining the nature and conditions of translation equivalence" (Catford, 1965, p. 21). Several people have tried to further define and classify equivalence into sub-types (e.g. Koller, 1989; Nida, 1964). An equivalence approach sees the source text as the leading yardstick in translation (Nord,

2006, p. 32), implying that the "the key to translation lies in the source text only" (Zethsen, 1997, p. 13).

This approach to translation could be linked to an essentialist view of communication. Essentialism claims that meanings are stable and objective, which means that the translator's job is to find this meaning in the source text and transfer it to the target text, and remaining as invisible as possible. This approach to translation can thus be compared to the transmissionist communication paradigm, which sees communication as a sender-oriented linear event with focus on one-way communication (e.g. Shannon & Weaver, 1949, p. 7). Such early communication models have been criticised for their way of regarding the receiver as passive and because they ignore context (Frandsen, 2009b, p. 253). This stability of meaning is well described by Kiraly using a medical metaphor: "meanings are thus understood to be first injected into, and then extracted from the words through which they are transmitted" (Kiraly, 2000, p. 26). In the equivalence approach to translation, communication is thus seen as deterministic. The view is taken that the sender can control through the language the effect on the receiver (receiver is tabula rasa, input equals output). Such an equivalence approach also has consequences for the view of the translator and his/her job and expertise. The translator's job is to transfer meaning from a text in one language to a text in another (Kiraly, 2000, p. 25), which limits the expertise of the translator to mere decoding and encoding processes.It should be noted that some of the approaches within the equivalence paradigm saw the possibility of orientation towards to target text and situation, such as Nida's dynamic equivalence (Nida, 2004, pp. 162-163), which is more in line with the functionalist approaches presented below.

3.3.2. Functionalist approaches to translation - introduction

In the 1970s and 1980s, a shift started to occur. Translation changed focus away from purely linguistic and contrastive equivalence issues to the investigation of cultural aspects of translation (Munday, 2012, p. 111). During this time, it became clear that translation could not be encompassed in a linguistic model, but that it was essential to consider cultural aspects as well. Research thus shifted its focus to culture and sociolinguistic aspects of translating culture (Tymoczko, 2005, p. 1084). The attitude emerged that a new approach was needed; functionalism[9] was born (Nord, 1997b, p. 8). Functionalist approaches see translation as purpose-driven, outcome-oriented, human interaction. This was a new approach to translation, as the source text was no longer the leading yardstick for translation; instead the main task of

[9] I am aware that *functionalism* is used in other fields such as communication with reference to the transmissionist paradigm (Frandsen, 2009a, p. 249).

the translator is to produce a translation which is functionally communicative for the translation receiver (Nord, 1997b, p. 23). All texts are thus perceived as serving a specific purpose, and therefore, the translator should translate in a way which enables the text to function in the situation in which it is to be used and with the people who want to use it and in the way they want it to function (Nord, 1997b, p. 29). Functionalism therefore contains an acknowledgement that meaning is not stable, but that each translation situation is new and ad hoc translation strategies must be used, thus accepting, that even though meanings are not stable, the translator is able to tailor the translation towards specific receivers taking the full context into consideration as this context plays a part in forming the communication and the meaning. As a consequence of this view, the role of the translator also changes, because s/he has to determine what is *functionally communicative*. These approaches thus place translation in its sociocultural context instead of merely focussing on transferring source text content without reference to the contextual situation and the players involved (Munday, 2012, p. 133). With functionalism, translation thus shifted from being viewed as a mere act of transcoding to an act of communication, which also had the consequence that the translator is viewed as an expert in this communicative action.

Even though the cultural turn in Translation Studies is seen to have occurred in the 1980s (culminating with Bassnett & Lefevere's *Translation, History and Culture* (Bassnett & Lefevere, 1990)), which means that functionalist approaches are often viewed as predating the cultural turn (Nord, 2012, p. 30), functionalist theories of translation can to be considered within a cultural orientation to translation (Gentzler, 2004, p. 167; Nord, 2012, p. 30; Tymoczko, 2005, p. 1084), because of its focus on sociolinguistic aspects of translating culture and its opposition against the essentialist understanding of translation within the equivalence approaches (more about this below).

3.3.3. Other approaches

Before presenting functionalism further, it should be briefly mentioned that there are of course other approaches than equivalence and functionalist approaches within TS. With the cultural turn of the 1980s, questions of power and ideology started to take centre stage in TS (Bassnett & Lefevere, 1990), and non-essentialist approaches to translation were seen. Such approaches claim that no meanings are stable; they must be interpreted in each individual instance, meaning that the translator is inevitably visible (Chesterman & Arrojo, 2000, p. 151). Meanings are thus always context-bound (Chesterman & Arrojo, 2000, p. 158). Such approaches to translation include poststructuralist and deconstructionist methodologies to

areas such as Gender and Translation (e.g. Flotow, 1997; Simon, 1996) and Postcolonialism (e.g. Spivak, 1992 (reprinted 2004); Tymoczko, 1999).

Within these approaches, the receiver's unique knowledge universe controls the effect and language, and therefore, interpretation is completely open. This means that it is impossible to control the communication (and translation) process. However, if we are not able to say when a meaning is *likely* to be understood as something, i.e. it is not a guarantee, but if we argue that meanings are never stable in any way, how do we then perform translation? Therefore, here the theoretical premise is based on Becker Jensen (2001) that there is a certain amount of correspondence; i.e. in principle, it is possible to tailor the effect of a given text by using different linguistic and stylistic means. "If you do not accept this premise, you also say no to any kind of communication planning" (Becker Jensen, 2001, p. 103; my translation).

3.4. Different approaches within functionalism

Several scholars can be seen as influential in the emergence of the functionalist approaches to translation, i.e. Justa Holz-Mänttäri with her theory of *Translatorisches Handeln* (translatorial action) (Holz-Mänttäri, 1984), Hans J. Vermeer with his *Skopostheorie* or *skopos theory* in English (Reiss & Vermeer, 1984), and later also Christiane Nord, who elaborated on the functionalist approaches (Nord, 1991, 1997a, 1997b, 2002, 2006, 2012). The different approaches taken by these scholars will be further elaborated below.

3.4.1. Translatorisches Handeln – translatorial action

Holz-Mänttäri views translation as purpose-driven, outcome-oriented, human interaction, leading to the view that the main task of the translator is to produce a translation which is functionally communicative for the translation receiver (Schäffner, 1998a, p. 3). Translation thus changed from focus on words and sentences (in the linguistic equivalence approach) to the facilitation of intercultural communication. As a consequence of this view, the role of the translator also changes, because s/he has to determine what is *functionally communicative*. This leads to a new view of the translator as an expert in translatorial action. Furthermore, Holz-Mänttäri stressed that translation is a communicative process, which involves several players and roles, such as initiator, commissioner, source text producer, target text producer, target text user and target text receiver (Holz-Mänttäri, 1984, pp. 109-111). The translator is seen as unilaterally committed to the target situation as an expert communicator located at the crucial centre of the communication chain (Schäffner, 1998a, p. 3). The functionalist approaches are thus also seen as the first sociological approach to translation as it situates

translation and the translator within a wider social context. Holz-Mänttäri was one of the first to situate translation within a context of cooperative interaction between professionals (experts) and clients (Schäffner, 1998a, p. 3). With this theory, the translator is framed as an expert and as a responsible and independent agent (Holz-Mänttäri, 1986, p. 354).

3.4.2. Skopos theory

One of the most well-known approaches within functionalism is skopos theory. Skopos theory was introduced in the late 1970s by Hans Vermeer, and further described in Reiss and Vermeer (1984). Also Hans G. Hönig and Paul Kussmaul have contributed to the development of skopos theory (Hönig, 1998b, p. 9). *Skopos* is the Greek word for aim or purpose, and it is the aim or purpose of the target text[10] which is the main focus of the skopos theory (Munday, 2012, p. 122; Nord, 1997b, p. 27). The target text must be fit for its purpose, which is called *functionally adequate* (Munday, 2012, p. 125). Skopos theory sees translation as translational action based on a source text, and the translator is an expert in this kind of action (Vermeer, 2004, pp. 227-228). The translator is thus viewed as a responsible agent as it is the translator's main task to produce a target text that satisfies the cultural expectations of the target text receivers and their expectations of that kind of text. Hence, the skopos theory rejects and goes beyond the eternal problem of equivalence and also the constant battle over whether source text orientation or target text orientation should always prevail. Skopos theory does not prefer one macrostrategy over the other, but it is the translator who has to make this choice in the given communicative context based on a translation brief (see below). This also emphasizes the wide definition of what constitutes translation within functionalist approaches.

Vermeer formulated his skopos theory according to the six following rules (Reiss & Vermeer, 1984, p. 119 in Munday 2012, p. 122-123):

- **The first rule** is the skopos rule which states that a target text is determined by its skopos, which means that the purpose of the target text is the main determinant for the chosen translation methods and strategies, which produce a functionally adequate or appropriate target text.
- **The second rule**: a target text is an offer of information in a target culture and a target language, which is based on an offer of information (the source text) in a source culture and source language.

[10] The translated text is called a *translatum* by Vermeer, but here I will use the more widely used term *target text*.

- **The third rule:** the function of the target text does not necessarily match the function of the source text, i.e. a target text is not necessarily reversible. Hence, a back-translation of the target text might not lead to a translation which is similar to the original source text.
- **The fourth rule**: the target text must be coherent for the target text receivers in their situation. The receiver must be able to understand the target text, and the target text has to be meaningful in the communicative situation and target culture.
- **The fifth rule**: a target text must be coherent with the source text, which means that there must be coherence between the source text information received by the translator, the interpretation the translator makes of this information and the information that is encoded for the target text receivers i.e. intertextual coherence.
- **The sixth rule**: the first five rules are in hierarchical order with the skopos rule being the predominant rule.

3.4.3. Translation-oriented text analysis and *loyalty*

Nord extends the functionalist approach by incorporating elements of source text analysis. The purpose of such analysis is to deduce the overall feasibility of the translation, to choose which source text elements need to be taken into account to translate functionally and the translation strategy needed to fulfil the translation brief. Nord also adds the concept of *loyalty* to functionalism (the functionality plus loyalty principle). Loyalty refers to the responsibility translators have toward their partners in the translational interaction by committing the translator to both the source text side and the target text side. It is different from faithfulness or fidelity, which usually refers to relationships between the source and target texts, in that it refers to the relationship between people (Nord, 1997b, p. 125).

This overview of the different approaches within functionalism serves as an introduction to functionalism in general. Below, some of the main assumptions central to all approaches to functionalism are presented.

3.5. Main assumptions within functionalist approaches

3.5.1. Translator as responsible agent and expert

Vermeer maintains that in the skopos theory, the function of the target text may differ from the function of the source text (Vermeer, 2004, p. 236). Pursuant to this theory, it is therefore the translator's main task to produce a target text that satisfies the cultural expectations of the target text receivers and their expectations to that kind of text. This shows that the skopos

theory does not prefer one macrostrategy over the other, but it is instead the translator who has to make this choice in the given situation, i.e. the translator is perceived as a responsible agent, and an expert in translational action (Vermeer, 2004, p. 228). This also means that the translator is made co-responsible for the success of a communicative act (Vermeer, 1994, p. 13). Nord states that "[m]ost translational actions allow a variety of *Skopoi*, which may be related to each other in a hierarchical order. Translators should be able to justify their choice of a particular *Skopos* in a given translational situation" (Nord, 1997b, p. 29). This shows that the translator should be able to make conscious translation choices and be able to justify these decisions. Furthermore, the translator as expert must also be able to negotiate with clients as to whether a translation commission can be carried out successfully under the given circumstances (Schäffner, 2011, p. 159). Because clients are not translation experts, they often do not know what information the translator needs in order to produce a translation that will fulfil their needs and expectations. Therefore, it is the translator's responsibility to educate clients so they can learn to provide the necessary information and other available data (Nord, 2006, p. 30). What distinguishes expert translators from lay translators is the ability of the expert to substantiate the function of the text (Holz-Mänttäri, 1986, p. 352). Holz-Mänttäri does acknowledge that real-life translators may be constrained in their professional expertise by the power of clients (Schäffner, 2011, p. 160), which is also noted by Chesterman "it [skopos theory] also accords the translator greater freedom of action (provided that this freedom is accepted by the commissioner…)" (Chesterman, 1998, p. 157).

3.5.2. The translation brief

One of the elements most emphasized by skopos theory is the translation brief[11]. The concept of the translation brief has been defined differently by different scholars. Chesterman (2007, p. 178) argues that it includes the ST, the skopos, the resources, the deadline, fee etc. Other scholars argue that the skopos is not part of the brief as the skopos is what is elicited from the brief by the translator. Vermeer defines it as the instruction, given by oneself or by someone else, to carry out a given action, in this connection: to translate (2004, p. 235). According to Nord (1997b, p. 60), the client should give the translator very thorough instructions, either explicitly or implicitly, about the purpose, the receivers, time, place, occasion and medium.

[11] The term *Übersetzungsauftrag* is the originally coined German term for this concept. However, the German term can be translated in different ways, such as *translation commission* or *translation assignment*. These terms have been used by functionalist translation scholars when using the term in English. Furthermore, Nord introduced the term *translation instructions*. However, the term, *translation brief*, introduced by Fraser (1996) seems to be preferred by several scholars (one of them being Nord who switches from using *translation instructions* to using *translation brief* (Nord, 1997b, p. 30) and Translation Studies sources, which is why this term will be used throughout this thesis when referring to the German *Übersetzungsauftrag*.

Vermeer, however, acknowledges that in real life, the brief, including purpose and receivers, can be apparent from the situation itself, i.e. there is then an implicit skopos (2004, p. 235). Despite this realization that often no explicit brief is given, Vermeer argues that there is a "necessity for a change of attitude among many translators and clients: as far as possible, detailed information concerning the skopos should always be given" (2004, p. 235). The initiator and the translator should together negotiate the purpose of the translation; however, the decisions concerning the translation task itself and applied translation strategies ultimately rest with the translator, who is the expert (Vermeer, 2004, p. 235). Montalt Resurrecció & González Davies (2007, p. 29) and Nord (2006, p. 30) agree that it is the translator's responsibility to ask the client for more information if the client does not provide it as clients are not always aware of the information needs of translators.

3.5.3. *Dethronement* of source text

With functionalism, also the source text acquires a new status compared with the equivalence approaches. The needs of the target text receiver become the determining factor, leaving the source text with the function of *source material* (Schäffner, 1998a, p. 4) or a mere *offer of information* and the translator's *raw material* (Nord, 1997b, p. 37). This has been referred to as the *dethronement* of the source text, a term used by Vermeer himself (Vermeer, 1986, p. 42).

3.5.4. Contingent translation quality

When taking a functionalist approach to translation, it is not possible to set up universal error typologies or similar. Translations are texts that are contextually bound interactions, and therefore, translation assessment should instead show whether the translation is appropriate for the required translation skopos (Nord, 1991, p. 163). It therefore requires "a frame of reference, i.e. a set of criteria for the assessment of the translation" (Nord, 1991, p. 165). Thus, when taking a functionalist view to translation an expression or utterance cannot in themselves be incorrect, but translation errors must be mirrored against the translation function (Nord, 1991, p. 169). Translation quality is therefore contingent, and thus, in order to analyse any translation, the communicative situation must first be analysed to establish the translation skopos (more about skopos establishment below).

3.6. Criticism of functionalism and response

Even though functionalist approaches to translation offered a new way to view translation and the role of translators and hence was welcomed by many, it has also received criticism. The

purpose of this section is not to give an exhaustive overview of the criticism presented against functionalism, but to present the criticism which is relevant in the context of PIL translation.

Skopos theory has been perceived by some as being unethical as it potentially produces translators who are "mercenary experts, able to fight under the flag of any purpose able to pay them" (Pym, 1996, p. 338), and the translator can pick any skopos s/he wants. This is contested by Nord, who says that this is a misinterpretation of the theory (1997b, p. 117). To avoid this misinterpretation, Nord introduced a principle of *loyalty* as the answer to this criticism (treated above in section 3.4.3). This gives the skopos theory an ethical element because it limits the unlimited range of skopoi which could otherwise be used (Nord, 2006, p. 33). I would argue, however, that even without the loyalty concept, there would not be an unlimited range of skopoi; the skopoi would always be limited by the context of a given translation situation.

Moreover, criticism has been put forward by Stolze concerning the fulfilment of a given skopos. Skopos theory does not deal with translation strategies at micro level and therefore, it does not give any suggestions or help on how to fulfil the skopos (Stolze, 1994, pp. 164-165, 180). Furthermore, skopos theory does not suggest how to evaluate or determine whether a skopos has been achieved. According to Vermeer, the reason for this is that skopos theory says that you must "translate consciously and consistently, in accordance with some principle respecting the target text. The theory does not state what the principle is: this must be decided separately in each specific case" (Vermeer, 2004). Skopos is therefore situation-dependent, and hence, it is not possible to categorise into different microstrategies. This means that *ad hoc* microstrategies must be used instead. Skopos theory would probably say that these choices should be based on the skopos, but that only leads us full circle back to the question of how to establish and operationalize a skopos. I would also argue that it is problematic that skopos theory emphasizes that translations should be aimed at target text receivers, but it hardly discusses the problems of doing so. It could be argued that this is circumvented in skopos theory by statements such as "if the TT [target text] fulfills the skopos outlined by the commission, it is functionally and communicatively adequate" (Munday, 2012, p. 125). But according to this quote, adequacy is not linked to the receivers, but only to the brief. Of course, ideally, the brief should be linked to the target text receivers, but it is possible to imagine competing skopoi. This thus means that a translation could fulfil its skopos according to the brief, but it might not do so in real life, i.e. its success is gauged against the brief, not the real life receivers. As far as the criticism of the potential problematic of assessing whether a text achieves the function we want it to achieve, Nord argues that we have to "rely on the

audience's willingness to cooperate in a given situation, otherwise communication would be impossible" (2006, p. 31).

Another criticism of skopos theory is the terminological issues concerning the word *skopos*. To Nord, *skopos* is the more or less explicit description of the prospective target situation, and it is to be derived from the instructions given by the initiator (Nord, 1991, pp. 9-10). However, it also seems that Nord, especially in older sources, uses the term skopos both when referring to the function/situation of the target text (as above), and also when referring to the translation brief (e.g. Nord, 1991, p. 34). In Reiss & Vermeer (1984), skopos refers to both the function of the source text and the target text, and Vermeer also sometimes uses skopos to refer to the aim of the translation process (Vermeer, 2004, p. 227). In this thesis, the term *skopos* is based on Nord's newest definition, i.e. it only refers to the function of the target text, which is established based on a brief, and therefore, skopos is not used for the source text and skopos is never given to translators by clients; it is always established by the translator from an analysis and interpretation of the brief.

3.6.1. Functionalism – realistic or idealistic?

Some of the criticism of functionalist approaches to translation has been grounded in its status as a theory. Some claim that functionalism is problematic because it sets up prescriptions; however, these prescriptions have not been empirically tested, and they therefore merely describe ideals. For example, it has also been claimed that functionalism is invalid because translators in practice do not have a specific goal or a specific receiver in mind; they merely translate what is in the source text. Vermeer responds to this criticism by arguing that there is always a receiver, it might just be a very fuzzy and indeterminate group of receivers (2004, p. 233), but in any case, translators have a clear idea of who they are *not* addressing (Nord, 1997b, p. 111). Furthermore, the translator does need to make a conscious decision about the target text receiver when presented with a situation in which there are two or more translation solutions and the solution is dependent on the target text receiver "with regard to receiver-dependant qualities such as acceptability or comprehensibility" (Nord, 1997b, p. 111). To exemplify this, Nord gives the following very PIL translation-relevant example of the choice between a Latinism and a common German term in medical translation, i.e. the example of Appendizitis (expert term for appendicitis) vs. Blinddarmentzündung (lay term for appendicitis). Here, the translator would need to take the target text receiver into consideration when deciding on a translation choice.

Functionalist approaches do not pretend to be descriptive, and empirically based. As opposed to Descriptive Translation Studies, its main aim is not to describe naturally

occurring translation phenomena. Nord argues for this by the following analogy: "If we take existing translations to be the norm governing any future translation process, we risk getting the fox to keep the geese" (1997a, p. 42). Also Holz-Mänttäri clearly states that her theory depicts an ideal system which describes optimal translator behaviour (Schäffner, 2011, p. 161).

Some attempts have been made to test some of the aspects of functionalism, e.g. the use of briefs by professional translators. The empirical research conducted shows that some translators experience difficulties getting the information and resources they need from their clients, i.e. getting *explicit* briefs (Nisbeth Jensen, 2009), which some translators think are of great importance for the translation task (Fraser, 2000, p. 54). Fraser's study shows that professional translators think that having a translation brief is very important; however, often, they are not given one, and interestingly, many of them do not ask for one.

3.7. Functionalism and its relevance for PIL translation

For PIL translation, the contextual situation and especially the target text receiver are extremely important because if the receiver is not able to understand the content, it could have major health consequences, which means that the target text receiver needs to be a determining factor for translation and hence translation analysis. The main purpose of PIL translation is thus to facilitate communication between different linguistic communities, not to reproduce a source text accurately. Furthermore, a comparative analysis of equivalence would not reveal the problems with lay-friendliness linked to differences in linguistic systems as will be illustrated in the following example taken from a PIL. The translator has made a literal translation of the source text compound noun *insulin injection syringes*, i.e. *insulininjektionssprøjter*. According to Danish grammar rules, compound nouns must be written in one word. The literal translation of this compound noun would impede on comprehension because it becomes such a long word (Becker Jensen, 1998, 2001, 2007b; Charrow, 1988, p. 99; Halliday, 1990, p. 13). A more functionally appropriate translation for *insulin injection syringes* could e.g. be *insulinsprøjter* [insulin syringes] as the Danish word for *syringe* already carries the meaning of *injection*. Another option would be to change the compound to a clause: *sprøjter til at indsprøjte insulin* [syringes to inject insulin]. In order to take such translation choices into consideration when analysing whether the translators have tailored their translation toward the target text receiver, a functionalist approach is useful for PIL translation. The functionalist approach emphasises the receiver of the target text as one of the most important elements when determining the purpose of a translation (Nord, 1997b, p.

12). Thus, an approach to translation based on an equivalence principle would not lead to successful PIL translations.

Some might argue that the skopos theory is not suitable for the translation of PILs because functionalism dethrones the source text and regards it as a mere *offer of information* and the translator's *raw material* (Nord, 1997b, p. 37), because according to the EU legislation, the source text is the authorised text. In this context, it is important to bear in mind that skopos theory does not say that target text orientation is the only way to translate; the skopos of a given translation can also recommend a strict word-for-word translation (source text orientation) or depending on the skopos of a translation, anything between these two extremes (Nord, 1997b, p. 29). Furthermore, as seen in the background chapter introducing the legal framework, EMA now has realised that strict literal translation is not a good solution for the translation of PILs, and more freedom is allowed. It should be noted here that even though a translation skopos might lead to source text orientation, i.e. if the translation has the same function as the source text, the translation process is not merely a *transcoding* process, because the target text should still be oriented towards the target culture situation or situations (Vermeer, 2004, p. 229).

For PILs, a functionalist skopos-theoretical approach is thus useful because of its focus on the function of the target text, the contextual environment surrounding this mandatory genre, and especially the target text receivers, who need to be able to understand the pharmaceutical information. Functionalism states that a translator should translate in a way which enables the text to function in the target situation in which it is to be used and with the people who want to use it and in the way they want it to function (Nord, 1997b, p. 29). However, one of the main criticisms against functionalism concerns the establishment and fulfilment of a skopos, both of which are needed when having to assess whether PIL translators have fulfilled the skopos. Furthermore, because functionalism views translation as a complex communicative activity that requires expert competences, it is possible to hypothesize that the competences of the translators might also influence the translation product, which is the main research interest in this dissertation. Below, functionalism is mapped against PILs with a view to establishing the skopos of PIL translation.

3.7.1. The skopos of PIL translation

According to EU legislation, PILs must be "written and designed to be clear, understandable and enable the users to act appropriately" (European Parliament and of the Council, 2001, Article 63(2)). It is thus explicitly stated that PILs must be easy to understand for the receiver. Based on the institutional context of PILs and the communicative situation presented in

Chapter 2, I would argue that PILs have two main skopoi: 1) ensuring that the source text is translated accurately and completely and 2) ensuring that the target text receivers are provided with an optimally understandable text which is characterised by easy-to-understand language, i.e. lay-friendliness. In this dissertation, the second skopos is of main concern in the light of the studies showing that translated PILs are more linguistically complex than their source texts. The skopos of PIL translation is thus established as lay-friendliness. The concept of lay-friendliness and its operationalization is further treated in Chapter 6.

3.7.2. Summary of functionalism and its relevance for PIL translation

This translation-theoretical chapter served to present the main disciplinary context of Translation Studies as well as the theoretical approach to translation. The importance of this theoretical foundations chapter will also become evident in the next chapter on methodology because the presentation of Translation Studies is relevant for the paradigmatic approaches to translation research. Furthermore, this chapter served to introduce and discuss the skopos of PIL translation, i.e. lay-friendliness which will be further unfolded in Chapter 6 when the textual analysis of PILs is introduced, because "the perception and evaluation of an error as a translation 'error' depends on the theoretical approach to translation and the evaluator's ethical norms with respect to translation" (Hansen, 2010, p. 385). Therefore, to analyse the PIL translations, it is necessary to emphasize that functionalist approach to translation, which means that an error is defined as relative to the fulfilment of the target text function and the receiver's expectations.

3.8. Conclusion - Two diverging approaches to translation

So far, for PIL translation, two views of translation have been presented, the view presented by functionalist approaches within Translation Studies and the view presented by the European Medicines Agency elicited through their written communications presented in Chapter 2.

The functionalist approaches to translation are characterised by three main elements:

- Translation is a complex, communicative act.
- The function of target text and role of target text receiver are the main foci of translation.
- The translator is a responsible agent and an expert of translatorial action.

EMA's approach can be characterized by the following elements:

- Translation can be performed quickly (pharmaceutical companies only have *five days* to provide all the translations).
- Equivalence of content is the only relevant factor (the quality checks are only based on content, correctness and accuracy).
- A good source text leads to a good target text (only one language version needs to be tested with users, most often the English source text).
- It is possible to produce a source text that can *easily* be translated into 23 languages (When drafting original PIL, it should be ensured that the PIL can be translated from the original to the various national languages in a clear and understandable way).

EMA's approach thus seems to be more transmissionist-oriented with an equivalence view of the translation process.

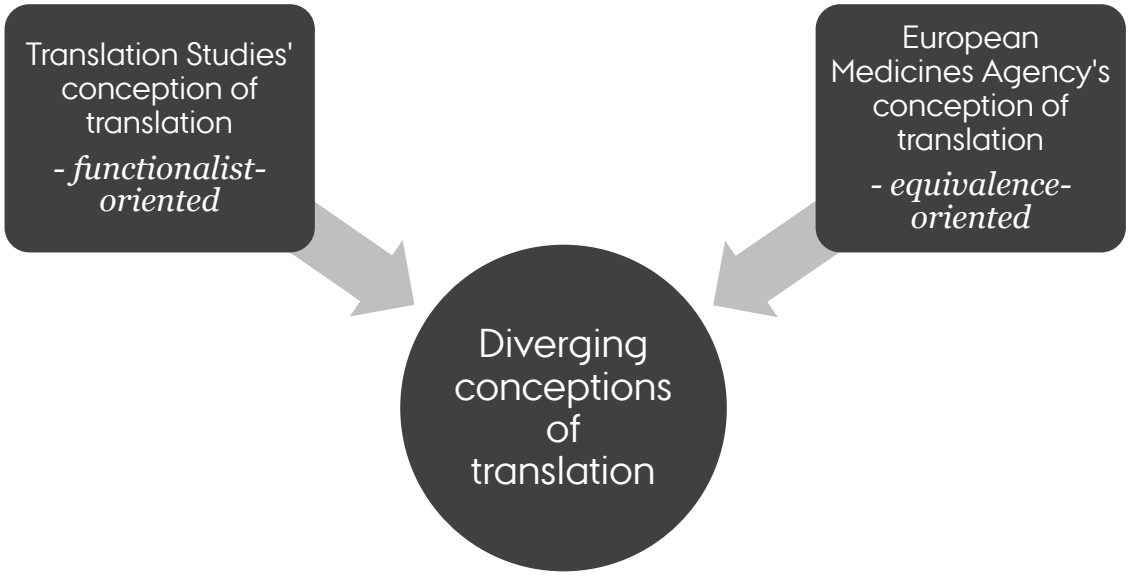

Figure 7: Diverging conceptions of translation between Translation Studies and the European Medicines Agency.

Figure 7 shows the approaches to translation of functionalism within Translation Studies and EMA; however, there are more relevant voices in PIL translation. Therefore, it should be emphasized here that the functionalist approach to translation is the approach to translation taken in this dissertation; it might not be the approach taken by the PIL translators. This in itself would influence the translation process and product, which is why in the empirical studies, the approach to translation taken by the PIL translators will be investigated.

As mentioned in Chapter 2, only few previous studies have focused on PILs as translations, and therefore, the studies into PILs have primarily focussed on the PIL texts themselves, i.e. the products, not on the translation process and the translator. Shifting the

main focus away from the translation product and instead focussing on the translation process and the players involved allows us to investigate whether the increase in complexity in the translation could be linked to the contextual circumstances such as the background of the translators and their translation competences. Within translation approaches that take these contextual factors into consideration, such as functionalism, translation is viewed as a complex communicative activity that requires expert competences (PACTE, 2003, p. 44). We can therefore assume that the competences of the translators might also influence the translation product. The concept of translation competence and the hypothetical competences of PIL translators are presented and discussed in Chapter 5; however, first the overall methodology of the dissertation is presented in the next chapter.

4. Methodology

> Translation – the concept as well as what it does and represents – has been studied in the most diverse ways: inductively, deductively, analogically, dialectially, didactically, descriptively and symbolically, postmodernly and, yes…haphazardly. (Simeoni, 2000, p. 340)

We saw in Chapter 3 that TS is a very young discipline, born out of other research disciplines, and that it continues to borrow research models, theories and methods from other disciplines as well as developing its own to be able to investigate the complex phenomenon of translation. All these elements have shaped and continue to shape the field, and they have consequences for the research conducted and the methods used. A complex phenomenon like translation, with interdisciplinary roots, opens up for the possibility, even need, to be studied from various angles and using various approaches. Thus, it is not desirable or feasible to contain the research of translation within one single paradigm (Gile, 2004a, p. 126). This chapter will briefly present the main research paradigms within TS to provide the reader with an understanding of the research eclecticism leading to various research design possibilities within TS. After this, the chapter will be structured according to Creswell's framework for research designs presented just below in Figure 8. Creswell argues that the elaboration of a research design involves the interconnection of worldview assumptions, strategies of inquiry and specific methods (Creswell, 2009, p. 5). Therefore, in the following, I will introduce pragmatism as the dominant worldview of this dissertation and argue for a pragmatist approach to research. A pragmatist approach opens up for the possibility of making choices driven by the research problem and using the methods relevant for the particular study. Then, I will present the so-called *third methodological movement* of mixed methods as the strategy of inquiry (Tashakkori & Teddlie, 2002b, p. 5) and argue why a mixed methods strategy best answer the research questions of this dissertation. Finally, the overall research design comprised by three studies and their methods will be discussed.

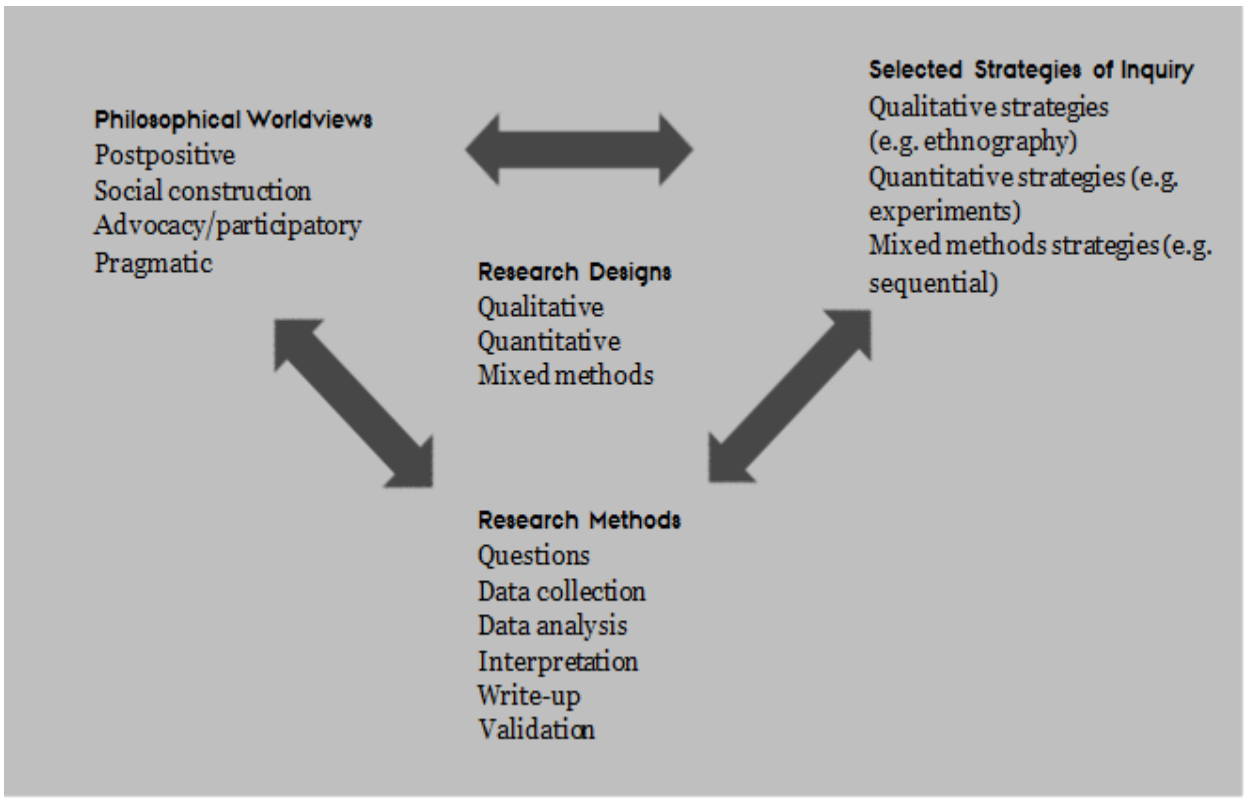

Figure 8: The interconnection of worldviews, strategies of inquiry and research methods (Creswell, 2009, p. 5).

4.1. Research approaches within Translation Studies

> The proliferation of translation studies from the second half of the twentieth century until now has produced a multitude of approaches, models, concepts and terms (Vandepitte, 2008, p. 569).

Chapter 3 showed the different approaches to understanding the concept of translation. It was demonstrated that there are different approaches to the definition and concept of translation, and thus still no *shared ground*, but what does this mean to the *research* conducted within Translation Studies? First of all, it could be argued that because of this young age, TS has not been dominated by discussions about philosophical approaches to research. Secondly, because of the interdisciplinarity of the field, no one single fixed research paradigm exists. Thirdly, because of the inherent complexity in the phenomenon of translation, both as a concept and as a practice, one could argue that no one research model would be able to encompass the entire field. This has led to an accepted eclecticism (Crisafulli, 2002, p. 26; Gentzler, 2001, p. 163; Martín Ruano, 2006, p. 48). For these reasons, many different philosophical approaches and both quantitative and qualitative methods are being used depending on the nature and area of

the research. According to Hansen, in TS, quantitative and qualitative methods can be used in a variety of combinations without a universally ideal way of combining these methods (Hansen, 2008a, p. 2). Two main paradigms have, however, been identified, and these will be further presented below.

According to Gile, there are two main paradigms within TS, i.e. the *natural science paradigm* (Gile, 2004a, p. 126) and the *humanities-inspired paradigm* (Gile, 2004b, p. 16). In simple terms, these two paradigms can be linked to the two major philosophical poles, i.e. a positivist position (natural science paradigm) or an interpretive/constructivist position (humanities-inspired paradigm). This dichotomy of paradigms is a simplification with e.g. researchers from the humanities-inspired paradigm doing empirical research and vice versa. Furthermore, it does of course not represent an exact division as there is room for diversity within each. None of these paradigms are dominant, and according to Hansen: "what is most interesting and important in this connection is that Translation Studies of all disciplines absolutely cannot make do without *both* paradigms" (Hansen, 2008b, para 5). According to Creswell, the choice of paradigm is not given, but contingent, and thus needs to be based on the research interest and the research questions asked as illustrated in Creswell's model above (Figure 8). Along the same line, Sullivan & Porter argue that "research methodology should not be something we apply or select so much as something we *design out of particular situations and then argue for* in our studies" (Sullivan & Porter, 1993, p. 221), which then opens up for the possibility of mixing and integrating different approaches and methods. This fits well with a pragmatist approach to research, which I will present and argue for below.

4.2. Pragmatism - "What works"

This section introduces pragmatism as a philosophical approach to research, as an alternative to an either strict positivistic or interpretive/constructivist approach, and as an answer to the *paradigm war* (Tashakkori & Teddlie, 2008, p. 15) or the *incommensurability of paradigms* (Morgan, 2007, p. 67).

By the late 1970s, many researchers in Social Sciences grew frustrated with the positivist paradigm, leading to the surge of the metaphysical paradigm with focus on qualitative methods (Morgan, 2007, p. 55). The fundamental assumptions of the positivist paradigm were questioned, and focus shifted to an emphasis on metaphysical questions about the nature of reality and the possibility of truth (Morgan, 2007, p. 58). An important aspect of the metaphysical paradigm was its reliance on *incommensurability of paradigms* (Morgan, 2007, p. 58), which resulted in the impossibility of mixing paradigms and thus approaches and methods.

In recent times, however, a new paradigm shift has occurred, and Morgan believes that the metaphysical paradigm is exhausted (2007, p. 55). One of the main problems with the metaphysical paradigm is its focus on abstract discussions about philosophical assumptions and little attention to how these abstract ideas relate to practical decisions to be made by "workaday researchers" (Morgan, 2007, p. 63). The metaphysical paradigm has a top-down approach in that it starts with ontological assumptions about the nature of reality, which then limit the subsequent epistemological assumptions about the nature of knowledge (Morgan, 2007, p. 57; see Figure 9).

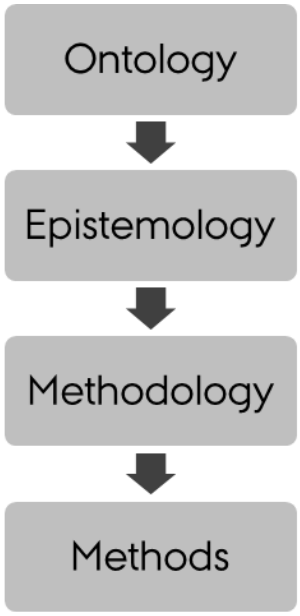

Figure 9: Top-down approach in the meta-physical paradigm.

Morgan suggests the pragmatist paradigm as a replacement of the metaphysical paradigm, i.e. as a philosophical basis supporting research that combines qualitative and quantitative methods, but also as a way to refocus attention on methodological issues rather than metaphysical one (Morgan, 2007, p. 48). This means that instead of focusing on a top-down approach which privileges "epistemology over methods but also to emphasize ontological issues above all others" (Morgan, 2007, p. 68), pragmatists would consider issues that are directly connected to the research interest itself (Morgan, 2007, p. 68; see Figure 10). Thus, in pragmatism, the research problem is emphasized and researchers use the approaches available to understand this problem instead of having an overarching worldview as the dominant yardstick (Creswell, 2009, p. 10). This means that pragmatist epistemology is empirical not foundational (Scott & Briggs, 2009, p. 230). Pragmatism can also be seen as a solution to the *paradigm incompatibility thesis*, which says that the conflict between qualitative and quantitative research is so fundamental that it is impossible to combine them, as this would entail the combination of different worldviews. Pragmatism thus circumvents the antagonistic

issues of truth and reality, and "accepts, philosophically, that there are singular and multiple realities that are open to empirical inquiry and orients itself toward solving practical problems in the "real world"" (Feilzer, 2010, p. 8).

Pragmatism can be seen as a bottom-up approach in that it is the research interest which guides the selection of methods etc. (Johnson & Onwuegbuzie, 2006, p. 16; Tashakkori & Teddlie, 1998, p. 21). However, as visually depicted in Figure 10 below, it is more accurate to see the approach with the research interest in the central position (instead of at the bottom). Such an approach to research opens up the possibility of mixing different methods within the same study. This is the case because pragmatism circumvents the divide between quantitative and qualitative methods, and thus the paradigm war, because it argues that the most important element is whether the researcher has been able to find out what s/he wanted to know (Feilzer, 2010, p. 14).

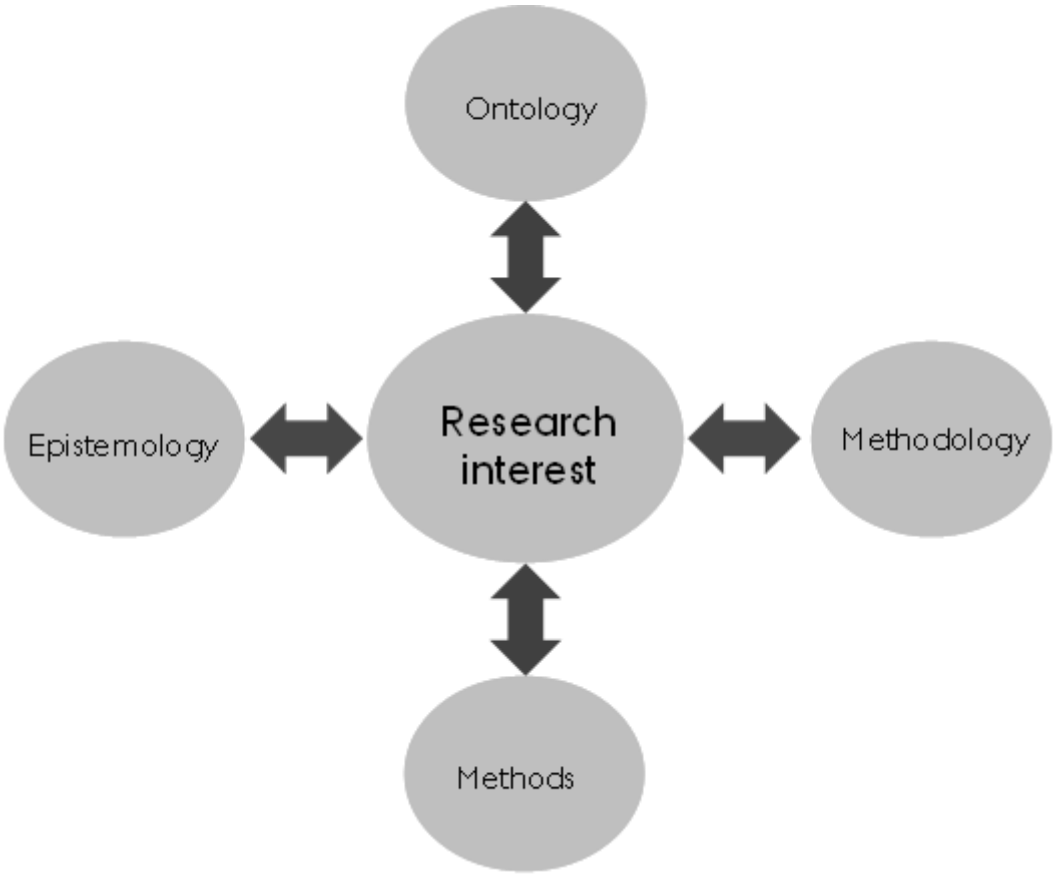

Figure 10: The central role of the research interest in the pragmatism.

4.2.1. Pragmatist approaches within Translation Studies

It seems that a pragmatic approach is often taken with TS, in that the choice of method depends on the research questions: "The choice of qualitative and/or quantitative methods has to be taken in relation to the particular research issue(s) under study" (Hansen, 2005b, para 3);

however, researchers rarely explicitly state that they adhere to this approach. As we saw above, translation is a very complex phenomenon, which according to Martín Ruano means that no one scientific approach or research model is possible:

> Once translation has been recognized as the complex, plural, multifaceted phenomenon it is, it seems incongruous, not to say short-sighted, to pretend that the progress of knowledge about it can or should only follow a unidirectional, cumulative pattern eliding rather than highlighting its diversity. (Martín Ruano, 2006, p. 50)

This can be seen as an indication that the research study in question should lead the way, not an *a priori* worldview. Pöchhacker suggests the possibility of using a pragmatic position because "pragmatists accept multiple realities and will use any philosophical and methodological approach that works best for a given research problem" (2011, p. 13). He argues that pragmatism might be especially suitable for Interpreting Studies (which I extend to Translation Studies), because:

> mixing methods, in the paradigmatic sense, and thereby, to some extent, blending epistemological orientations and research traditions would seem to suggest itself as **the policy of choice** for **a field with as complex and multi-faceted an object of study and as great a diversity of conceptual approaches as interpreting studies.** (Pöchhacker, 2011, p. 22; my emphasis)

The importance of the research question as the guiding element in research is supported by Pöchhacker as he argues that the purpose of research in interpreting is not a matter of philosophy, but about "*doing* science by asking research questions and answering them by adopting an appropriate method of inquiry" (Pöchhacker, 2011, p. 16). Also Chesterman argues for the appropriateness of a pragmatist approach to research in TS (2004, p. 54).

In the above sections, it becomes clear that pragmatism is not only a suitable approach to research within TS, but it is also often the preferred approach within TS; however, often without researchers explicitly claiming to adhere to this approach. Despite the acceptance of eclecticism and pragmatism, clarity about concepts and assumptions is paramount to avoid potential misunderstandings as a results of the different paradigms within TS (Gile, 2005, para 4).

4.2.2. Pragmatism and methods

Pragmatism is seen as the philosophical underpinning for mixed methods studies (Morgan, 2007; Tashakkori & Teddlie, 1998). Because pragmatism is not committed to any one ontology and epistemology, it is possible to design a study that includes both quantitative and qualitative methods, i.e. a mixed methods research study. Consequently, for mixed methods researchers, pragmatism provides the possibility for the use of multiple methods and different assumptions, as well as different forms of data collection and analysis (Creswell, 2009, p. 11). In line with Sullivan & Porter, here, methods are not seen as static, and instead as dynamic and negotiable, and something which is shaped continuously by the practice of research or by the situation (Sullivan & Porter, 1993, p. 230). Sullivan & Porter thus see methodology "as heuristic rather than determining" (1993, p. 221), which is also the view taken in this dissertation. In the following, mixed methods research is presented before the overall research design of this dissertation is presented.

4.3. Mixed methods research designs

Overall, there are three types of research designs, i.e. qualitative, quantitative and *mixed methods*[12]. I will here argue for a mixed methods research design, but first, I will introduce mixed methods, also known as the *third methodological movement* (Tashakkori & Teddlie, 2002b, p. 5) or the *third research paradigm* (Johnson & Onwuegbuzie, 2004, p. 14). According to Creswell, qualitative and quantitative approaches should not be seen as poles or dichotomies, but at different ends of a continuum (2009, p. 3), which opens up for the possibility of combining them within the same study. It should in this connection also be noted that qualitative and quantitative data are not easily distinguishable. According to Coffey & Atkinson, this "distinction is more arbitrary than a reflection of major, inherent differences" (1996, p. 5). Mixed methods research has been defined in various ways witnessed by e.g. the article by Johnson, Onwuegbuzie & Turner "Toward a definition of mixed methods research" in which they found 19 definitions (2007, p. 118). One of the most comprehensive definitions of mixed methods is provided by Creswell & Plano Clark:

> a research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis and the mixture of qualitative and quantitative

[12] Also sometimes referred to as *multi-method approach*, *multimodality* or *triangulation*, but here, *mixed methods* will be used as this is the term agreed upon by scholars who has developed this approach such as Creswell (Creswell, 2009), Plano Clark (Creswell, Plano Clark, Guntmann, & Hanson, 2003), Teddlie, Tashakkori (Tashakkori & Teddlie, 1998, 2002a; Teddlie & Tashakkori, 2009), Onwuegbuzie and Johnson (Johnson & Onwuegbuzie, 2006).

> approaches in many phases of the research process. As a method, it focuses on collecting, analyzing, and mixing both quantitative and qualitative data in a single study or series of studies. Its central premise is that the use of quantitative and qualitative approaches, in combination, provides a better understanding of research problems than either approach alone. (2007, p. 5)

Mixed methods studies thus combine both qualitative and quantitative approaches by mixing and integrating them in one study. Mixed methods is more than simply collecting and analyzing quantitative and qualitative data as it has a cumulative force involving both approaches simultaneously or sequentially giving a study an overall strength which is greater than either qualitative or quantitative research (Creswell & Plano Clark, 2007, p. 2).

Before embarking on a mixed methods study, four essential factors must be considered, i.e. timing, weighting, mixing and theoretical perspective (Creswell, 2009, p. 206 pp; Creswell & Plano Clark, 2011, p. 66 pp) as seen in Table 2 below.

Fundamental characteristics of the research design	
Timing	In mixed methods research, first of all, the timing of the research needs consideration. It can either be sequential (in phases) with either qualitative or quantitative first, or concurrently where both kinds of data are collected at the same time.
Weighting/priority:	The weighting or priority given to the qualitative or quantitative research needs to be considered. It might be equal or one part might be prioritized more than the other.
Mixing – stage:	The mixing can occur temporally at different phases in the research process, i.e. at data collection, data analysis, interpretation or at all these three phases.
Mixing – type:	There are three types of mixing: 1. Connected: a data analysis of the first phase of research is connected to the data collection of the second phase of research 2. Integrated: the merging quantitative and qualitative data 3. Embedded: a secondary form of data is embedded within a larger study; the secondary data plays a supporting role
Theoretical perspective:	This is whether a larger, theoretical perspective guides the entire design. It can be either explicit or implicit.

Table 2: Fundamental characteristics of the research design.

Linked to these aspects are the three main mixed methods designs (Creswell, 2009, pp. 14-15):

- **Sequential mixed methods**: the researcher seeks to elaborate on or expand on the findings of one method with another method, the operative word being sequential. The researcher can e.g. commence with an exploratory, qualitative study that informs a second, quantitative study,
- **Concurrent mixed methods**: the researcher unites or merges quantitative and qualitative data in order to provide a comprehensive analysis of the research problem, but here both forms of data are collected at the same time.
- **Transformative mixed methods**: the researcher uses a theoretical lens as overarching perspective with focus on change and advocacy. The design contains both quantitative and qualitative data.

4.3.1. Strengths and weaknesses of mixed methods research

Before embarking on a mixed methods research design, the strengths and weaknesses should be considered. These can be found in Table 3 below:

Mixed Methods Research	
Arguments for MMR	**Arguments Against MMR**
- Words, pictures and narratives can be used to add meaning to numbers – quantitative research is weak in understanding context - Numbers can be used to add precision to words, pictures and narrative – qualitative research has difficulties generalizing - Can draw on strengths from both quantitative and qualitative research - Gives the opportunity for both generating and testing theory - The strength of one method can be applied to overcome the weaknesses of another - Can provide more complete knowledge and stronger conclusions through convergence and corroboration of findings	- Can be difficult for *one* researcher to carry out – especially in case of parallel designs - Includes weaknesses of both qualitative and quantitative research - Time-consuming - Expensive - A challenge to learn and master multiple methods - Often requires researchers to work in teams - Problems of paradigm mixing - Methodological purists who hold that one should always work within either a qualitative or a quantitative paradigm - Problem of convincing others of validity

Table 3: Advantages and disadvantages of mixed methods research designs, borrowed from Schmeltz (2012, p. 43).

As can be seen in Table 3, there are several challenges when embarking on a mixed methods design; this is especially the case for one researcher because mastering multiple methods can be challenging as well as time-consuming. These challenges can be overcome, which is also the case with the disadvantages listed that are related to paradigm mixing and method mixing as these become irrelevant in the pragmatist worldview. The potential of mixed methods in

producing more complete knowledge and stronger conclusions through convergence and corroboration of findings thus outweigh the disadvantages.

4.4. Research design of this dissertation

In line with the above overview of the pragmatic approach, the research questions will lead the way for the studies to be conducted. The leading yardstick is thus the research interest, and the methods used are the methods found to be most appropriate to explore this interest. The main research question of this dissertation is as follows:

> *Does the profile and translation competence of PIL translators influence the linguistic complexity of translated PILs?*

I have opted for a mixed methods design as in order to answer my research question, both quantitative and qualitative methods are needed as the research design involves both explanatory and exploratory element as will be demonstrated below. More specifically, the research design follows a type of the sequential design which combines explanatory and exploratory approaches, i.e. the iterative sequential design, which is a sequential study with more than two phases (Teddlie & Tashakkori, 2009, p. 274), in this case, three phases. Iterative designs are characterized by the mixing of qualitative and quantitative methods which occurs in a dynamic, changing, or evolving manner over the course of the research project, meaning that the findings at one stage influence decisions about the next stage (Nastasi, Hitchcock, & Brown, 2010, p. 320). Figure 11 below shows an overview of overall research design.

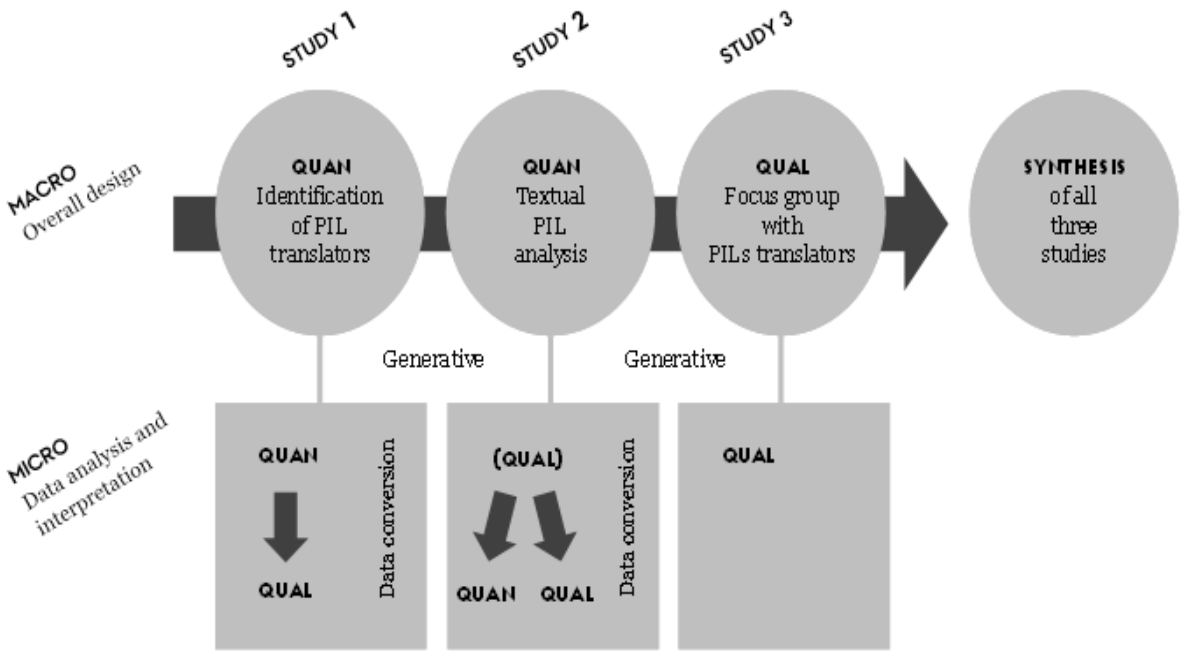

Figure 11: Overall research design.

As can be seen in Figure 11, the research design is structured according to the strategy QUAN→QUAN→QUAL on the macro level. This depiction follows the mixed method notation system developed by Morse (2003, p. 198) The arrows signify that the design is sequential with each study having generative input for the next study, i.e. the initial quantitative results will be used as a basis for conducting study 2 which will inform the qualitative data collection, analysis and interpretation in study 3. Therefore, research questions and methods depend on the previous study. The capital letters signify an equal weighting to all studies[13]. The data from the three studies are separate, but still interconnected. At the micro level, i.e. at the level of analysis and interpretation, data conversion (Teddlie & Tashakkori, 2009, p. 146) occurs in study 1 and 2. Data conversion involves either qualitizing, i.e. converting quantitative data into data which can be analysed qualitatively (Teddlie & Tashakkori, 2009, pp. 269-271, see study 1) or quantitizing, i.e. converting qualitative data into numerical codes which can be statistically analysed (see study 2). The translation-theoretical perspective is explicit in all three studies. These fundamental characteristics of the research design are summarized in Table 4. In the following, each study will be introduced.

[13] Prior to conducting the studies, the third, qualitative focus group study was planned to have less weighting than the quantitative studies; however, after finalizing the study, its importance for the overall study was found, which is why it is given equal weighting. More information about this is found in Chapter 7.

Fundamental characteristics of the research design of this dissertation	
Timing/Implementation:	**Sequential** or concurrent data collection
Weighting/priority:	Qualitative priority, quantitative priority or **equal priority**
Mixing – stage:	Data collection, **analysis** or **interpretation**
Mixing – type:	**Connecting**, integrating or embedding
Theoretical perspective:	**Explicit** or implicit

Table 4: Characteristics of the research design of this dissertation.

The methods used in the individual studies will only be briefly presented as these will be explained in more detail in the chapters belonging to the respective studies, i.e. Chapters 5-7.

4.4.1. Study 1: Translation competence and Danish PIL translators

The objectives, methods of data generation, data analysis and the concepts introduced and reviewed are presented in Table 5 below.

Study 1: Translation competence and Danish PIL translators (exploratory)			
Objectives	**Method of data generation**	**Method of analysis**	**Concepts introduced and reviewed**
1) To investigate who the Danish PIL translators are and to map these translator profiles against a model of translation competence. 2) To elaborate a hypothesis and identify participants for the second study.	Quantitative 51 pharmaceutical companies are contacted and asked "what kind of translator do you use for your translation of PILs into Danish?"	Qualitative Mapping profiles against the concept of translation competence	Translation competence Medical translators

Table 5: Characteristics of study 1.

The data collection in study 1 is quantitative, consisting of a one-question questionnaire with fixed answer categories. In the analysis of the results, data conversion takes place in that the quantitative results are qualitized as they are mapped against the concept of translation competence and a literature review of medical translators. The outcome of this study is a hypothesis which will be tested in study 2.

4.4.2. Study 2: PIL translation choices made by pharmacists and professional translators

The objectives, methods of data generation, data analysis and the concepts introduced and reviewed in this second study are presented in Table 6 below.

Study 2: PIL translation choices made by professional translators and pharmacists (exploratory)			
Objective	**Method of data generation**	**Method of analysis**	**Concepts introduced and reviewed**
To investigate the hypothesized competences from study 1, and investigate whether there are any differences in the PIL translation products translated by the two types of translators in relation to lay-friendliness.	Quantitative 54 Danish PILs, translators (N = 27), pharmacists (N = 27)	Qualitative coding of linguistic elements (deductively and inductively) Statistical analysis (t test)	Skopos Lay-friendliness Plain Language

Table 6: Characteristics of study 2.

At the macro level, this study is quantitative, as the main objective of this study is to compare the translation choices of the two types of translators in relation to lay-friendliness. It involves an analysis of PILs from companies identified in study 1. The PILs are coded based on a linguistic analytic framework[14]. At the micro level, the coded categories with enough instances are quantitized and statistically analysed, whereas the other categories without sufficient instances are reported on qualitatively.

The relationship between study 2 and study 3 follows the sequential explanatory strategy characterized by Creswell as "the collection and analysis of quantitative data in the first phase of research followed by the collection of qualitative data in a second phase that builds on the results of the initial quantitative results" (Creswell, 2009, p. 211). This study thus has an exploratory focus.

[14] This linguistic coding could be seen both as a qualitative and quantitative process, which is why in Figure 11, QUAL is written in parentheses. Whether this is a qualitative or quantitative coding is not seen as important following the approach to quantitative and qualitative methods as a continuum, not as dichotomous categories (Miles & Huberman, 1994, p. 41; Teddlie & Tashakkori, 2009, p. 28).

4.4.3. Study 3: Focus groups with professional translators and pharmacists

The objectives, methods of data generation and data analysis of the third study are presented in Table 7 below.

Study 3: Focus groups with professional translators and pharmacists (explanatory)		
Objective	**Method of data generation**	**Method of data analysis**
To investigate the reasons behind the choices found in study 2. To gain an understanding of how the PIL translators view their translation choices and process and argue for them. To investigate how the PIL translators view their expertise and their roles as PIL translators.	Qualitative Focus groups with translators and pharmacists	Qualitative content analysis-inspired coding

Table 7: Characteristics of study 3.

This third study consists of a focus group with PIL translators, which is purely qualitative both at the macro and micro level. This study serves as an explanatory study to shed some explanatory light on the results of the two first studies.

4.4.4. Part 4: Synthesis of findings

In Chapter 8, the results of all three studies are synthesised and discussed to draw the overall conclusions of this dissertation. This is referred to as *mixing during interpretation* in mixed methods terminology, i.e. a mixing that occurs:

> when quantitative and qualitative strands are mixed during the final step of the research process after the researcher has collected and analyzed both sets of data. It involves the researcher drawing conclusions or inferences that reflect what was learned from the combination of results from the two strands of the study, such as by comparing and synthesizing the results in a discussion. (Creswell & Plano Clark, 2011, pp. 66-67)

After this synthesis, the main conclusions of the dissertation are drawn along with the contributions, before future perspectives are presented.

5. Translation competence and Danish PIL translators[15]

Chapter 3 introduced the functionalist approach to translation, and a view of translation as a complex communicative activity that requires expert competences. The main purpose of translation is to facilitate communication between different linguistic communities, not (necessarily) to reproduce a source text accurately as was the main purpose of translation within the equivalence approach. This shift towards the target text purpose and audience places a certain obligation on the translator and gives the translator a greater responsibility for the translation process and product as a responsible agent and an expert in translation. But how is a translation expert defined? What is translation competence and what does it entail and include? This chapter first introduces the concept of translation competence before it goes on to discuss the PACTE competence model as the chosen model for this study.

On the basis of PACTE's theoretical view of translation competence, one may assume that the competence of a translator may be an important factor for quality of the translation product. Previous research has suggested that pharmaceutical companies located in Denmark often use pharmacists to translate PILs into Danish (Askehave & Zethsen, 2002, p. 24), which might well have been the case in 2000 when their study was conducted. However, it has never been systematically investigated who PIL translators actually are, and whether this might affect the translation process and hence the product. In an attempt to provide an answer concerning who is responsible for the interlingual translation phase of the PIL production, a study identifying Danish PIL translators is conducted. The methods used and the results found in this study are presented.

To further explore the findings of this study, the PACTE model of translation competence will be used to structure and discuss the hypothetical competences of the identified types of PIL translators. Based on the results from this study identifying PIL translators, it is possible to map the Danish PIL translator profiles against the PACTE competence model. This mapping is based on a literature review of medical translators and translation competence of professional translators and translation amateurs, and it forms the basis of the elaboration of the main hypothesis to be used in study 2.

5.1. Translation Competence

Translation competence is a very complex, multifaceted concept within Translation Studies (Montalt Resurrecció, Ezpeleta Piorno, & Garcia Izquierdo, 2008, para 6). It is a concept which has been widely discussed theoretically (e.g. by Alves, 2005; Chesterman, 1997;

[15] Parts of this chapter has been published in Nisbeth Jensen (2012).

Neubert, 1994; Pym, 2003; Wilss, 1994) and researched empirically (PACTE, 2002, 2003, 2005, 2009). Translation competence has been referred to using a plethora of terms such as *transfer competence* (Nord, 1991), *translational competence* (Neubert, 1994), *translatory competence* (Hönig, 2008), *translatorial expertise* (Kaiser-Cooke, 1994) etc. Some scholars incorporate a large variety of sub-competences into their definitions and explanations of translation competence (e.g. Bell, 1991; Corpas Pastor, 2000), and others opt for a more minimalist approach[16] (Pym, 2003). There seems to be consensus in TS literature that translation competence is not an innate human skill (Shreve 1997 in Alves, Gonçalves, & Rothe-Neves, 2001, pp. 46-47), but a competence that can be learned through formal instruction and which can thus evolve. In addition, there is agreement that it involves more than L1 and L2 knowledge and skills; in other words, it is not enough to be bilingual. However, there is still a lack of consensus about what other abilities and skills are required of a professional translator. One important aspect of translation competence is its acquisition as a gradual process argued by some scholars (Montalt Resurrecció, et al., 2008, para 5) as successful translation is based on an extensive body of declarative and procedural knowledge, which evolves from extensive experience (Kaiser-Cooke, 1994, p. 136). This goes against the conception that translation is an innate skill and the concept of *born translator* and at the same time, rejects that bilingualism is enough to translate (also supported by Hönig, 1998a, p. 89). Similarly, the expert knowledge possessed by translators has a complex, heterogeneous and approximate nature as it is not possible to be expert in all areas, and thus, translation competence is always a non-finite state (Montalt Resurrecció, et al., 2008, p. 1).

To be able to discuss the hypothetical competences of PIL translators needed for PIL translation, a construct of translation competence is needed. The only comprehensive model which to my knowledge has been systematically tested empirically (besides Alves & Gonçalves, 2007) is the PACTE competence model (PACTE, 2002, 2003, 2005, 2009, 2011). PACTE has aspired to test the model in a controlled environment using an empirical-experimental research design. This can of course be criticized for leading to a lack of ecological validity when investigating the translation process which is taken out of its natural context; however, despite this, the PACTE model has been chosen as the model of competence in this dissertation because of its holistic nature, empirical basis and its practical applicability. Furthermore, the model has been tested using various different languages,

[16] According to Pym's minimalist definition, translation competence involves the following two-fold abilities: 1. The ability to generate a series of more than one viable target text for a pertinent source text and 2. The ability to select only one viable target text from this series, quickly and with justified confidence (Pym, 2003, p. 489).

translation directionalities and participants (PACTE, 2003, p. 50). Below, an overview of the model is given before its application is discussed.

5.1.1. PACTE's competence model

PACTE (Process of Acquisition of Translation Competence and Evaluation) is a group of scholars devoted to researching the concept of translation competence empirically. PACTE has a functional approach to translation "as a communicative activity directed towards achieving aims that involves taking decisions and solving problems, and requires expert knowledge" (PACTE, 2003, p. 44). The PACTE model is thus in line with the functionalist approach to translation presented in Chapter 3. The model aspires to describe the characteristics defining the professional translator (PACTE, 2003, p. 44) rather than only defining competence for the purpose of translator education. Moreover, the PACTE group sees translation as a decision-making and problem-solving process, which is particularly relevant for this study; the reason being that my study focuses on the decisions made by the translators when faced with translation problems, especially problems which influence lay-friendliness. The PACTE model is especially suitable for this study into lay-friendliness in translated PILs as PACTE believes that competence is not only reflected in the process, but also in the product (PACTE, 2005, p. 611).

According to PACTE, translation competence is the underlying system of knowledge needed to translate. It consists of declarative (knowing what) and procedural knowledge (knowing how), but procedural knowledge is predominant (PACTE, 2009, p. 208). It includes the ability to complete the transfer process by understanding the source text and re-expressing it in the target language, taking into account the purpose of the translation and the characteristics of the target text receivers thereby satisfying the functionalist perspective on translation**.** As seen in Figure 12, the model consists of five main sub-competences: bilingual sub-competence, extra-linguistic sub-competence, knowledge about translation sub-competence, instrumental sub-competence and strategic sub-competence and psycho-physiological components. In the following, the five sub-competences will be briefly presented with a main focus on the factors relevant for PIL translation. Unless otherwise specified, the below presentation of the components of the model is based on PACTE (2009, pp. 208-209).

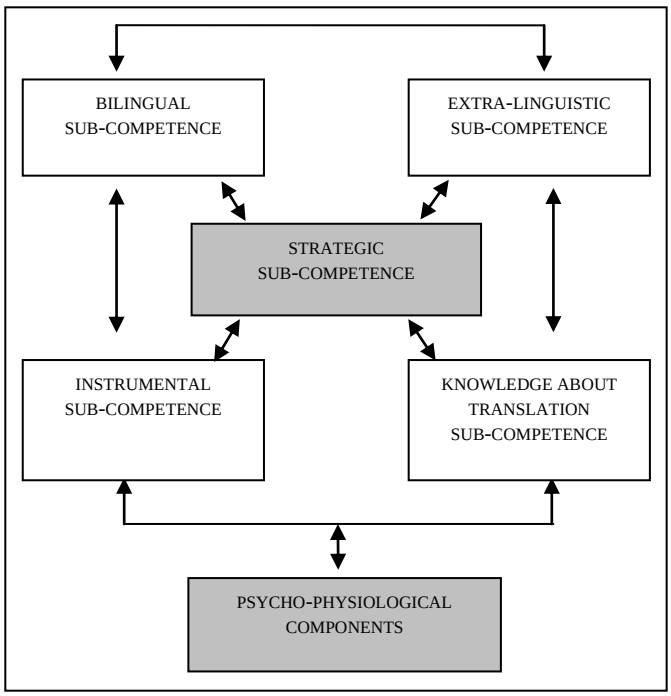

Figure 12: PACTE translation competence model (PACTE, 2003, p. 58).

PACTE's five sub-competences in relation to PIL translation

The first sub-competence, *bilingual sub-competence*, logically deals with procedural knowledge needed to communicate in two languages; however, it is much broader than merely bilingual competence, because it involves the following elements: 1) interference control (i.e. avoiding interferences between the two languages used), 2) knowledge of pragmatic conventions that are acceptable in a given context, knowledge of socio-linguistic conventions, 3) knowledge of language registers (variations according to field, tenor, mode), 4) knowledge of texture, i.e. cohesion and coherence mechanisms, 5) knowledge of genres and their conventions (structure, language features etc.) and 6) knowledge of vocabulary, morphology and syntax. This sub-competence is thus relevant for any kind of interlingual translation as knowledge of the two languages involved would be a necessity. However, as interference control is part of the sub-competence, it is especially important for PIL translation, because PILs are directed at lay receivers without specialist knowledge who might be anxious in the reception situation (see Chapter 2). Therefore, it is important that the PIL translator has strong interference control because of the differences between English and Danish medical language (more about this in Chapter 6). If the translator's inference control is weak, it might lead to false friends and calques in the target texts (Montalt Resurrecció & González Davies, 2007, p. 36). Furthermore, as bilingual competence includes "knowledge of pragmatic conventions that are acceptable in a given context", it is very relevant for PIL translation as the translator must be familiar with the genre and have an idea of who the

potential receivers could be in order to make sure all translation choices are acceptable in the context to fulfil the skopos. As PIL translation is a specific kind of medical translation, the translator needs to have knowledge of various language registers, particularly which terms and expressions belong to medical register and formal, bureaucratic register as opposed to informal, lay-friendly register. Especially in medical language, it has been shown that there are large register differences within the same language (Montalt Resurrecció & González Davies, 2007, p. 156). Finally, for PIL translation, which includes medical terminology, knowledge of vocabulary is very important. This is supported by Montalt Resurrecció and González Davies (2007), who say that it is important for medical translators to know the form and function of medical terms in the languages involved and differences between them. Translators must be able to *de-terminologize* medical terms, i.e. explaining them or replacing them with lay terms so they are comprehensible for lay readers (Montalt Resurrecció & González Davies, 2007, pp. 251-252).

The second sub-competence, *extra-linguistic sub-competence*, is mainly declarative knowledge, both implicit and explicit knowledge about the world in general and specific areas of knowledge. The most relevant part of this sub-competence for the present study is subject-specific knowledge, i.e. medical and pharmaceutical knowledge to ensure accuracy in the translation. Because of the differences in language use of e.g. Latin-based terms between Danish and English, the translator needs to understand the Latin-based terminology to know when it is possible and appropriate to use a lay term as opposed to when it is not possible to leave the Latin-based terms out. When the first option is chosen – to translate using a Danish (non-Latin-based term), the translator needs to understand the term fully to ensure that the Danish word does in fact include all relevant meaning. Furthermore, as the PIL is not an expert-to-expert genre, it is also important to have general world knowledge to translate them. In addition, knowledge about the legal requirements surrounding PILs can be included in this sub-competence; Chapter 2 shows how influential these are in the production of PILs.

The *knowledge about translation sub-competence* mainly includes declarative knowledge about translation and aspects of the translation profession, e.g. how to work with different types of translation units, strategies, techniques and types of problems. This sub-competence also involves knowledge about professional translation practice such as how to work with different types of briefs, clients and audiences. This sub-competence is important for the translation of PILs, because of the knowledge asymmetry between the sender and the receiver as discussed in Chapter 2. Translators must thus know how to tailor the translation and the choices made for a lay person. Montalt Resurrecció & González Davies (2007) agree that it is important for medical translators to be able to translate for different types of target

readers, their motivations, their expectations and their purposes. Similarly, PIL translators need to be able to know which translation units in the source text might cause problems during the transfer process, such as the use of Latin-based terminology or the use of specific syntactical constructions. As Montalt Resurrecció & González Davies state: medical translators need to know the "main transference errors in medical translation to anticipate and avoid them, spot problems and correct them" (2007, p. 41).

The *instrumental sub-competence* involves procedural knowledge related to the use of documentation sources, technologies and dictionaries, grammars and parallel texts. This sub-competence is relevant for PIL translation as both medical professionals and professional translators might need to research PIL content such as the language use in relation to certain medical conditions and symptoms. Likewise, for this sub-competence, it is important that the translators are able to critically evaluate the sources they use, to avoid recycling bad translation choices from previous PILs.

The fifth sub-competence, *strategic sub-competence*, includes the ability to evaluate the translation process and results as well as being able to identify translation problems and apply suitable procedures to these problems. This sub-competence is seen by PACTE to be the most important sub-competence as it serves to activate the various sub-competences and to compensate for deficiencies by identifying translation problems and applying procedures to solve them (PACTE, 2005, p. 610; 2011, pp. 33-34). Its importance is visually depicted by its central position in the model (Figure 12 above). In relation to PIL translation, this sub-competence is relevant as translators need to be able to first apply suitable strategies and then critically evaluate their translation choices. For this sub-competence, it is hence possible to see in the target text analysis if the translators have not been able to apply procedures to correct translation problems.

Finally, the model includes psycho-physiological components, which include cognitive and behavioural psychomotor mechanisms (including memory, attention span, perseverance, critical mind) (PACTE, 2005, p. 610). The psycho-physiological components are not relevant here as it is only possible to discuss these when discussing individual translators, not translator *types* as it the case for this study. PACTE argues that the three sub-competences: knowledge about translation, instrumental and strategic are specific to translation competence, as any bilingual might have knowledge of two languages and extralinguistic knowledge (PACTE, 2005, p. 611).

Based on this presentation of translation competence, it is possible to assume that different types of translators may have differences in their translation sub-competences making up the overall translation competence, and also, that the competences of the

translators may also influence the translation product. Therefore, to investigate whether the competences of the translator might impact on the translation of PIL, it is necessary first to systematically investigate who Danish PIL translators are before their competence can be discussed against the PACTE model. The next section presents an empirical study identifying Danish PIL translators.

5.2. Research design of study 1

For the identification of Danish PIL translators, European pharmaceutical companies were contacted by email. To identify companies to be contacted, a study of all the PILs published on the EMEA website (about 580 PILs) was conducted to count how many PILs each company had. Subsequently, all pharmaceutical companies with at least three PILs in the EU were contacted[17]. I contacted a total of 51 companies, which represents almost the entire population of pharmaceutical companies required to provide PILs in the EU. They were asked what kind of translator they use for the translation of their PILs into Danish, e.g. whether they use a person with a medical background, an in-house translator, a freelance translator or a translator recruited through a translation agency. The possible answer categories were (see also Appendix 5 for email sent):

- Internal translation, which included:
    - a person with a medical background
    - state-authorised translator
    - a person with another language background
    - a person with a different professional background – if so, which background?
- External translation, which included:
    - state-authorised translator company in Denmark
    - a translation company outside Denmark
    - a freelance translator or freelance state-authorised translator?
    - a person with a different background – if so, which background?

40 companies responded (response rate: 78.43%). Three replies were discarded as these three pharmaceutical companies did not have any translated PILs authorised in the entire EU[18], leaving 37 usable replies.

[17] There were five companies with three or more PILs which could not be contacted, either because it was not possible to find their contact details, or because they had merged with other, already contacted companies.
[18] Not all companies get marketing authorization through the so-called Centralised Procedure (i.e. authorization to sell in all EU countries), but only sell their products in their national market or a few other markets.

5.2.1. Results

The responses obtained from the 37 companies shows that a slightly higher number of the contacted pharmaceutical companies use mainly pharmacists for the translation of PILs into Danish, i.e. 15 (see Figure 13), whereas 13 pharmaceutical companies use professional translators. Of the pharmaceutical companies using translators, two of them use only in-house translators, and three companies use either in-house translators or freelance translators. The remaining eight companies using translators use only freelance translators. Three of the 37 contacted companies have a co-production of the PIL in which both a professional translator and a pharmacist participate, which is what has been recommended by Askehave & Zethsen based on their extensive research in PIL translation (2000b, p. 36). The last six companies sometimes use a translator and sometimes a pharmacist. However, the majority of these six pharmaceutical companies said that they primarily use pharmacists.

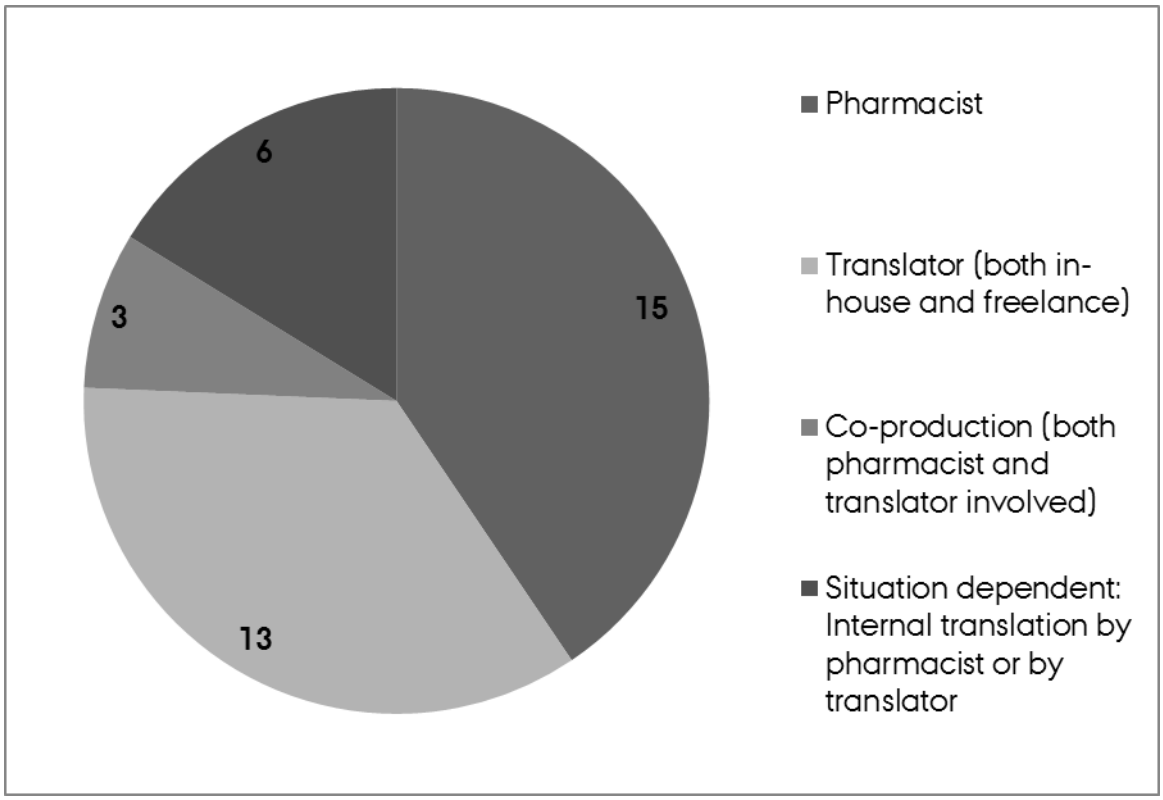

Figure 13: The translators of Danish PILs used in pharmaceutical companies.

Even though the results show that pharmaceutical companies use either pharmacists or translators to an almost equal extent (15 versus 13 out of 37), it should be noted that when linking the authorised and published PILs with these contacted pharmaceutical companies, it is seen that the companies using pharmacists as translators have a greater number of PILs. Therefore, the majority of available Danish PILs are translated by pharmacists.

The companies were only asked what kind of translator they use and not the reason for this choice. The decision to ask only one question was made so as to ensure a high response rate. Even though they were not asked about their reasoning, a few companies provided explanations. Interestingly, a few companies said that they used to use pharmacists, but now use translators. One company explains this by saying that a translator seems to make a better translation, and another that it is not interesting for the pharmacist to translate. One company argued that they use pharmacists because the translations made by translators were unreadable for experts.

So what might these translator profiles mean for the production of PILs? Could these different translator profiles lead to differences in the translation products? According to the translation-theoretical perspective taken in this thesis, functionalism, and the PACTE model of translation competence, translation is viewed as a complex communicative activity that requires several translational sub-competences. It is thus reasonable to assume that the competences of the translators may also influence the translation product. Therefore, in following, the quantitative results are qualitized, i.e. they are converted into data which can be analysed qualitatively (following Teddlie & Tashakkori, 2009, pp. 269-271). This is done by mapping the PACTE model of competence against a literature review of research on medical translators. Based on this, the hypothetical competences of these two types of translators are discussed. However, before this is possible, their profiles in the Danish context will be briefly presented to gain an understanding of the title of state-authorised translator and the educational background of pharmacists in Denmark.

5.2.2. Profiles of Danish PIL translators

Before their presumed competences are discussed, the two translator groups and their backgrounds are introduced further. This is of course only an overview of the profiles of the translators as *types,* but a necessary and useful prerequisite for the following analysis of PIL translators' sub-competences. As far as professional translators are concerned, Denmark has been training and accrediting translators at MA level for the last 40 years and Danish translators are said to be "among the most well-educated in the world" (Dam & Zethsen, 2009a). *Professional translators* are here used in a broad sense in this dissertation. In the Danish context, we have a protected title of *state-authorised translator,* which is generally awarded on the basis of a master's degree in Translation Studies[19], and many translation companies only employ state-authorised translators as full-time employees. Therefore, in

[19] To be awarded state-authorisation, one also needs to be at least 25 years of age and have no outstanding amounts to the state.

order to work as a professional translator, an MA in Translation and Interpreting is often a prerequisite to get translation jobs. However, because the pharmaceutical companies use external translation agencies, it is not possible to know whether they have used a state-authorised translator or a freelance translator without state-authorisation.

As far as the pharmacists as a group are concerned, these are usually pharmacists who typically do not have any translation courses or training during their education as pharmacists[20], and furthermore, because each pharmaceutical company does not have many PILs in the EU, the typical Danish pharmacist is likely to be a translation novice as s/he might not have much translation experience. Moreover, from the curriculum of pharmacists, it can be seen that no communication or linguistics courses are provided. Some pharmacists might, however, have oral communication with lay people if they have been employed at a pharmacy prior to working with translation in the pharmaceutical company.

The following contains an analysis in which the presumed competences of a typical medical professional/pharmacist and professional translator, respectively, will be mapped against the five sub-competences of the PACTE model. The mapping is based on the above overview of the profiles of the translators as types. This mapping will then be discussed on the basis of previous research of medical translators and novice translators. The purpose of this discussion is to investigate whether the presumed competences of the translator types could be theoretically linked to the decrease in lay-friendliness in the translated PIL, and why it would be relevant to research the translation products from pharmaceutical companies using professional translators and pharmacists, respectively.

5.2.3. Mapping the five sub-competences against the two translator profiles

Table 8 below shows an overview of the sub-competences that we could assume to be possessed by the two translator types based on the analysis described below. The “typical” Danish professional translator could be presumed to possess all the sub-competences because of their translation training and experience; however, s/he may possess the medical extra-linguistic sub-competence to a lesser extent. The *bilingual sub-competence* could be presumed to be possessed by both translator types to some extent since they are both performing translation from English into Danish; however, they are not likely to possess it to an equal extent. The translators have received training and had their bilingual competences tested as a certain level is a prerequisite to pass university exams. The pharmacists are not likely to have had their English language skills tested as an obligatory part of their job.

[20] Information obtained from the websites on curriculum from the two universities training pharmacists in Denmark, i.e. Copenhagen University and University of Southern Denmark.

The pharmacists are subject matter specialists because they are trained pharmacists, and therefore, specialised in pharmacology and the language used within this field; they would therefore possess the *extra-linguistic competence* to a very large extent. This sub-competence is extremely important for the translation of PILs because of the importance of terminology and accuracy. As far as the professional translators are concerned, unsurprisingly, they are not likely to have the same level of subject knowledge as the pharmacists. However, to my knowledge, most Danish translators specialise after their MA in Translation, and may therefore have subject matter knowledge to some extent, though, much more limited than the pharmacists.

As the *knowledge about translation sub-competence* mainly includes knowledge about how to work with different types of translation units, strategies, techniques and types of problems as well as with different types of audiences, the pharmacists have no training and may have no experience that would support this sub-competence. Professional translators, on the other hand, are trained in declarative knowledge about translation and in the functionalist approach to translation, and hence in translating for different audiences.

As far as the *instrumental sub-competence* is concerned, it is not possible to know how much pharmacists use translation tools and instruments; however, as each pharmaceutical company has a limited number of PILs authorised through the Centralised Procedure and hence sold all over the EU, it is unlikely that the pharmacists have extensive experience translating as this would only happen quite rarely for each company. Translators, on the other hand, would be familiar with different translation instruments such as dictionaries and translation software through their training and professional experience.

One of the main elements included in the *strategic sub-competence* is the ability to evaluate the translation process and results as well as being able to identify translation problems and apply suitable procedures; therefore, it could be argued that the pharmacists would find this more difficult than trained translators as they are not trained in communication and translation strategies.

Sub-competence	Pharmacist	Professional translator
The bilingual sub-competence	(X)	X
Extra-linguistic sub-competence	X	(X)
Knowledge about translation sub-competence		X
Instrumental sub-competence		X
Strategic sub-competence		X

Table 8: Overview of the sub-competences presumed to be possessed by pharmacists and professional translators[21].

5.2.4. Discussion of mapping against literature review of medical translators

Based on the above analysis, in the following discussion, the five sub-competences will be individually discussed based on previous research of medical translators and novice translators with a view to discussing whether there might be any differences in the lay-friendliness of PILs from pharmaceutical companies that use professional translators and pharmacists, respectively. The purpose of this section is also to emphasize the relevance of researching the translation competence differences of the two types of translators and why there are likely to be differences in their translation products.

It should be noted here that the literature review might seem biased towards the strong sub-competences of trained translators and the weak sub-competences of the medical professionals. Unfortunately, this is a mirroring of the literature as most interest in and research of medical translators has taken place within Translation Studies. Furthermore, as very little literature exists on the translation competences of pharmacists (only Askehave & Zethsen, 2002, 2003), the literature review focuses more broadly on the larger group of medical professionals (hence also physicians).

Bilingual sub-competence

Previous research has shown that some medical professionals have weak interference control skills and that this may be one of the reasons for the excessively complex target texts as they have a tendency to translate in an uncritical word-for-word manner (Askehave & Zethsen, 2002, p. 23). This can result in awkward and sometimes incomprehensible texts (Gile, 1986, p. 28). Translators, on the other hand, are likely to have stronger interference control due to knowledge and experience about translating different genres for different receiver groups. In

[21] *X* signifies a sub-competence, which the translator type is likely to possess, and *(X)* signifies a sub-competence, which the translator type is likely to possess to some extent.

addition, they would have experience translating with variation in language register, such as tenor, which is important in PIL translation because there is an asymmetry between the expert sender and the lay receiver. They are also trained to know which pragmatic conventions are acceptable in a given context.

Extra-linguistic sub-competence

According to Andriesen, translation businesses sometimes find it challenging to have medical texts translated because translators without a medical background lack medical translation expertise (2001, p. 5). One problem in relation to this is that a translator without extensive medical knowledge might have difficulties both in comprehending the source text and in re-expressing the meaning in the target text (Gile, 1986, p. 27). It could be expected that medical professionals would be very knowledgeable of medical content and able to understand the medical content. Reexpressing this content in the target text might, however, lead to problems (see below).

Knowledge about translation sub-competence

Previous research suggests that some medical professionals lack knowledge about translation theory and methods, and therefore, they might have problems targeting a text at a specific receiver group (Askehave & Zethsen, 2002, p. 24). Medical professionals have been shown to lack knowledge about what translation choice is acceptable in a given context and how to translate for the correct receiver especially because of their expert background: "medical experts cannot free themselves from their own background knowledge and linguistic habits (and possibly expert status) and fail to reach a realistic perception of their audience" (Askehave & Zethsen, 2003, p. 39).

Furthermore, being able to translate for different audiences according to different briefs should lead to functional translations in which the translator focuses on the target text receiver. However, some medical professionals seem to have a more literal, equivalence-based approach to translation. Some medical professionals see literal translation as the ideal way of translating, i.e. keeping to the original and producing an accurate and precise target text in which no parts of the source text are lost (González Davies, 1998, p. 100). This could lead to the problems seen in Askehave & Zethsen's (2002, p. 27) study in which the medical experts often uncritically, but "faithfully", transferred flaws found in the source text to the target text. Moreover, some medical professionals view specialised terminology as the most important factor in medical translation. This is seen for example in a study carried out by González Davies (1998) in which she had medical specialists assess

students' medical translations. The specialists saw specialised terminology as of paramount importance, whereas syntax and grammar were the least relevant points, and cohesion and coherence were seen as of minor importance (González Davies, 1998, pp. 99-100). Other researchers found that medical professionals have weak writing and translation skills, and they often have problems with simple items (O'Neill, 1998, p. 74). Furthermore, medical professionals' lack of translation competence can lead to target texts which are incomprehensible and contaminated by the source text language (Gile, 1986, p. 28).

Most medical professionals are likely to have limited translation training and experience and can thus be viewed as translation novices. Faber (1998) argues that translation novices even with good command of two languages often begin translation with a wrong perception of what translation is and what the translation process involves. Similar results were found by Alves & Goncalves who say "Corroborating evidence found in the literature […] the results also show that novice translators seem to operate on the basis of mere encoding and decoding processes and have difficulties in establishing a link between their work and the contexts out of and into which they translate" (Alves & Gonçalves, 2007, p. 14). A similar view is expressed by Hönig, who argues that lay people's view on translation (also engineers and technicians) is based on a model of accuracy and precision where no parts of a source text are lost (Hönig, 1998b, p. 16).

The professional translators have both training and experience working with different briefs and targeting their translation to different audiences, whereas we must presume that medical professionals have very limited experience, and that instead of working with lay people, they generally work with other experts.

Instrumental sub-competence

It is not possible to know the extent to which pharmacists are accustomed to using translation instruments, but translators would be familiar with different translation instruments, which is why some scholars think that professional translators will produce better translations as they "master[s] the techniques of translation, research and documentation" (Lee-Jahnke, 2005, p. 81).

Strategic sub-competence

Previous research shows that experts in general have problems predicting reader problems when they produce texts (Lentz & de Jong, 2009, p. 119) and would therefore have problems evaluating their own process. Moreover, medical professionals tend to stick closely to their expert language to ensure medical accuracy (Gal & Prigat, 2005, p. 489) and "lack the ability

to down-grade their special language to accommodate the non-specialist target group" (Askehave & Zethsen, 2000b, p. 68), because they do not know what makes texts difficult to understand for lay people. Some medical professionals also struggle to apply suitable translation procedures, as they would not know "how to raise or lower the level of formality in a text" (Askehave & Zethsen, 2003, p. 39).

5.3.5. Conclusions of mapping

To conclude this mapping of the hypothetical sub-competences of both medical professionals and professional translators, it is seen that typical medical professionals are presumed to possess extensive subject matter knowledge, which means that they are likely to be able to ensure accuracy in the translated PIL. Furthermore, they are presumed to possess the bilingual sub-competence to some extent, but they are not translation experts as they are likely to lack the three translation-specific sub-competences, which could lead to translation problems at several levels such as problems with tailoring for a lay audience. Therefore, it could be argued that PILs translated by medical professionals may create lay-friendliness problems in their translations, as these translators are likely to mainly focus on transferring the propositional and medical content of the source text accurately. Moreover, they may not be able to assess the level of knowledge possessed by lay persons or to predict potential reader problems. Even if they are able to do so, they may lack the translational and linguistic knowledge, declarative and procedural, which is required to produce a translation which is easy to read, understand and act upon as is required by law. At the same time, we could argue that trained translators, because they may lack subject matter knowledge, may not always be able to transfer the medical content correctly and accurately. This is of course of utmost importance as giving patients a lay-friendly, but medically incorrect or inaccurate, text could have catastrophic consequences.

As mentioned in the introduction to this literature review and as has probably become evident throughout its reading, there is a inclination towards professional translators and their competences. Another caveat is that much of the research presented is not empirical in the sense that the actual sub-competences of the two groups have been analysed through translation process or product studies, but instead, some of the research is based on opinions concerning the two translator groups. Therefore, empirical research into the actual translation competences of the two types of translators is needed. In addition, some of the research presented in the literature review is based on the translation of medical expert-to-expert genres, not expert-lay genres like PILs. Finally, the two groups might not be completely

distinct as it might be possible to find professional translators with subject-specific expertise and pharmacists with translation expertise.

Based on this theoretical discussion of medical translation competence in relation to the translation of PILs, we could argue that there may be linguistic differences in the Danish PILs from pharmaceutical companies that use pharmacists and pharmaceutical companies that use professional translators, respectively, in relation to lay-friendliness.

5.3. Conclusion

The aim of this chapter was to discuss the concept of translation competence in relation to PIL translation. Based on the PACTE model of translation competence, this chapter presented a study which identified Danish translators. As seen in the literature review on PILs in Chapter 2, one study suggested that one reason PILs are not optimally lay-friendly is that they are often translated by pharmacists; however, this has never been systematically empirically researched. Therefore, this study 1 was conducted, which showed that pharmaceutical companies use both professional translators and pharmacists as translators, but a majority of PILs are translated by pharmacists.

As seen in the literature review of PIL research, most PIL research focuses mainly on monolingual versions of PILs or on intratextual elements. When taking the translation factor into consideration and when viewing translation as a complex, functional, communicative activity that requires expert competences, it can be assumed that there may be some differences in the translation choices and hence translation products of translators with different degrees of translation competence. Based on the above literature review, pharmacists-cum-translators may mainly focus on transferring medical content accurately, might not be able to realistically assess the knowledge of the lay receivers, and also, might not have the linguistic and translational knowledge and ability to ensure a lay-friendly target text. Professional translators, on the other hand, might not be optimally knowledgeable about medical terminology.

The introduction to the concept of translation competence and the subsequent mapping against the translator profiles was needed as a starting point as to whether there is likely to be an impact on the lay-friendliness of PILs translated by translators with potentially very different profiles. Based on the analysis and discussion, it can be concluded that differences in lay-friendliness in the translation products are likely to be found. The following hypothesis can thus be elaborated:

Pharmacists – compared to professional translators – lack translation competence in relation to lay-friendly PIL translation

This hypothesis needs to be investigated empirically. Following the iterative sequential design, this study forms the basis upon which to build the next study. Therefore, in the next chapter, study 2 of this thesis will be introduced. This study is an empirical study into the translation products from pharmaceutical companies that use professional translators and pharmacists, respectively.

6. PIL translation choices[22] made by professional translators and pharmacists

In the previous chapter, we saw that Danish PILs are translated by either professional translators or pharmacists, but that a majority of translated Danish PILs come from pharmaceutical companies that use pharmacists as translators. Based on a functionalist approach to translation, which sees translation as a complex communicative activity requiring expert competences, and on the construct of translation competence, it is possible to hypothesize that there might be differences in the translation process and products of the two different types of translators. The limited research on medical translators and translation novices compared to professional translators, discussed in Chapter 5, gives support to this hypothesis. The next step is to empirically investigate the hypothesis.

As a starting point, two main possibilities for research design are reviewed, i.e. an experimental study and a naturalistic study of PIL translations. I will argue that a study using existing, naturalistic PILs is most suitable to answer the research question. The next step is to decide on an analysis method for these PILs, and here a contrastive linguistic analysis is suggested. The choices made in connection with the building of a PIL corpus are presented. Before deciding on an analysis procedure, the question of how to analyse translations within the functionalist approach is discussed. Translation analysis can be claimed always to touch upon the concept of Translation Quality Assessment; a concept which will be introduced and discussed. As a translation skopos is always context-based, before the translation analysis, the skopos of PIL translation of *lay-friendliness* presented in Chapters 2 and 3 is discussed.

After this, the next section discusses the operationalization of this skopos for the purpose of analysis. This operationalization of lay-friendliness is made through a literature review of research related to the assessment of textual complexity drawing on research from Health Communication, Document Design, Linguistics and Translation Studies. A linguistic approach to the analysis of lay-friendliness is suggested, and it is argued that the field of Plain Language, which has mainly been used for intralingual translation (translation within same national language), can be broadened to be also applied in the field of interlingual translation. Based on these literature reviews, a lay-friendliness framework is elaborated for the purpose of deductively analysing PILs. The next part of the chapter explains the analysis procedure,

[22] There is a quite extensive terminological confusion concerning what to term the *shift* that occurs between source text element and target text element, such as strategy, technique, tactic, etc. See e.g. Gambier (2010) for a discussion of this.

including the choices made prior to analysis, the coding procedure and the iterative process of analysis.

The results section shows that during analysis, to keep with an iterative analysis model, the framework was further refined and more sub-categories were added. These categories are presented and discussed and examples of the qualitative analysis are given. The qualitative analysis results with enough instances are then quantitized (following Teddlie & Tashakkori, 2009, pp. 269-271), and both the quantitative and qualitative results of this study are presented and discussed. In conclusion, the limitations of the study are presented before the overall conclusions of the study are made. On the basis of these conclusions, a third, explanatory study is suggested.

6.1. Research design of study 2

We saw in Chapter 3 that TS is a young and interdisciplinary field which encompasses diverse research paradigms. As a result of this diversity, TS also does not have a set selection of methods, thoroughly tested, and readily available for researchers. This is not perceived as a problem as it fits well with the pragmatist approach to research in which methods are not perceived as static, given constructs (Sullivan & Porter, 1993, p. 230). They are negotiable and dependent on the research question and situation. This is not an argument for starting from scratch with the construction of a new method for each research study, but an argument stating that methods can be moulded to best fit the research problem. A further argument for this approach to method is the fact that this study is conducted within the functionalist approach to translation where analysis frameworks (by definition) need to be contingent on the translation context. The following sections will thus introduce and discuss the research design, which is based on previously used research methods within TS, but which is also designed to best fit the research question of this study.

6.1.1. Experimental vs. naturalistic study

Two main paths can be taken to empirically research the translation choices of pharmacists and professional translators: there is a choice of either an naturalistic study, in which PILs are studied as they occur naturally in the field (Gile, 1998, p. 70), or an experimental study, in which PILs are generated for the specific purpose of studying them (Gile, 1998, p. 70). I have opted for a study which studies existing PILs. The strengths and weaknesses of these two options are presented in Table 9, and these will be described in the following.

	Experimental	Naturalistic
Strengths	Control of variables: • Production process • Profiles of translators	Ecological validity: • Real-life PILs • Authorized PILs Large number of PILs possible
Weaknesses	Lack of ecological validity • "Artificial" PILs • PILs have not been through authorization process Only small number of PILs possible	Lack of control of variables: • Production process • Profiles of translators

Table 9: Strengths and weaknesses of experimental vs. naturalistic studies for the study of PILs.

The translated PILs could be investigated using an experimental study in which the two types of translators translate the same English PIL into Danish under the same instructions and in a controlled environment. This would make it easier to control the variables in connection with the PIL translator profiles and backgrounds, and it would be easier to compare translation choices; however, this research design would jeopardize the ecological validity (defined as "maintaining the integrity of the real-life situation in the experimental context while remaining faithful to the larger social and cultural context" (Schmuckler, 2001, p. 421) of the study. The results of such a study might be skewed as the participants would know that they are participating in research and that their translation products would be assessed. The problems in relation to ecological validity have been expressed very fittingly for this situation by Gile (2010) as:

> Not unlike medical drugs which have both beneficial and unwanted (toxic) side effects, research action can cause damage – to itself. Ecological validity problems in experimental research are perhaps the best known example: in order to be able to observe and/or measure accurately, experimenters create a particular environment at the risk of removing it from natural conditions to such an extent that doubts arise as the question whether what they reveal is truly applicable to the real-life phenomena under investigation. (p. 1)

This describes the potential problems of experimental studies, i.e. that the controlled environment has the consequence that the results cannot not be applied to the real-life situation. Another problem which would arise from using these PILs is that they would not be translated for the purpose of going through the EU authorization process. As seen in Chapter 2, the authorization procedure is regulated and extensive, which influences the genre significantly. Therefore, in an experimental study, one might risk that the task is not taken as

seriously as in a real task or that the participants might produce texts which are lay-friendly, but that do not conform to the legislative environment. This view is supported by Gile, who argues that "the experimental situation itself, being 'unnatural'…may generate processes somewhat different from the ones occurring in the natural environment" (Gile, 1998, pp. 77-78).

Finally, even though it would be possible to have a small group of professional translators translate a PIL in a controlled environment, I expect it would be problematic financially and practically having a group of pharmacists do this for research purposes. Furthermore, doing a study which is quantitative to the same degree as a naturalistic study would not be feasible because of the feasibility, financial and practical, associated with having around 50 translators translate a PIL each.

To make the study as naturalistic as possible, i.e. being able to study the translation product as it occurs naturally in the field, I have opted for a study in which existing, authorised PILs are analysed. However, one obvious limitation linked to this is the risks associated with not being able to control variables (Gile, 1998, p. 73; Muijs, 2004, p. 22). Therefore, the overall challenge of using existing PILs is the lack of control of the production process. Using the investigative findings from Chapter 5 that identified who the majority of Danish PIL translators are, it is possible to source PILs for each contacted company and match these PILs with a translator type. The challenge of conducting such a naturalistic study is that it is not possible to know with certainty the relationship between an individual PIL and a translator, i.e. a pharmacist or a professional translator, and whether that type of translator was the only person involved in the production process. However, for the translation of PILs, an experimental setting would arguably be even more problematic as seen above. To limit the lack of control of the production process, specific choices were made in connection with the PIL corpus selection (see section *PIL corpus selection* below). This study will thus be a study of existing PILs, and in the next sections, the specific research design decisions are presented.

6.1.2. Comparative analysis of PIL corpus

To investigate the potential translational differences between PILs produced by pharmaceutical companies using either pharmacists or professional translators for their translation of PILs into Danish, a research design consisting of contrastive analysis of Danish PILs translated from English was chosen. Using such a contrastive analysis, one can investigate the micro level translation choices made by the two groups of translators in

relation to the translation skopos of lay-friendliness. First, a PIL translation corpus[23] must be built. All language versions of EU PILs which have been authorized through the Centralised Procedure are freely available on the European Medicines Agency's website (http://www.ema.europa.eu/)[24]. These PILs have thus all been through the strict authorization process and all been subject to the same legal requirements and time constraints (as explained in Chapter 2). These PILs are meant to live up to the legal requirements of producing a clear and understandable PIL, enabling the users to act appropriately. Before the actual analysis, it is necessary to identify and purposefully select a corpus of PILs which would best help to understand the problem and the research question. The next section presents the choices made in relation to building the PIL corpus.

PIL corpus selection

The results of study 1 (Chapter 5) identified the translator types used by pharmaceutical companies, which makes it possible to build a bipartite corpus consisting of PILs from pharmaceutical companies that use pharmacists and pharmaceutical companies that use professional translators, respectively. To limit the lack of control of the translation process inherent in a naturalistic study, the following precautionary measures were taken: Some pharmaceutical companies stated that they sometimes use professional translators and sometimes pharmacists for their translation of PILs. To avoid blurring translator categories, only pharmaceutical companies who said that they mainly rely on either professional translators or pharmacists were included in the corpus. Furthermore, identical double PILs (i.e. PILs for similar drugs where two or more PILs were identical, and thus not new translations) were excluded. PILs reserved for use by health professionals were excluded because it could be argued that these might not need to be as lay-friendly as PIL intended only for lay people[25]. PILs intended for initial use by a health professional, but later potential self-administration (such as injections) were included as the PIL would be the only source of information for the patients when they are at home, and, for example, need to inject themselves.

To avoid blurring categories, the two pharmaceutical companies that use in-house translators, i.e. translators who are employed by the pharmaceutical company, were

[23] According to Corpus-based Translation Studies, a translation corpus consists of a collection of text or a collection of pieces of language (Laviosa, 2002, p. 33). The corpus built for the purposes of this dissertation is called a bilingual, monodirectional corpus (Laviosa, 2002, p. 37).

[24] These PILs are in PDF-format, which means they are different from the actual inserts, in that the PDF uses A4 size with large font whereas the actual PILs are smaller font, with colours and have a two-column layout (Pander Maat & Lentz, 2010, p. 114). This is not seen as problematic here as the contrastive translation analysis is purely linguistic.

[25] Legally, however, these PILs must be as lay-friendly as PILs for lay people.

excluded. This means that only professional freelance translators and in-house pharmacists are included in the corpus.

These criteria left a forced corpus of 27 PILs translated by professional translators. When the potential corpus of PILs translated by pharmacists was subjected to the same criteria, a potential corpus of 76 PILs was left. It was not possible to match the two corpora based on medicine type as the medicines encompassed too many different diseases and conditions. The 27 PILs translated by professional translators came from seven pharmaceutical companies, as did the PILs translated by pharmacists. The pharmaceutical companies that used only translators had a number of PILs ranging from 1 to 5 (1, 3, 4, 4, 5, 5, 5) whereas the number from the seven pharmaceutical companies using pharmacists ranged from 3 to 27 (3, 5, 8, 9, 11, 13, 27). In order for the two corpora to be as similar and comparable as possible, with PILs from all seven companies, a spread was chosen for the pharmacist corpus similar to that of the translator corpus but proportionate to the number of PILs each company had (2, 3, 4, 4, 4, 5, 5). The random sampling function in Excel was used for the actual choice of pharmacist PILs. Table 10 below shows the PIL corpus. In the table, the range of different medications included in the corpus is illustrated.

	Professional translator, number of PILs	Pharmacist, number of PILs	Medication type
Company 1	1		Blood clots
Company 2	3		Lower cholesterol Control serum phosphorus levels Control serum phosphorus levels
Company 3	4		Antiepileptic AIDS-related Kaposi's sarcoma Cancer Antiepileptic
Company 4	4		Angina pectoris Osteoporosis Osteoporosis Antidepressant
Company 5	5		Growth hormone Alzheimers Anaemia Cancer Cancer
Company 6	5		Hyperammonaemia Homocystinuria (a genetic disease) Kidney cystinosis vitamin E deficiency Wilson's disease
Company 7	5		Antibiotic Hepatitis B HIV HIV HIV/Hepatitis B
Company 8		2	Cancer Parkinson
Company 9		3	Hepatitis C Antifungal Fertility
Company 10		4	Diabetes Diabetes Blood clots Hypertension
Company 11		4	HIV Osteoporosis Parkinson Anaemia
Company 12		4	Parkinson HIV Hypertension Blood clots
Company 13		5	Blood coagulation Diabetes Diabetes Diabetes Diabetes
Company 14		5	Alzheimers Parkinson Hypertension Hypertension Iron overload
Total	27	27	

Table 10: PIL corpus.

The next step in the research design process was to decide on a method to analyse the PILs. When conducting research involving analysis of translation products, the concept of Translation Quality Assessment always becomes relevant. I will briefly introduce this concept and discuss what Translation Quality Assessment would entail within the functionalist approach to translation. Then, I will discuss skopos establishment and operationalization as both are needed to be able to analyse the PILs.

6.1.3. Analysis method

Translation Quality Assessment

Translation Quality Assessment (TQA) is not part of the overall purpose of this thesis, but I would argue that to do any kind of translation analysis, it is a relevant concept. *Quality* is a highly charged concept within Translation Studies, and it is defined and operationalized differently from study to study depending on assessment criteria (Hansen, 2009, p. 391). Before the 1970s, with the equivalence approach, the source text was often seen as the benchmark against which the quality of the translation was assessed, whereas within the functionalist approach, quality is assessed on the basis of skopos fulfilment, and terms such as *skopos-adequate* (Göpferich, 2009, p. 31) or *functionally appropriate* are used (Schäffner, 1997, p. 2). Even though it is beyond the scope of this thesis to discuss and define the concept of TQA extensively, all translation analysis requires some theoretical framework as "evaluating the quality of a translation presupposes a theory of translation. Thus different views of translation lead to different concepts of translation quality, and hence different ways of assessing it" (House, 1997, p. 1). It is therefore necessary to refer back to the theoretical approach to translation when performing translation analysis.

From a functionalist perspective, a particular expression or utterance does not in itself have the characteristic of being incorrect, but it is assigned that quality by the receiver in the light of a particular norm or standard. Within functionalism, translation errors, and thus quality, are therefore inherently closely linked to the translation skopos. To evaluate a translation, the target text skopos must be the starting point for TQA, meaning that the target text is assessed against the skopos. That is why the translation skopos needs to be established for each individual translation task. Therefore, according to functionalist translation theories, the degree to which a translation is skopos-adequate can be regarded as a measure of its translation quality (Göpferich, 2009, p. 31), i.e. not its concordance with the source text.

According to Hönig, even within the functionalist paradigm, sometimes "linguistic evaluation on a contrastive basis (i.e., on a source text-oriented basis) is re-integrated through the backdoor" (Hönig, 1998b, p. 15). This can be interpreted as critique of

scholars or teachers who say that they operate within a functionalist paradigm, but still view the source text as the leading yardstick and perform translation analysis and quality assessment based on the source text. I would argue that it is possible to perform a contrastive analysis while staying within the functionalist paradigm; however, the contrastive analysis needs to have the purpose of investigating analysis strategies taking place when source text items are translated into the target text language, and then judging the appropriateness of these strategies in relation to the skopos – not in relation to the source text.

Within TS, the question of how skopos fulfilment can be determined empirically without leaving the functionalist paradigm has been discussed (House, 1997, p. 12), and has also been one of the targets for criticism of functionalism (Stolze, 1994, pp. 164-165, 180). As a first step, to perform translation analysis within the functionalist approach, the translation skopos needs to be established (see section 3.7.1. *The skopos of PIL translation* and below). The next step is to evaluate whether this skopos has been fulfilled.

Using the terms, *adequate*, *appropriate* and *skopos fulfilment* gives the impression of a dichotomous relationship in which a translation can be either *adequate*, i.e. fulfilling its skopos or *non-adequate*, i.e. not fulfilling its purpose. Instead of assessing a translation using an either-or dichotomy, I would argue that skopos fulfilment should be viewed as a continuum where translation choices can lead to more or less adequate translations. Below, the assessment of skopos fulfilment for PILs will be discussed.

PIL skopos fulfilment

In Chapter 3, it was argued that PILs have two main skopoi: 1) ensuring that the source text is translated accurately and completely and 2) ensuring that the target text receivers are provided with an optimally understandable text which is characterised by easy-to-understand language, i.e. *lay-friendliness*. The first skopos seems to be only skopos thoroughly checked by the authorities (cf. the section *The quality checks of the translations* in Chapter 2). Because of the increased complexity of translated PILs identified in previous studies, the main interest of this study is to investigate the second skopos – that of lay-friendliness, which will be further discussed below.

To unfold the concept of lay-friendliness a bit further, two main elements can be seen as important in relation to the concept of lay-friendliness in PILs: first, the PIL must be translated using language that is clear and understandable. This is related to general literacy, i.e. to general linguistic complexity and can be assessed by looking at the linguistic complexity of PILs. Examples could be the use of complex syntax such as nominalization or the use of long compound nouns. Second, PIL translations must be understandable for lay

people. This is related to medical expert register such as the use of complex medical terminology. Lay-friendly language is linked to the comprehension of medical content, and can thus be related to the concept of health literacy. Health literacy originally meant the ability to read and understand health information, i.e. focus was on whether people could read and understand information (Raynor, 2012, para 2). Today, the term has a much wider scope, encompassing three aspects:

- the ability to read and understand health information
- a wider ability to engage with the healthcare process
- removal by healthcare systems of unnecessary complexity and barriers to patient understanding and involvement (Raynor, 2012, para 2)

For our purposes, especially the first aspect of health literacy is important. As seen above, lay-friendliness in PILs is linked to general literacy and general linguistic complexity as well as health literacy and medical linguistic complexity. For the purpose of this dissertation, these two aspects are seen as overlapping, following Sand-Jecklin: "[a]lthough health literacy encompasses more than reading ability, the ability to read and understand written material, undoubtedly, significantly impacts health literacy" (2007, p. 120). Health literacy can thus be seen as a superordinate category to general literacy as it encompasses general literacy. Therefore, in this dissertation, the concept of lay-friendliness will be used as a superordinate term encompassing linguistic complexity – general and medical – in PILs.

Before an attempt at operationalizing lay-friendliness is made, a question presents itself: What is a lay person? In connection with PILs, lay people comprise a potentially very diverse group. It has been decided to define them negatively, i.e. based on what they are not. The lay receivers of PILs are all receivers that are non-experts, i.e. not medical professionals. As this group would include people of all ages, social, educational and cultural backgrounds, I propose, following Askehave & Zethsen (e.g. 2003, p. 33), that a *lowest common denominator* approach is taken, which means that "the writer constantly asks whether something can be simplified or explained" (Askehave & Zethsen, 2003, p. 33). Some would argue that a PIL which is too simple may be perceived as dull (Koo, et al., 2003, p. 260), patronizing or lacking in authority (Kenny, et al., 1998, p. 473). This might be from the point of view that simple means distorted as in "the message should use simple, rather than complex, technical terms, but oversimplification and distortions must be avoided" (Amery, 1999, p. 127). Producing a text which is linguistically simple is not the same as *over*simplifying a message, and along the same line, a text can be simplified without any distortion. Furthermore, this fear of oversimplification and distortion does not seem valid in

the light of the studies showing that highly educated people do not mind that PIL content is simplified (Harwood & Harrison, 2004, p. 216), and also in the light of the fact that people of all literacy levels may have difficulties understanding information when confronted with their own or a loved one's stressful or unfamiliar situation (US Department of Health, 2008, para 4). Finally, it could be argued that highly educated people who find the information too simplistic would often have the resources to find more information elsewhere. Also, this can be viewed as a minor problem compared with the consequences it could have for the less educated lay group.

It should be noted here that expert-lay is of course a simplification, and should be seen as a continuum, not as dichotomous categories similar to Nation's (2001, p. 198) and Chung's (2003, p. 229) continuum of *technicalness*. Expert-lay should also be seen as a simplification in the sense that in general the patient is not seen as lay *per se*, but as an expert in his/her own life world, values and preferences (following e.g. Caron-Flinterman, Broerse, & Bunders, 2005; Thorne, Ternulf Nyhlin, & Paterson, 2000).

To analyse the PILs, lay-friendliness needs to be operationalized in a framework to be used for the analysis. As seen in Chapter 2, several studies have found that PILs are complex for lay people and thus difficult to understand. To gain an understanding of how the legal requirement of lay-friendliness is implemented and researched in these previous studies, the methods used in existing literature are explored to approach an operationalization of this concept.

6.1.4. Literature review of methods used to assess textual complexity in PILs

By its nature, the PIL genre is interesting for various research fields, such as Health Communication, Linguistics, Document Design, Discourse Analysis and Translation Studies, and research on PIL complexity has thus be explored employing the various approaches used in these research fields. These various approaches have been used as the structuring elements in the below literature review of complexity in PILs. First, the quantitative approaches to research of PIL complexity will be presented and critically discussed. Secondly, the qualitative approaches to research of PIL complexity as well as their sub-categories of reception studies and textual studies will be presented and discussed.

Quantitative research - Readability formulas

Because the PIL is a health genre, the research undertaken into PILs has traditionally been conducted within the field of Health Communication. One of the resulting issues is that "studies of the effectiveness of such material have historically been limited by a biomedical

approach which fails to take into account sociocultural and linguistic issues" (Clerehan, forthcoming). Still today, there are issues with linguistic research rarely being quoted by researchers in the field of health (Clerehan, forthcoming). Therefore, there has also been an overemphasis on assessing complexity of health documents for the general public using quantitative measures such as readability formulas (examples of this include Buchbinder, Hall, Grant, Mylvaganam, & Patrick, 2001; Hedman, 2008; Ley & Florio, 1996; Mottram & Reed, 1997; S. Payne, Large, Jarrett, & Turner, 2000; Williams-Deane & Potter, 1992). Harwood & Harrison (2004) used the readability formulas available in Word 2000 to asses 26 orthodontic PILs, which were subsequently sent to the Plain English Campaign for assessment of their eligibility for the Crystal Mark[26]. Not even the PILs being rated as *standard* or *fairly easy* to read, meaning that 70-80% of the UK population would be able to understand them (according to the readability formula that is) were eligible for the Plain English Campaign's Crystal Mark.

There are several problems with this quantitative approach to the assessment of text complexity. First of all, there are problems with interformula reliability as different formulas might give different grade level scores on the same piece of writing; up to three grade levels have been seen (Schriver, 2000, p. 139). Readability formulas can be criticized for lacking criterion validity as the scoring systems of some formulas are suspected to be based on very short passages of 100 words (Schriver, 2000, pp. 138-139). Furthermore, the predictor variables of sentence length and word frequency used in many formulas are not the only, and probably not even the best, predictors of text comprehension, meaning that the formulas are not in fact measuring what they are said to measure (Schriver, 2000, p. 138). Readability formulas ignore features of text organization such as cohesion; thus, it is possible to randomize every sentence, but still have the same score – a text written backwards would yield the same readability score. Hence, using readability formulas means taking the approach that readability is an inherent text quality that can be measured without contextualization and without attempting to take the readers' characteristics and resources into account. Moreover, readability formulas would be difficult to use to assess translation choices and differences between two languages because different languages might have different structures and words which makes them more or less complex. Finally, the readability formulas would assess the expert term *injection* as easier to understand than the lay term *indsprøjtning*, because injection is a shorter word.

[26] The Plain English Campaign's seal of approval.

Qualitative approaches

Reception studies

One of the main qualitative approaches to PIL analysis is the use of reception methods, also referred to as user-testing. This can be concurrent tests (the evaluation real-time problem-solving behaviour of readers as they actively engage in comprehending and using the text for its intended purpose) and retrospective tests (feedback after the reader has read and used the text), comprehension methods (asking readers to paraphrase, recall, summarize and recognize), surveys, interviews, focus groups etc.

The most popular methods subsumed under this heading include interviews adapted to a user-testing scenario (Clerehan, et al., 2009; Consumers' Association, 2000; Dickinson, et al., 2001; Pander Maat & Lentz, 2010), focus groups (Clerehan, et al., 2009; Consumers' Association, 2000; Koo, Krass, & Aslani, 2002; Raynor, et al., 2004) qualitative questionnaires (Knapp, et al., 2009), quantitative questionnaires (Berry, Raynor, Knapp, & Bersellini, 2004; Gustafsson, Kälvemark, Nilsson, & Nilsson, 2005; Horwitz, et al., 2009) and mixed questionnaires (Bernardini, Ambrogi, Fardella, Perioli, & Grandolini, 2001). The value of reception studies has been advocated by e.g. Sless & Wiseman (1997) and Raynor (2008a, 2008b; 2004) as a tool to provide important information on patients' perception and understanding of PILs. Reception studies are thus especially useful to elicit information about which sections of the PIL need improvement according to patients.

User-testing also has some disadvantages; e.g. sometimes, the group of users does not find all the problematic elements in a text, and they may be unable to pin down what they find difficult and why (Clerehan & Buchbinder, 2006, p. 62). Because of the artificial reading situation, users might attempt to impress the researcher to avoid showing incomprehension: "people may fear showing themselves to be stupid if they say they encountered problems, so they claim to understand" (Wright, 2003, p. 6), and also some people may not want to criticize the text as this could be viewed as impolite, and therefore fail to discuss the problematic areas (Wright, 2003, pp. 6-7).

A reception approach would be valuable in order to analyse whether the translation receiver is likely to understand the document as a whole, but to analyse translation choices at a micro level and to analyse whether professional translators and pharmacists translate differently in relation to lay-friendliness, this method is not suitable.

Textual studies

Another very popular approach to qualitative assessment of PILs is textual analysis. PILs have been studied textually employing various approaches including Document Design

(Pander Maat & Lentz, 1994, 2010), Systemic Functional Linguistics (Clerehan & Buchbinder, 2006; Clerehan, et al., 2004; Clerehan, et al., 2009; Hirsh, Clerehan, Staples, Osborne, & Buchbinder, 2009; McManus, 2009), discourse analysis (Askehave & Zethsen, 2010; Dixon-Woods, 2001; Dray & Papen, 2004; Fage-Butler, 2011a, 2011b; S. A. Payne, 2002), Translation Studies (Askehave & Zethsen, 2000b, 2002, 2003, 2006, 2008; Cacchiani, 2006) and contrastive rhetorics (Connor et al., 2008). The studies which gauged linguistic complexity of PILs will be presented and discussed below.

Document Design

Document design principles were used by Pander Maat & Lentz in their work (2010) to improve text structure and visual signalling in PILs previously approved by the Dutch Medicine Evaluation Board. They felt their freedom to innovate was constrained by the template, but it was possible to improve the PIL within the guidelines. They conclude that all PILs should be written according to evidence-based Document Design principles. However, the aim of Document Design is broader than lay-friendliness as it mainly takes into account overall structure and layout whereas lay-friendliness in this study is interested in linguistic complexity. Only two parameters in their design can be seen as related to lay-friendliness, i.e. the change of passive voice into active voice and some lexical simplifications, which they do not define further.

Systemic Functional Linguistics (SFL)

Clerehan, Buchbinder & Moodie (2004), Clerehan & Buchbinder (2006) and Clerehan et al. (2009) have proposed an approach based on SFL to assess drug information materials. Their model is based on the assumption that genres are expected to show a conventional text structure according to their specific purpose, and that the comprehensibility of the information conveyed depends to a great extent on whether the text shows the generic patterns expected by the reader (Clerehan & Buchbinder, 2006, p. 42). Using an SFL-based approach, Clerehan et al. analysed the generic structure, rhetorical elements, metadiscourse, headings, technicality of lexis, lexical density, writer-reader relationship and factual content of the leaflets (Clerehan, et al., 2009).

A genre approach to the evaluation of translation choices made in PILs is not suitable as the moves are likely to be the same in the English and Danish PILs because of the templates and other legal regulations of structure and content. Furthermore, even though patients might be able to recognize the PIL as a genre with a conventionalised move structure, this will not necessarily equal lay-friendliness in PILs, because PILs have a somewhat

tarnished reputation and patients might just recognize them as something too complex and difficult. Pander Maat & Lentz found that the move structure of EU PILs does not match receivers' expectations for PIL structure (2011, p. 214).

Moreover, because a framework suitable for the analysis of micro level translation choices is needed, a genre approach is not appropriate. However, the clause and word level linguistic elements suggested by Clerehan et al. such as technicality of lexis and lexical density are relevant for the lay-friendliness framework.

Linguistics and Translation Studies

Askehave & Zethsen propose that "the discussion of userfriendliness should be approached from a linguistic perspective and that most of the problems can be solved by considering *language use* in PPIs [PILs]" (2000b, p. 4). For the purpose of investigating the degree of lay-friendliness in translated PILs compared to their source text, such an approach seems very suitable as it would allow textual analysis on micro level such as the use of expert versus lay terminology as well as on clause and text level. Askehave & Zethsen propose several parameters which should be avoided in PILs because they belong to expert language such as specialised lexis, officialese, passive constructions, nominalizations, long sentences etc. (Askehave & Zethsen, 2000a, 2003).

Summing up and looking forward

The quantitative approaches to lay-friendliness are lacking and not suitable for my purposes as described above. The reception-studies approaches to PIL complexity are highly useful to elicit patient understanding; however, they are not suitable for assessing micro level translation choices. The most suitable approach is the textual approach; however, in order to textual differences in translation products, a linguistic framework with specific elements said to increase or decrease lay-friendliness is needed. As the framework must enable the examination of translation choices and differences in translation choices, it is necessary to look at the choices made at word, clause and text level. Furthermore, to take translation choices into consideration, it must be contrastive, comparing the English and Danish source and target texts. Probably because there is consensus about many linguistic elements said to make a text more or less difficult, Askehave & Zethsen did not build an actual lay-friendliness framework, but their studies include many elements relevant for the lay-friendliness, and will be used as inspiration for the elaboration of the framework.

To elaborate a linguistic framework to be used as an operationalization of lay-friendliness, a literature review of elements said to increase or decrease textual complexity

was conducted. During the process of the literature review, it became evident that textual complexity could be encompassed in one main "discipline", i.e. Plain Language. The definition of Plain Language put forward by the International Plain Language Working Group is: "Plain Language uses language and design to present information to its intended readers in a way that gives them a good chance of easily understanding the writer's meaning and of using the document at first reading" (International Plain Language Working Group, 2009, p. 5). Plain Language can therefore be seen to have strong parallels to the PIL skopos of lay-friendliness. I refer to Plain Language as a "discipline" using quotation marks as it is not yet a fully established research discipline (Stewart, 2010, p. 64), and Plain Language research thus draws on research from the above-mentioned fields and is conducted by scholars from these fields. Below Plain Language is further presented.

6.1.5. Introducing Plain Language as an operationalization of lay-friendliness

Plain Language (PL) research draws on results from many other research areas including fields related to lay-friendliness and health literacy (such as Linguistics and Health Communication) and plain language and general literacy (such as Linguistics, Education and Communication). It is therefore possible to use PL research as the basis for the literature review operationalizing lay-friendliness.

Within PL research, different methods have been suggested and used for the analysis of PL, i.e. numerical or formula-based, elements-focused and outcomes-focused methods (International Plain Language Working Group, 2009; Schriver, 1990). Within these categories, several methods have been used, but based on the literature review on methods in PIL research above, it was concluded that to analyse translation choices in PILs, a linguistic framework of elements said to increase or decrease lay-friendliness is needed. Therefore, only elements-focused methods are reviewed below. Below, PL is elaborated further and PL in relation to medical communication and PL in the Danish context will also be introduced. As a conclusion to this section, some of the criticism of PL and will be discussed.

Introducing Plain Language

The term *Plain Language* is used in several contexts and with several meanings; some use it in a very specific narrow sense, i.e. as a reference to the work done by the PL movements, while others give it a more general sense, i.e. with reference to "communication that an audience can understand the first time they read or hear it" (Wicklund & Ramos, 2009, p. 178). PL as a concept came into existence in the 1970s in the UK with the formation of a consumer and citizens' advocacy movement (Stewart, 2010, p. 51). Around the same time, PL

appeared in the US, but here, the beginnings of PL had government ties, e.g. President Nixon's statement that Federal Register must be written in "layman's terms" (Dorney, 1988, p. 49) as well as commercial ties, e.g. banks producing PL documents (Stewart, 2010, p. 52). Also in Australia, PL was introduced when the banking and insurance industries saw the commercial value in PL (Stewart, 2010, p. 52). PL as an organised movement has grown since the 19th century, because in a world with economic development, growth of the middle class and literacy, it is necessary for people to deal with complex legal, financial and medical matters on a daily basis leading to a need for clear communication (Stewart, 2010, p. 53). The need for PL increased and the initial focus was on the social benefits of clear communication to enable citizens to make informed decisions (Balmford, 2002, p. 3). PL is therefore linked to notions of democracy, equity, authenticity and transparency (Petelin, 2010, p. 212), and today, the interest in PL has become more widespread for reasons such as newly introduced legislation, but also because of economic benefits such as cost savings, competition and consumer satisfaction (Balmford, 2002, p. 3).

As mentioned above, still today, PL is not an established research discipline in itself, but is a meeting point for researchers and research from the fields presented above as well as from professions such as law and public administration (Petelin, 2010, p. 214; Stableford & Mettger, 2007, p. 81). The fact that PL is not an established academic discipline has led to some criticism, which will be discussed below (section *Criticism of Plain Language*).

PL and medical communication

Traditionally, PL research, PL communication and PL advocacy has focused on legal language or on public documents, i.e. the public sector communicating with the general public. Combining PL and medicine has been less explored (Stableford & Mettger, 2007, p. 72), even though the value and importance of this combination speaks for itself. In recent years, there seems to be an increasing understanding of combining PL and health communication (e.g. Stableford & Mettger, 2007), especially because of the mismatch between available health information and health literacy (Stableford & Mettger, 2007, p. 71; US Department of Health, 2008). There are several reasons why PL is suitable, if not essential, for health communication. First of all, the complexity of medical information is often quite high (Wicklund & Ramos, 2009, p. 178), and medical communication between experts usually uses complex terminology and medical jargon (US Department of Health, 2008, p. 1). Furthermore, some argue that PL leads to greater "patient safety, shared decision-making, health literacy, cultural competence, treatment adherence, informed consent, and

accurate diagnoses" (Wicklund & Ramos, 2009, p. 179), because patients are able to understand, learn and act. Finally, people of all literacy levels might have difficulties understanding material when they are in an unfamiliar situation in which they might just have been diagnosed with a disease: "People can be very well educated and highly literate in their area of expertise, and still not fully understand complex medical information (US Department of Health, 2008, p. 5).

Plain Danish

Historically, plain Danish – not as a specific term, but as an idea – was introduced with the Danish Ministry of Justice's guidelines published in 1969 (Justitsministeriet, 1969), which aimed to identify some of the linguistic and textual features considered problematic. After this, there have been several campaigns within the Danish public sector with elements of PL advocated. An example is that writers in municipalities and courts are recommended to avoid certain terms, the use of passive and long sentences (Kjærgaard, 2010). Because a contrastive framework needs to be elaborated for my purposes, the research done within the Danish context is relevant because some language factors will be unique to the Danish language.

PL as a movement has been much stronger in English-speaking countries, such as the US, the UK, Canada and Australia, and also, PL advocacy is very widespread in Sweden. The Swedish term for PL *klarspråk* is used in Sweden, and according to the Swedish national encyclopaedia, it came into existence as early as 1970 (Dansk Sprognævn, 2005). It is also from Swedish that the Danish term *klarsprog* has its roots; however, it is not a very widely used term (Dansk Sprognævn, 2005). Both in Sweden, as well as in Denmark, PL is mainly linked to how the public sector communicates with the general public. Some new efforts are currently being made from the Danish Language Association to put PL on the map in Denmark more systematically (pers comm. Anne Kjærgaard, PhD, June 2011), and also to give a more comprehensive overview of plain Danish elements linked with user-testing of documents that have been revised using PL elements compared to ones that have not been revised.

Criticism of PL

PL has attracted a quite extensive amount of criticism, partly because PL started as a movement with roots within the professions, and not as an academic discipline. Table 11 below contains an overview of some of the most common criticism of PL and answers to the criticism.

Criticism	Example	Answer
PL is not thoroughly defined	There is no "single, world-standard definition" (Baldwin, 1999, p. 17). Therefore, some argue that it is not possible to talk about PL if it is not defined more thoroughly.	It might not be possible, or even desirable, to have one single definition of PL, but what is needed is clarity in each study or publication concerning the use of the term.
PL guidelines are not empirically based	PL is not an established academic discipline at present and therefore, PL is rarely the direct focus of research (Stewart, 2010, p. 64). This also means that for some of the guidelines, the empirical base is not clear or lacking (Sanders & Lentz, 2007, p. 197).	One defence against this criticism is that, because many PL sources are written for the general public, they do not cite academic sources (Mazur, 2000). Also, for some PL guidelines, the empirical base is clear such as the use of nominalization (Coleman, 1964).
PL is not objective	PL is not objective, which means that "what is plain to one reader may be incomprehensible to another, and irritatingly simplistic to a third" (Stewart, 2010, p. 67). This also means that writing (or rewriting) PL can only lead to a higher likelihood that something is lay-friendly, it can never be a guarantee.	Thus, the problem with standards or guidelines is that they will probably not cover all cases and therefore, standards and should be genre- and audience-specific. This is not seen as a problem as it is in line with the approach to communication and the skopos-theoretical approach to translation, which is always context-dependent.
PL is dumbing down	PL and similar approaches to language have been criticized for "dumbing down" text and some professionals are concerned that using plain language will oversimplify information to the point where it is inaccurate or worthless.	As argued above, research has shown that simple, lay-friendly language does not offend well-educated people as people of all education levels prefer concise information especially in the case of communication outside our area of expertise (US Department of Health, 2008, p. 5). As mentioned above, it is important to emphasize that PL does not mean oversimplification or distortion.
PL is prescriptive	Some have interpreted PL guidelines as prescriptive rules instead of what is the most widespread attitude among PL advocates – as guidelines. This interpretation might be linked to the fact that some of the very early resources on PL guidelines saw PL guidelines as set in stone (Mazur, 2000).	Today, PL advocates see PL guidelines as guidelines only, i.e. suggestions to help writers achieve the goals of communicating clearly with their receivers (Cutts, 2009, p. x)

Table 11: Criticism of Plain Language.

Methods within PL

Three main categories of methods for analysis of text complexity have been suggested within PL, i.e. numerical or formula-based, outcomes-focused and elements-focused methods (International Plain Language Working Group, 2009, p. 2). The formula-based methods use readability formulas or similar tools as have been presented and criticized above. The elements-focused methods list the desirable stylistic features of PL and the outcomes-based ones describe the desired effect of the writing on the reader (Stewart, 2010, p. 56). As found in the literature review above on methods gauging complexity in PILs, a linguistic elements-focused approach would be the most suitable approach to assessing PIL translations.

Elements-focused methods within PL consist of checklists or elements assumed to influence textual PL such as nominalisations, passive voice etc. They are aimed at giving writers advice on linguistic, stylistic or graphic features of text. The elements-focused methods seem the most suitable as an analysis of PIL translation as this category includes linguistic elements assumed to make a text more or less complex. As some criticism has been brought against element-focused methods, i.e. that they are too generic and therefore, it is argued that they ignore context (Schriver, 1990, p. 250), the guidelines need to be adapted to each specific situation and audience, which is in line with the skopos-theoretical approach. Thus, based on discussion of the PIL skopos of lay-friendliness, an analytic framework was elaborated based on linguistic elements said to increase or decrease text complexity.

6.1.6. Towards a lay-friendliness framework

Based on a literature review from the fields encompassed under Plain Language identifying aspects of text complexity, an analytic framework to assess the lay-friendliness of the PIL translation was elaborated to be used as the starting point for the analysis of the PIL corpus. The framework was elaborated based on consensus in the literature concerning what linguistically makes a text difficult or easy to understand. To my knowledge, no such framework has previously been elaborated with focus on contrastive analysis (here English-Danish).

Lay-friendliness and medical register

The use of specialized terminology is often quoted as one of the main reasons why medical texts are difficult for lay people to understand (Bromme, Jucks, & Wagner, 2005; Bromme, Rambow, & Nückles, 2001; MHRA, 2005). One of the main issues is that what constitutes specialised terminology is not straightforward, because medical register is very diverse. The

concept of *register* can be defined as "the specialized language that occurs when certain topics are discussed by people with shared background knowledge and shared assumptions about those topics, particularly when this stems from their occupation or profession" (Frawley, 2003, p. 455). This might, however, be too narrow a definition for my purposes as I would argue that medical register belongs to the worlds and contexts of both medical professionals and patients in line with Nation's (2001) and Chung's (2003) continuum of technicalness mentioned above. It is therefore important to say that even though some talk about medical language as a specific register, it must be emphasized that it has extensive variation within: "Medical language may be described as a type of register, i.e. a variety of language appropriate to different occasion and situations of use. Ranges of variation of this register have been described in terms of technicality, formality, and channel of communication" (Pilegaard, 1997, p. 159). Medical language is thus not uniform, because many genres exist with a range of different audiences, such as expert-to-expert, expert-to-semi expert, expert-to-lay person and lay person-to-expert. Hence, it is important to be aware of these variations in register as they can make a text more or less lay-friendly.

Some argue that medical communication has changed, and because patients today want to be more involved in their own health, they understand more medical terms (Černý, 2008, p. 45). This is sometimes seen as an argument for the use of specialized register, also when communicating with patients. Some might argue that patients today are more knowledgeable about medical terms than previously; however, specialized expert medical terminology is still a source of confusion: "knowledge of medical terminology increased significantly in the last couple of decades but comprehension levels are still low and misunderstandings or miscommunication is still observed" (Dahm, 2011, p. 24). This means that even though patients are more involved in their own health and in health-related topics today, the use of medical terms may still constitute a comprehension barrier between medical professionals and patients (Herget & Alegre, 2009, para 2). A further problem is that this miscommunication might not be known and apparent. Boyle reports significant differences between patients' and doctors' interpretations of some common medical terms (1970, p. 286). This was also confirmed by Jucks & Bromme: "[a]s research on medical expertise has shown, experts compared with novices associate not only **more** but also **different information** with a certain specialist term" (2007, p. 269, my emphasis). Even though lay people have started to use specialist terms (Cabré, 1996, p. 30), for some terms, patients only have a shallow understanding of their meaning (Dahm, 2011, p. 18). Dahm gives the example of the use of the terms headache and migraine, which some lay people use interchangeably "since symptoms associated with the latter term such as nausea or the presence of visual auras have

been lost during reintegration" (Dahm, 2011, p. 18). Meyer & Mackintosh (2000) have called this borrowing process de-terminologization[27] and stress that often the meaning of the word is lost because lay people do not have the deep knowledge of the concept. This means that even though the general public might be more knowledgeable than in the past, the use of medical terms can still cause significant communication problems between experts and lay people. Furthermore, I would argue that for patient communication, it is not sufficient that the majority of the population understands the information given; it should be clear and understandable for everyone, which is why a lowest common denominator approach is taken (as described above).

Even educated patients, with high levels of education, who generally know more medical terminology, still experience difficulties with a wide range of terms, and misunderstandings are still likely to occur even with increased comprehension levels (e.g. Becker, Bromme, & Jucks, 2008, who used students in their third year of university). Furthermore, according to Wright (1999), medical texts pose specific problems because "readers can be emotionally involved when their own health is at issue" (p. 696).

Latin-based terms

There are different kinds of terminology that can make a text more or less lay-friendly; one of them is Latin-based (LB)[28] terminology which is very widespread in medical genres. LB terms are one of the most frequent elements quoted to hamper lay-friendliness, both in English and in Danish. Many scholars agree that LB terms are problematic and should be avoided when writing for lay people (Becker Jensen, 2007b; Domstolsstyrelsen, 2003, p. 15; Wille, 2001; Zethsen, 2004), and it is suggested that they should be replaced by a lay term or be explained. Moreover, in a study done by the DHMA in which five language experts assessed PILs, they found that LB medical terms were used extensively instead of Danish terms and this was considered to make the PILs more difficult to understand (Lægemiddelstyrelsen, 2004). Another interesting finding in a study by Thompson & Pledger (1993) is that patients lacked knowledge about those medical terms that medical doctors had identified as *common*, which shows a gap between what experts would perceive as common terminology and what patients would. A further problem with LB terms is that lay people might think they know the meaning of a term, but in fact, the term means something else. In

[27] This kind of de-terminologization is different from the one suggested by Montalt Resurrecció & González Davies (2007) and mentioned on page 75 as their use of de-terminologization refers to the replacement of an expert term with a lay term or an explanation.
[28] Latin-based here includes both Greek- and Latin-based terminology.

her MA thesis, Ottzen tested 10 LB terms using a questionnaire answered by 44 non-medically educated Danes at a pharmacy (Ottzen, 2012). One of the tested words was *hepatitis*, which 1/3 of the participants said they knew; however, several participants *(*23%) thought that they knew the meaning of hepatitis, but actually did not; suggestions included a *sexually transmitted disease*, *eczema* and a *brain disease* (Ottzen, 2012, p. 96). LB terms can therefore be seen as leading to increased text complexity, and should thus be included in the analytic framework. But is it permissible to eliminate the LB terms? Some of the criticism put forward against PL and simplifying complex expert language has centred around it being less precise; however, this dissertation follows Becker Jensen (2001, p. 141), who emphasizes that what seems to be a very precise concept or term for an expert is not a precise term for a lay person; especially, if s/he does not understand it.

PL – from intralingual translation to interlingual translation

Because most PL guidelines have been elaborated for the English language only, they would not include terms like *inject* and *oral* in the category of specialised, expert register. In Danish, these terms belong to expert register. LB terms have different semantic positions within English and Danish medical register. Even though the concept of equivalence has been overshadowed by functionalism, it has sometimes been claimed that equivalence still exists within LSP translation (which includes medical translation) (Zethsen, 1997, pp. 41-43). It is claimed that for technical terms, there is a one-to-one relationship between two languages (Halliday, McIntosh, & Strevens, 1964, p. 129). This would mean that a source text term can be directly transferred into the target language. “A technical term is a technical term, it is claimed, and it is often assumed by scholars and translators alike that most of these terms are purely denotational and can therefore be transferred directly from English to Danish” (Zethsen, 2004, p. 127). Similarly, Fischbach (1986) argues that medical translation “is the most universal and oldest field of scientific translation because of the homogeneous ubiquity of the human body” (p. 16), and claims that this sameness of object or concept to be translated “gives the medical translator an edge over his colleagues in other fields” (Fischbach, 1986, p. 16).

However, there are major differences between the usage of medical terms in different languages, i.e. in what constitutes expert and lay register. Even today, an extensive amount of medical terminology is based on Greek and Latin, which can be explained by the history of medicine (McMorrow, p. 14). Scientific terminology in Europe originates from the Greek language, and the terminology was subsequently translated into Latin. Later, these Latin terms were borrowed into modern European languages (Halliday, 2006 (reprint from

1998), p. 65). English medical language, and medical language in general, is therefore mainly based on terminology made up of roots, prefixes and suffixes drawn from Greek and Latin (van Hoof, 1998, p. 49). The same is true for Danish medical language; however, only the Danish medical language used by experts for experts. One of the most apparent differences between English and Danish medical language for lay people is the use of LB terms. Latin was not incorporated into all European languages to the same extent (Zethsen, 2004, p. 132), which means that for example English often uses a LB term both in expert and lay registers, whereas Danish (as well as German and other Scandinavian languages) has doublets, i.e. both the LB term which belongs primarily to an expert register, and a native word belonging to a lay register. "In contrast to English, Scandinavians will mostly use native, simple and immediately understandable words ("blunt and commonplace") when talking about a medical subject in a non-expert context" (Zethsen, 2004, p. 134)[29]. According to Zethsen (2004), who has conducted research on LB terms in English into Danish translation, a translator must be very careful when translating medical English, especially for lay people. English uses an extensive amount of LB medical terms, even in everyday language as often there is no non-specialized equivalent; this is, however, not the case for Danish. An example of this is the translation of *ovary*. In English, this term belongs both to the expert-to-expert and expert-to-lay medical register. In Danish, the direct translation would be *ovarie*, but this term only belongs to expert-to-expert register whereas in lay Danish, the term would be *æggestok* [egg stalk]. This is not only the case for nouns; also verbs such as *inject* have a Danish lay equivalent, i.e. *indsprøjte* [squirt into], a word which also provides a figurative image of its meaning. Some of the Danish lay terms thus also carry semantic content which is likely aid understanding. This is supported by Pilegaard in his example: "For example the Danish lay expressions for *stofskifte* (in English *metabolism)* and *gulsot* (in English *jaundice)* are intuitively more readily understandable than the corresponding English lay-terms" (Pilegaard, 1997, p. 171).

Therefore, in a translation for a non-expert receiver, if the LB medical terms are directly transferred into Danish, even though there seems to be total equivalence, the formality and complexity level will be considerably higher (Zethsen, 2004, p. 125). It will be higher than in the source text and in some cases, much higher than the target text skopos prescribes (for example in PILs).

[29] See also Herget & Alegre 2009 on the difference between Romance languages and Germanic in relation to Latin-based terms.

Furthermore, in addition to raising the complexity level, the use of LB terminology in Danish might also scare the target text receiver as when non-English speakers hear a LB term, they may think that the condition is much worse than in reality (Abramsky & Fletcher, 2002, p. 1192; Clyne & Platt, 1991, p. 24). Therefore, medical terminology that would be suitable in an English PIL could be to the detriment of lay-friendliness when used in a Danish PIL.

Therefore, to use PL for interlingual translation analysis, the guidelines must be broadened to take the linguistic differences between English and the target language into consideration – in this example, usage of LB medical terms.

Polysemic medical terms

Medical language or register is not purely medical vocabulary, it also includes professional language and jargon (van Hoof, 1959, p. 419). In their study of Danish PILs, Askehave & Zethsen (2000b, p. 19) found the use of polysemic terms, i.e. words with several meanings. These words were part of normal, non-specialised register, but in the PIL context, they carried a specialized meaning. These are thus terms which cross over between specialist and general language. Examples are *lokal* [local], which is normally used in a context of something being within geographical proximity and *administrere* [administer], which normally means to perform work by taking care of financial matters, manage staff and allocate tasks on the basis of rules and regulations (Det Danske Sprog- og Litteraturselskab, 2012). Also a Danish study by Thorsen, Witt & Brodersen found that such common Danish words used in a medical context are difficult for lay people to understand (2012, p. 928). Because PIL receivers might misunderstand these terms or even not understand their semantic content, the use of such polysemic terms might make the PIL less lay-friendly, and they thus need to be included in the framework.

Summing up: medical register and lay-friendliness

The PIL is an expert-to-lay genre, and therefore, the use of medical register should be limited to terminology which the lay receiver is likely to understand. LB terms are one of the most frequently quoted elements hampering lay-friendliness, both in English and in Danish, but the use of LB terms in Danish is even more problematic than in English because of the linguistic differences in usage between English and Danish. It is therefore possible for a translator to make a text more or less lay-friendly depending on her/his choice of LB terminology. We also saw that specialized medical register also includes polysemic terms that can potentially both belong to normal, non-specialised register, but also to medical register in that they can have a

specialized meaning depending on the context. Such words are likely to hamper lay-friendliness as lay people might not be able to decode them.

Quite an extensive amount of literature on medical communication has focused on the use of specialized terminology as the source of misunderstanding and miscommunication. However, a text can also be made more or less complex even without specialized medical register. Medical texts can also contain an extensive amount of non-medical register, i.e. specialized, officialese, which makes a text linguistically complex. This does not only operate at word-level, but also at clause and text level. Below, the non-medical elements from the literature review which make a text complex will be introduced.

Nominalization

Coleman (1964) did an experimental study in which he found that transforming nominalizations using active verbs makes a text easier to comprehend than using their nominalized counterparts (p. 186). The fact that nominalizations are more difficult for receivers to understand is supported by many other scholars (Askehave & Zethsen, 2000a; Charrow, 1988; Halliday, 1990; Harms Larsen, 1987; Justitsministeriet, 1969; Schriver, Cheek, & Mercer, 2010). Several reasons are given for this. First of all, nominalizations make a text impersonal (Charrow, 1988, p. 98) because the acting subjects disappears, but also make a text compact, hard to process and more abstract (Becker Jensen, 2001, p. 142; 2007b, p. 53). Halliday agrees that nominalization makes a text difficult to understand for lay people:

> This kind of nominalizing metaphor probably evolved first in scientific and technical registers, where it played a dual role: it made it possible on the one hand to construct hierarchies of technical terms, and on the other hand to develop an argument step by step, using complex passages ‘packaged’ in nominal form […] the writer presumably knows exactly what is means; but the reader may not, and so this kind of highly metaphorical discourse tends to mark off the expert from those who are uninitiated. (1994, p. 353)

Halliday also argues that the complexity of nominalizations is linked to the fact that we first learn to talk in clauses and not until later are we able to replace clauses with nominal groups (1990, p. 27).

Voice – active vs. passive

The use of passive voice instead of active is said to influence the complexity of a text negatively (Becker Jensen, 1998, 2007b; Bonk, 2009; Charrow, 1988; Fry, 1988; Harwood &

Harrison, 2004; Lægemiddelstyrelsen, 2004; Wille, 2001). One of the reasons to use active voice is to make it clear who is supposed to do what and in this way eliminate ambiguity about responsibilities as passive voice could obscure who is responsible. Because the active voice emphasizes the doer of an action, it is argued that it is often briefer, clearer, and more emphatic than the passive voice. According to Becker Jensen, the use of passives can cause comprehension problems and misunderstandings (2007b, p. 50).

Compounds

Within specialized registers, another typical characteristic is the use of compounds, especially compound nouns, which are sometimes called, very suitably, *tape worm words* in the Danish context (Becker Jensen, 2001, p. 145). The problem is that these are often hard to read and therefore, they impede comprehension (Charrow, 1988, p. 99; Halliday, 1990, p. 13). Compounds are especially problematic in translation between English and Danish, because of the difference between English and Danish in the way compound nouns are written. According to Danish spelling rules, compound nouns must be represented orthographically as one word. Thus, when translating English compound nouns consisting of several consecutive nouns into Danish, the Danish compound becomes very long, which can lead to both reading and comprehension difficulties. Andreassen (2010) gives a good example in her MA thesis on the translation of long compound noun in English-Danish medical translation: The English medical term *liver allograft rejections* may be translated into Danish as *leverallotransplantatafstødning*, a very long and complex compound noun (Andreassen, 2010, p. 40).

Compounds seem to be a very important element in Danish PL, and it is mentioned by many sources on PL in Danish (e.g. Becker Jensen, 1998, p. 86; 2001, p. 145; 2007b, p. 63; Domstolsstyrelsen, 2003, p. 16; Harms Larsen, 1987, pp. 59-60). It is suggested that the compounds should be split up using several words: so *blodprøvekontroltagning* [blood test control taking] becomes *tage blodprøver til kontrol* [take blood tests for control] (Becker Jensen, 2007b, p. 63). Becker Jensen suggests that the ‘pain threshold’ for compounds is three concepts, but he gives examples of compounds that are difficult which have only two concepts (2001, p. 145). In this situation, I do not think it is possible to say how many concepts are too many, the context would be relevant and the kinds of terms involved. For example, there would be no positive effect of splitting the compound *lungebetændelse* [pneumonia, lung inflammation] as *betændelse i lungerne* [inflammation of the lungs] as the compound is how this condition is known.

In the analysis, three coding options for the use of compound nouns are possible, i.e.:

- A lay-friendly option when a translator has replaced a compound with a non-compound.
- A non-lay-friendly option when a translator replaces a non-compound with a compound.
- A non-lay-friendly option when a compound in English is directly translated, but becomes a long compound word in Danish (because of the differences between English and Danish spelling).

Pronouns

Research shows that pronouns help readers relate better to documents as the receiver is directly addressed and is "more likely to understand what his or her responsibility is" (Plain Language Action and Information Network, 2011, p. 30). Previous research has found that personal pronouns are deleted when PILs are translated into Danish (Askehave & Zethsen, 2000a, p. 31). An example from a PIL is:

ST[30]: You may require blood tests
TT: Det kan være nødvendigt at få taget blodprøver
Explanation: It may be necessary to have blood tests taken

In the Danish translation, the personal pronoun is deleted and replaced by an impersonal construction. It should be noted here that Danish has two forms of the second person pronouns (you, i.e. De/du), where one is very formal (De). Lægemiddelstyrelsen (2004) suggests that it is situation-dependent which one to use in PILs, but that it is usually natural to use the informal *du*.

Sometimes the personal pronoun is deleted in Danish, but this is for grammatical reasons. In the example:

ST: Talk about your insulin needs with **your** doctor and diabetes nurse
TT: Tal om dit insulinbehov med **lægen** og diabetessygeplejersken

In the Danish translation, the personal pronoun *your* in front of doctor is replaced by a definite form *the doctor*. These instances are therefore not included in the framework as a less lay-friendly option as they merely follow Danish linguistic conventions.

[30] ST is an abbreviation of source text and TT of target text.

Cohesion

Within the systematic functional linguistic tradition, cohesion refers to the relations of meaning that exist within a text and that make it a text (Halliday & Hasan, 1976, p. 4). It is defined as the network of lexical, grammatical, and other relations which provide links between various parts of a text. Cohesion occurs when the interpretation of one element in the text is dependent on another element (Halliday & Hasan, 1976, p. 4). It is thus not possible to effectively decode one element without the other.

One type of cohesion is lexical cohesion, which is the role played by the selection of vocabulary in organizing relations within a text (Halliday & Hasan, 1976, p. 274). Lexical cohesion typically operates through lexical chains, and there are two categories, reiteration (with several sub-categories) and collocation (Halliday & Hasan, 1976, pp. 277-288):

1. Reiteration
    - Repetition (same word)
    - Synonymy (synonym or near synonym)
    - Superordinate
    - General word
2. Collocation: any instance which involves a pair of lexical items that are associated with each other in the language in some way.

Related to lexical cohesion is the concept of redundancy, i.e. the repetition of concepts. Redundancy is important in this context as it plays an important role in making a text readable for people with no specialized knowledge of a subject (Muñoz-Miquel, 2012, p. 190). It is often helpful to repeat concepts using synonyms and paraphrases; thay way, a reader who did not understand the first wording may understand the second one (Mossop, 2007, p. 61). Text level cohesion can thus also be related to the terminological lay-friendliness elements as when there is a shift in register, i.e. from lay to expert register, the overall textual cohesion falls apart.

For PIL translation and contrastive analysis, lexical cohesion seems especially relevant. The reason that cohesion is relevant for the analysis framework is that markers of cohesion raise the level of redundancy in text; their absence lowers it. It is therefore important for PILs that lexical variation is not used, but instead that the same term is repeated. A PIL example is the English term *kidney disease*, which sometimes is translated using the Danish lay term *nyresygdom* [kidney disease], but once, the translator opts for *nyreinsufficiens* [kidney insufficiency] which belongs to medical register. Instead of keeping the same lexical

items consistently, as was the case in the English source text, the Danish text mixes the two terms, which could potentially be confusing for the reader. Therefore, lexical cohesion, especially the use of synonyms, should be included in the framework.

Summing up Plain Language for contrastive analysis

Traditionally, PL deals with intralingual translation (see e.g. Jakobson, 1959/2000; Zethsen, 2007, 2009), i.e. *translating* a complex monolingual text into language which is plainer and easier to read and understand for lay people. As a consequence, most PL practice and research has been done within monolingual contexts, with special focus on communicating across knowledge asymmetries, and must be broadened to be use interlingually. Furthermore, because most PL guidelines have been elaborated for the English language only, the guidelines must be broadened to take the linguistic differences between English and the target language into consideration, in this example, usage of medical terms. This also means that medical terminology that would be suitable in an English PIL could be to the detriment of lay-friendliness when used in a Danish PIL. Also the Danish spelling rules for compound nouns must be taken into consideration as a literal translation of these compounds would make the target text less lay-friendly.

PL guidelines mainly focus on avoiding certain linguistic features, such as nominalization and medical register. To investigate and compare the two translator groups' competence in relation to fulfilling a certain skopos, a source text-target text analysis is needed. Thus, to use PL as an operationalization of PIL skopos, and hence as an assessment tool for skopos fulfilment analysis, the analytic framework cannot only take instances where non-lay-friendly strategies have been made; it also needs to be contrastive, and take both translation choices said to hamper and increase lay-friendliness into consideration.

In the above literature review, it was attempted to find elements of textual lay-friendliness. It was found that a text can be more or less lay-friendly on several levels, i.e. both lexically, syntactically and textually. Figure 14 shows the framework.

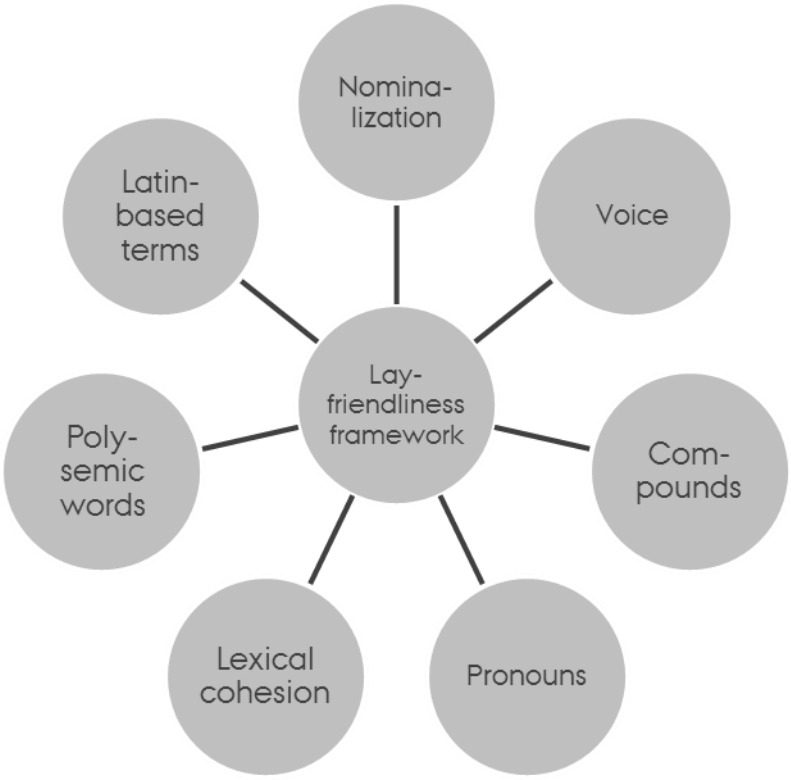

Figure 14: Overview of lay-friendliness framework.

The above framework will be the theoretical starting point for the analysis. In the following, the analysis procedure will be introduced.

6.1.7. Analysis

Before commencing analysis

According to Nord (1991), translation criticism should be based on a comparative analysis of both the source and target text and should provide information about the similarities and differences of source language and target language structures represented in both texts. It should show whether the target text is appropriate for the required translation skopos. Therefore, based on the lay-friendliness framework, each Danish PIL was analysed. The analysis was contrastive, meaning that each Danish PIL was analysed against its English source text to investigate which translation choices the translators had made. PILs were coded using the qualitative analysis software NVivo (QSR International Pty Ltd, 2011). The lay-friendliness framework was used as the coding scheme.

Before commencing the analysis, to avoid any bias, all PILs were grouped together, so it was not possible to see which ones came from the professional translator corpus and which ones came from the pharmacist corpus. In NVivo, it is possible to assign attributes to files, which means that each source was assigned an attribute of either *translator* or *pharmacist*, but these could not be seen at the time of analysis.

Commencing analysis

In the analysis, I used a strategy that both acknowledged the existing literature on lay-friendliness elements while simultaneously remaining open to possible new findings, i.e. a synthesis of deduction and induction. My approach tries to investigate a very specific issue and hence the coding scheme did not emerge from data inductively, it was predefined based on the above literature review. This does not, however, mean that the coding scheme was completely set before the commencement of data analysis; it still evolved based on analysis as some codes needed further sub-categories (see also Miles & Huberman, 1994, p. 61). Figure 15 below shows the analysis process, which shows that the coding was based on the above framework; however, when it was realized in the coding process that the framework needed further refinement, the framework was broadened based on inductive findings, which were checked against the Plain Language literature. Based on final framework, all PILs were analysed twice.

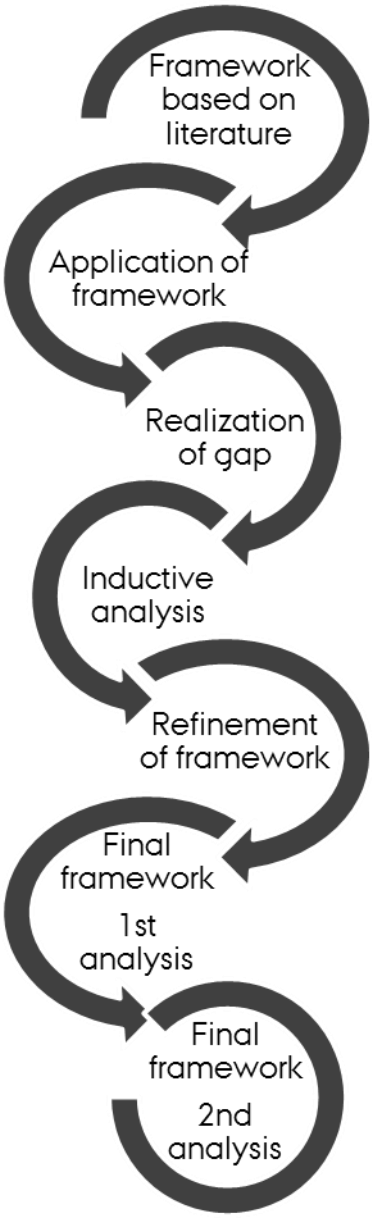

Figure 15: Analysis procedure.

As seen in Chapter 2, PIL templates have been elaborated by the EU for each language version. This means that the PIL is not produced from scratch every time, but some sections and sentences are copied directly from the template (Danish and English templates can be found in Appendices 1 and 2, respectively). This also means that these sections are not translated by the translator, but copied from the Danish template. Therefore, before contrastive analysis commenced, the templates were analysed against a randomly chosen leaflet to see which sections were mainly copied from the template, and in which sections, the original text producers as well as the translators would have some freedom of choice. This analysis resulted in several sections being left out of the analysis.

I used *double coding* (also called *simultaneous coding* (Saldaña, 2009, p. 24), which means that it was possible to code the same segment several times. An instance of double coding can be seen in the example below:

> ST: Travelling over time zones may affect your insulin needs and the timing of your injections
> TT: Tidsforskellen mellem landene kan påvirke insulinbehovet og injektionstidspunktet
> Explanation: The time difference between countries may affect the insulin need and the injection time [written in one word according to Danish spelling rules]

The item *the timing of your injections* has been translated using the Danish compound noun *injektionstidspunktet*. This is coded as a compound noun as well as the use of the LB term *injektion* (more about LB terms, such as *injektion* below).

Example from analysis: nominalization

To give an example of the analysis, nominalizations were coded both in instances where a nominalization was introduced or split up. An example of an introduction of a nominalization in the corpus (i.e. non-lay-friendly option) is:

> ST: To stimulate growth...
> TT: Til stimulering af vækst… [for the stimulation of growth]

An example of a nominalization being split up (i.e. lay-friendly option) is:

> ST: Some patients… experienced the development of heart failure
> TT: Nogle patienter... udviklede hjertesvigt [some patients…developed heart failure]

It could be argued that places where the translator has maintained, i.e. transferred directly, a nominalization could also be coded. Following the functionalist approach, the translator could potentially make the target text more skopos-adequate than the source text if these nominalizations were replaced; however, I have decided not to code these instances, only instances where the translator has made an active choice and translated using a more or less lay-friendly translation option.

The analysis procedure led to a realization during analysis that the analytic framework needed further elaboration, and inductive analysis was used simultaneously. The inductive coding was checked against the literature and the analytic framework was

subsequently broadened to include new categories and refined to include more sub-categories to existing categories. This broadening and these refinements will be discussed below. Based on the final framework, all 54 PILs were analysed twice.

6.2. Results

In this section, the results of the PIL analysis are presented. In the following discussion of the results, refinements and broadening of the framework are presented first. Secondly, in comparing the two groups of translators, only some lay-friendliness categories were found so extensively that it was possible to quantitize the results and perform statistical analysis. These quantitative results are presented first. Other categories were not found frequently enough for quantitative analysis; these categories are introduced and exemplified through qualitative presentation. Thirdly, all the results are synthesized and discussed before a conclusion including the limitations of the research design is made. Finally, the elaboration of research questions to be explored in the next study is presented.

6.2.1. Analytic framework after commencement of analysis

In the course of the analysis, it quickly became evident that the framework needed further refinement in line with the iterative deductive/inductive analysis process. The categories both needed further sub-categorization, but also, more categories were required, i.e. both a broadening and a refinement of the framework were needed. First, I found that the non-medical register was more predominant in the PILs than expected. Thus, below, the broadening of the framework with new codes is introduced. Second, the qualitative analysis also showed that the lay-friendliness framework was too simplistic to include all translation choices related to the medical register. The LB term coding scheme needed to be more detailed. Also, in the analysis, it was found that the PILs not only contained LB expert medical register, but also non-LB expert medical terminology.

Broadening of framework – officialese

When analysing the PILs, a category emerged which could not be implemented in any other category, i.e. formal words, not belonging to medical register, but more to a bureaucratic, official register. An example from an English PIL could be: “It is **preferable** not to take this product during pregnancy”, or “**in the event of** lengthy immobilisation”; both expressions which could be explained in less formal and less bureaucratic terms. Such use of formal or foreign-sounding expressions has been said to make a text more complex (Clerehan, et al., 2004; Delaere, Hoste, Peersman, Van Vaerenbergh, & Velaerts, 2009). In the Danish context,

this kind of register is sometimes called *paper clichés* (e.g. by Becker Jensen, 1998, 2001; Becker Jensen, 2007b; Harms Larsen, 1987). Paper clichés are words used on paper but never in daily speech, which usually have their roots in the bureaucratic writing tradition. These expressions make a text more formal (Becker Jensen, 2001, p. 146) and give a text "an aura of rigid and pompous language and they are often longer than the corresponding normal expressions" (Becker Jensen, 2007b, p. 24; my translation). Here, I have opted for the term often used in English, i.e. *officialese*. Examples from the analysis are given below. For each word, a less formal, shorter Danish word exists, which is written after the English explanation in square brackets:

tilstrækkeligt [sufficient, formal], "nok"
endvidere [furthermore, formal], "desuden" or "og"
tilrådelig [prudent, formal], "anbefales"
forhåndenværende [present/at hand, formal], "kendt"
såfremt [in case, formal], "hvis"

In this category, I also include foreign-sounding words if a Danish word exists (Domstolsstyrelsen, 2003) such as *irrelevant, obligatorisk [obligatory]*, *fakultativ*[31] [optional]. Furthermore, following Becker Jensen, this category also includes old-fashioned expressions (Becker Jensen, 1998, p. 53), i.e. expressions which are not part of modern Danish language as these will hamper comprehension if they are not understood by the receiver. Examples from the analysis include:

medens [while, old-fashioned spelling]
årvågen [vigilant, old-fashioned]
undertiden [sometimes, old-fashioned]
kraftesløshed [tiredness, old-fashioned]
filipenser [pimples, old-fashioned]

The officialese category also includes the use of formal verbs. The Danish PILs often used a more specialized verb than the verb in the English source text. Examples are:

ST: Use
TT: Anvende [use, more formal]

ST: Lead to
TT: Resultere i [result in]

[31] Some of these are clearly of Latin or Greek origin; however, the category of Latin-based terms is used exclusively for medical register in this dissertation.

ST: Talk
TT: Rådfør [confer with]

ST: Tell
TT: Underrette [notify]

This was also found in the opposite way with some PILs having for a less specialized verb in the Danish translation:

ST: Consult
TT: Tal [talk]

ST: Experience
TT: Får [get]

Latin-based terms[32]

The lay-friendliness framework needed further refinement and sub-categorization as it appeared from the data that in connection with the analysis of LB terms, this category was not as straightforward as distinguishing between *LB term transferred* or *LB term deleted or replaced*.

The analysis showed that a LB term may or may not have an equivalent in Danish lay register, or sometimes the translator might choose to use both the Danish term and a LB term. Therefore, two main superordinate categories were elaborated, i.e. *LB terms - lay-friendly option* and *LB terms - non-lay-friendly option*. The category *LB terms - lay-friendly option* includes translation strategies where:

1) the translator has used a Danish lay term instead of the expert LB term as in:

ST: injection
TT: indsprøjtning
Explanation: The translator could have chosen the term *injektion*, but this term belongs to Danish expert register.

2) the translator has switched the order, i.e. gives the Danish terms first followed by the original LB term in parentheses as in:

ST: if you are taking diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce)
TT: hvis du tager en type medicin, som kaldes vanddrivende tabletter (diuretika). Disse forhøjer den mængde urin, du producerer

[32] Part of this section can also be found in Nisbeth Jensen & Zethsen (2012).

or 3) the translator has added a Danish explanation to a LB term that cannot be translated into lay Danish with a single term as in:

> ST: purpura
> TT: purpura (spontan blødning i hud og slimhinder)
> Explanation: purpura (spontaneous bleeding in skin and mucous membranes)

The category *LB terms - non-lay-friendly option* includes translation strategies where:
1) the translator has transferred a LB term (without further explanation) in cases where no single Danish word exists in lay register as in:

> ST: polycystic ovarian syndrome (PCOS)
> TT: polycystisk ovariesyndrom (PCOS)
> Explanation: the syndrome PCOS does not have a name in lay Danish, but it will be more difficult to understand for a Danish lay person, because the term *ovary/ovarie* is not used in lay Danish; instead, the lay term is *æggestok* [egg stalk].

2) the translator has transferred a LB term, but the Danish word or a Danish explanation is there as well as in:

> ST: It may also be given intravenously by healthcare professionals under close supervision by a doctor
> TT: Det kan også gives intravenøst (i en vene) af en sundhedsprofessionel under nøje overvågning af en læge
> Explanation: In lay Danish, the term *intravenously* is not used; therefore, the fact that the term has been maintained is likely to hamper lay understanding. Moreover, the lay reader does not necessarily know that *in a vein* is an explanation of *intravenously*. It could be interpreted as further information.

3) the translator has transferred a LB even though it exists in lay Danish register as in:

> ST: XX is recommended for women who have had their menopause
> TT: XX anbefales til kvinder efter menopausen
> Explanation: In lay Danish, the term *menopause* is not used, but instead the term *overgangsalderen* [transition age].

4) the translator has introduced a LB term even though it is not in the source text and it does not exists in lay Danish register as in:

> ST: It works by making the blood clot at the site of bleeding
> TT: Det virker ved at få blodet til at koagulere på det sted
> Explanation: In the Danish translation, the expert term *koagulere* (coagulate) is used; the natural choice would have been the lay term *størkne*, which means *clot*.

Medical terms

In the analysis, I found that the two options for medical register included in the framework, i.e. 1) Latin-based expert medical register and 2) polysemic Danish word with specialized meaning in the PIL context were not exhaustive for the use of medical register in PILs. The translators also used a Danish medical term for an English lay term; a category which also needed to be included in the framework because the translator in these instances opt for a more complex word than in the source text, which is likely to hamper lay-friendliness. Examples include:

> ST: difficulties in passing urine
> TT: vandladningsbesvær [urination difficulty]
>
> ST: sweating
> TT: svedtendens [sweat tendency]
>
> ST: pregnancy
> TT: svangerskab [pregnancy, more specialised/old-fashioned]
>
> ST: drug rash
> TT: lægemiddelfremkaldt udslæt [medicament-caused rash]

Translation-specific choices - interference

Some translation choices could not be linked to the medical register or officialese, but could still be assumed to hamper comprehension. These choices were linked to the translation process and could be subsumed under the category of interference. Interference is "the importation into the target text of lexical, syntactic, cultural or structural items typical of a different semiotic system and unusual or non-existent in the target context, at least as original instances of communication in the target language" (Franco, 2009, p. 75). This category includes: 1) the use of English spelling, 2) un-Danish expressions and 3) accuracy. Examples of these three categories are:

1: English spelling

anorexi [anoreksi]

epinephrine [epinefrin]

lactoseintolerans [laktoseintolerans]

2: Un-Danish expressions

ST: vitamin D deficiency

TT: vitamin D mangel

Explanation: Normally, in Danish, vitamins are written with the letter first, e.g. *D-vitamin*.

ST: Blood abnormalities

TT: Unormaliteter af blodet

Explanation: The word *unormaliteter* is usually not used in Danish.

ST: Blood tests

TT: Blodundersøgelser

Explanation: The idiomatic Danish word would be *blodprøver*, not the word used here, which could be back-translated to *blood examinations.*

3: Accuracy

A few cases of inaccurate translation choices were found in the PILs, i.e. translation problems in relation to accuracy of content. One example is the English term *hives* (a skin disease in which a person's skin becomes red and sore), which has been translated using a similar-looking word in Danish, i.e. *hiven efter vejret*. This has a very different meaning as this means *gasping for breath*. It was interesting that the English word *hives* occurred three times in the ST, but was only translated inaccurately in this case, in the other two cases, the translator used the correct term *nældefeber* (see more on lexical cohesion problems below).

Another example of inaccurate translation is the translation of *somnolence* (a state of drowsiness; sleepiness), which has been translated using *søvnløshed*, which carries the opposite meaning, i.e. insomnia or sleeplessness. The category of accuracy not only includes lack of accuracy of content, but also accuracy of expression, which occurred more frequently than lack of accuracy of content. This category includes spelling mistakes and grammar mistakes. Examples are:

Spelling mistakes:

hjetesygdomme [hjertesygdomme]
vedrøende [vedrørende]
bib [bip]
maveirritatation [maveirritation]
de [De]
Straks [straks]
kontrollèr [kontrollér]
injecér [injicér]
pæventionsmidler [præventionsmidler]

Grammar mistakes:

lilla-farvet [lille-farvede]
tilstrækkelig [tilstrækkeligt]
vil ordinerer [vil ordinere]
en af de nævnte overfølsomhedsreaktionerne [overfølsomhedsreaktioner]
en følelse af at være sygdom [en følelse af at være syg]

One of the most frequently occurring grammar mistakes was compound nouns written in two words, conflicting with Danish spelling rules:

blodsukker niveauet [blodsukkerniveauet]
blodsukker kontrol [blodsukkerkontrol]

Figure 16 below shows the final framework against which the 54 PILs were analysed twice. In the following, the hypothesis is explored against the results.

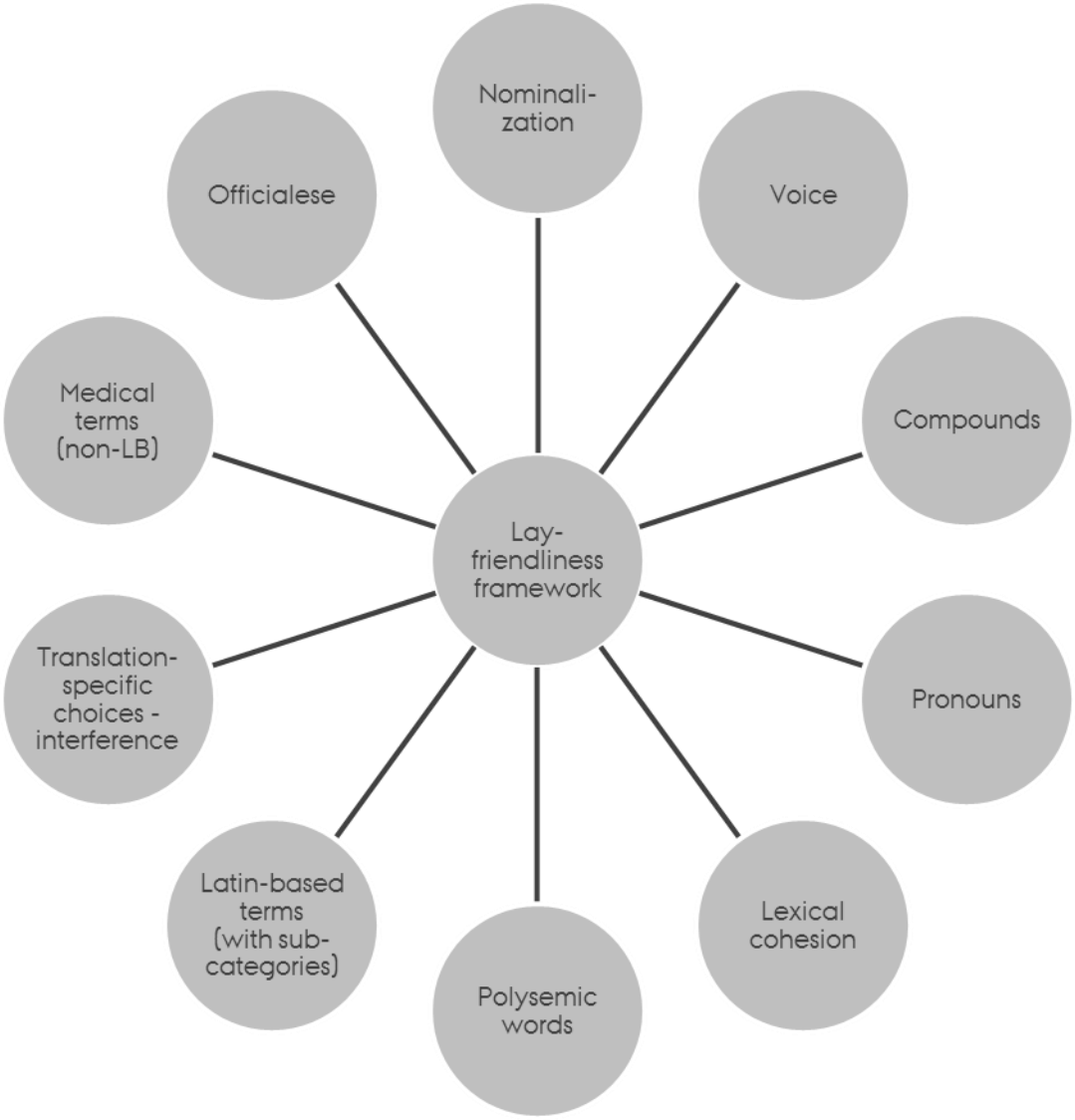

Figure 16: Revised analytic framework.

6.2.2. Comparing the pharmacist and professional translator corpora

The hypothesis elaborated as a conclusion of study 1 in Chapter 5 was:

> *Pharmacists – compared to professional translators – lack translation competence in relation to lay-friendly PIL translation*

To be able to answer and discuss the question whether there are differences in the translation products of the two different types of translators, the choices made in the two groups will be presented. For the categories with more than 100 occurrences overall, the categories were quantitized. The quantitative results will be presented and discussed first. For some of the categories, there was a limited number of translation choices found, which means that there

are not enough instances for statistical analysis. Therefore, these categories are discussed qualitatively.

Quantitative comparison

To be able to see potential tendencies and differences in the translation products, the qualitatively coded categories were quantitized (in line with the data conversion approach within mixed methods (Teddlie & Tashakkori, 2009, p. 146)). For the categories LB terms, nominalization, Danish medical term, compounds, officialese and accuracy, there were enough translation choices to see if there were statistically significant differences between the two translator corpora. Quantitizing is not seen as an end in itself, but "a means of making available techniques which add power and sensitivity to individual judgment when one attempts to detect and describe patterning in a set of observations" (Weinstein & Tamur, 1978). It is thus a way of showing the possible generality of specific observations.

The PILs in the corpus have differing word counts, with the pharmacist corpus consisting of more words than the professional translator corpus. Therefore, to even this out, for each PIL, the rate per 100 words for each linguistic feature was calculated based on target text word count[33]. Subsequently, the means were calculated for the overall pharmacist corpus and the overall professional translator corpus. Also, standard deviation (SD) was calculated for each corpus of translators[34]. The two groups were then compared using an independent samples t-test to test whether significant differences exist in relation to the use of each element from the analytic framework. A P-value of < 0.05 was deemed significant. A P-value represents the probability (ranging from zero to one) that the results observed in a study could have occurred by chance. It is conventional that a P-value of 0.05 or below is accepted as being statistically significant. Some argue that a P-value of 0.1 could be interpreted to be within the limits of significance in this type of study (PACTE, 2011, p. 51). In the following, the counts for each feature are described.

Latin-based terms

Table 12 below shows the differences between the two translator groups for the use of LB terms. The table shows that the two translator types do not differ significantly in relation to

[33] An example could be a lay-friendliness framework element such as the introduction of a nominalization, which might occur in a PIL 15 times. The PIL consists of 1407 words, which means that the element occurs 1.07 times per 100 words.

[34] Standard deviation shows how much variation or dispersion there is from the mean. A low standard deviation designates that the numbers tend to be very close to the mean and a high standard deviation means that the numbers are spread out over a large range of values (Wood, 2003, pp. 38-39).

avoiding LB terms in their translations, i.e. by using a Danish lay term instead, by adding a lay explanation to the LB term or by switching the order (putting the Danish first, LB term last) with a pharmacist mean of 0.76 and a translator mean of 0.70 (P = 0.615). However, the pharmacist corpus contains significantly more translation choices that involve using LB terms (mean: 1.87) than translators (mean: 1.26) (P = 0.030). For both lay-friendly and non-lay-friendly options, both groups of translators show large differences within the groups witnessed by the high standard deviations (lay-friendly: pharmacists: mean: 0.76, SD: 0.47; translators: mean: 0.70, SD: 0.41; non-lay-friendly: pharmacists: mean: 1.87, SD: 1.18; translators: mean: 1.26, SD: 0.78). For example, for the use of a *LB terms - non-lay-friendly option*, there is a range between two instances in one pharmacist PIL and 96 instances in another pharmacist PIL. Similarly, in the professional translator corpus, the range is from two to 90 instances.

Because the category *LB terms - non-lay-friendly option* showed a statistically significant difference between the two translator corpora, this category is further analysed below to investigate the procedures within this non-lay-friendly category further.

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
LB terms – lay-friendly option	0.76	0.47	0.70	0.41	0.615
LB terms – non-lay-friendly option	1.87	1.18	1.26	0.78	**0.030**[35]

Table 12: Differences between translators and pharmacists in their use of LB terms.

Table 13 below shows the statistical analysis for the four translation strategies that together make up the category *LB terms – non-lay-friendly option*. The table shows that the means are higher for pharmacists in relation to all non-lay-friendly categories, i.e. *LB term transferred without further Danish lay explanation* (mean 0.21 vs. 0.19), *LB term transferred even though a lay alternative exists in Danish register* (1.23 vs. 0.82) and *LB term introduced even though a lay alternative exists in lay Danish register* (0.05 vs. 0.02; it should be noted though that this is based on very few instances); however, there is no statistically significant difference between the two translator types[36]. For the category *LB term and lay word/explanation*

[35] Bold face indicates significant values.
[36] If a P-value of less than 0.1 is deemed significant, it can be seen that there is a tendency in the pharmacist corpus to introduce a *LB term even though a lay alternative exists in lay Danish register* (P-value = 0.062); however, as mentioned above, this category only has very few instances seen by the very low means of 0.05 (pharmacist corpus) and 0.02 (translator corpus).

transferred without any changes, the two translator corpora differ significantly (P = 0.036) with pharmacists opting for this strategy more often than translators.

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
LB term transferred without further Danish lay explanation	0.21	0.15	0.19	0.17	0.661
LB term and lay word/explanation transferred without any changes	0.38	0.31	0.22	0.19	**0.036**
LB term transferred even though a lay alternative exists in Danish register	1.23	1.10	0.82	0.66	0.104
LB term introduced even though a lay alternative exists in Danish register	0.05	0.07	0.02	0.04	0.062

Table 13: Use of LB terms that are likely to influence lay-friendliness negatively.

Nominalization

Table 14 shows the mean, standard deviation and P-values for the linguistic lay-friendliness feature *nominalization*, i.e. both when a nominalization was introduced and split up by the PIL translators.

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
Nominalization inserted	0.49	0.32	0.33	0.20	**0.041**
Nominalizations split up	0.13	0.13	0.11	0.10	0.570

Table 14: Use of nominalization.

The results show that pharmacists introduced significantly more nominalizations into their translations than the translators (P = 0.041). There was no significant difference between the two translator groups for *nominalization split up* (P = 0.570), though the mean was slightly higher for the pharmacists (0.13 vs. 0.11 for the professional translators). For both options, the two translator groups show large in-group differences (nominalization inserted: pharmacist: mean: 0.49, SD: 0.32; translators: mean: 0.33, SD: 0.20. Nominalization split up: pharmacists: mean: 0.13, SD: 0.13; translators: mean: 0.11, SD: 0.10).

More specialized Danish medical term than English source text item

Table 15 shows that for the category *more specialized Danish medical term than English source text item*, the pharmacist and professional translator means are very similar (pharmacist: mean: 0.15; translators: mean: 0.16), and no significant difference is thus seen (P-value = 0.840).

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
More specialized Danish medical term than English source text item	0.15	0.12	0.16	0.21	0.840

Table 15: The introduction of a Danish medical term as the translation of a lay item in the English source text.

Compounds

Table 16 below shows that numbers for the three sub-categories within the superordinate category *compounds.* For the categories *compound inserted* (pharmacists: 0.33; translators: 0.27; P-value = 0.290) and *compound transferred, leads to long word in Danish* (pharmacists: 0.13; translators: 0.22; P-value = 0.217) there are no significant differences between the two corpora. For the category *compound split up*, there is no statistically significant difference if a P-value of less than 0.05 is deemed significant (pharmacists: 0.14; translators: 0.22; P-value = 0.091); however, if a P-value of less than 0.1 is deemed significant, it can be seen that there is a tendency in the translator corpus to split up compounds, which are present in the source text, in the target text more often than in the pharmacist corpus.

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
Compound inserted	0.33	0.26	0.27	0.20	0.290
Compound transferred, leads to long word in Danish	0.13	0.16	0.22	0.24	0.217
Compound split up	0.14	0.15	0.22	0.18	**0.091**

Table 16: Use of compounds.

Officialese

Table 17 shows that for the two categories involving officialese expressions, there are no significant differences between the pharmacist and professional translator corpora. For the category *officialese expression inserted*, the professional translator corpus mean is actually slighter higher (pharmacist: mean: 0.87; translators: mean: 1.04), but the P-value shows no statistically significant difference (P-value = 0.236).

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
Officialese expression inserted	0.87	0.55	1.04	0.49	0.236
Officialese expression deleted	0.10	0.10	0.09	0.11	0.600

Table 17: Use of officialese expressions.

Accuracy problems

For the category *accuracy*, no statistically significant differences are found between the two corpora as seen in Table 18 below. The mean for professional translators is slightly higher (0.18) than for pharmacist (0.12); however, this category only has very few instances seen by the low means.

	Pharmacists		**Professional translators**		
	Mean	SD	Mean	SD	P-value
Accuracy problems	0.12	0.16	0.18	0.24	0.229

Table 18: Problems of accuracy in target texts.

In the following, the quantitative results are discussed before the categories which did not have enough instances to be quantitized are presented.

Discussion of quantitative results

Significant results

For two lay-friendliness elements, statistically significant differences were found between the pharmacist corpus and the translator corpus, i.e. the use of Latin-based terms and the use of nominalization. These two results will be discussed below[37].

The results showed that pharmacists generally used more LB terms in their translations than the professional translator corpus. They have transferred more LB terms without explanation and they have transferred or introduced more LB terms even when a Danish lay register term exists. The pharmacist corpus used the translation strategy *LB term and lay word/explanation transferred without any changes* significantly more than the translators. Some of the choices made within this category involve LB terms which might be useful for the PIL receiver to learn. It can, for instance, be useful for diabetics to learn the LB term for low blood sugar (EN: hypoglycemia, DK: hypoglykæmi) or that *diabetes* in Danish is called *sukkersyge* [sugar disease] as well as *diabetes* as these terms might be used by their doctor and in other oral and written patient information. Another useful situation in which to use a LB term is for example cases where the medication cannot be used by people with specific illnesses: e.g. one PIL instructs patients to be extra careful when taking this medication "if your doctor has told you that the thickness of your heart muscle is abnormally increased (called *obstructive hypertrophic cardiomyopathy*). Even though it has been explained what *obstructive hypertrophic cardiomyopathy* is (the thickness of the heart muscle is abnormally increased), it could be argued that it is still necessary to include the LB term in the translation as people are likely to know and/or recognize a term if it is personally relevant for them (Dahm, 2009, p. 26).

However, using a LB term when the Danish term or explanation is there cannot always be justified in this way. In other words, the LB terms may not be beneficial in educating patients about their illness. Sometimes, the LB terms may instead unnecessarily complicate the text for the Danish lay receiver, who is not familiar with LB terms. Examples from the analysis include:

ST: fast heart beat (tachycardia)
TT: hjertebanken (takykardi)

ST: Increased eating (binge eating, hyperphagia)
TT: Overspisning (uhæmmet fødeindtagelse, hyperfagi)

[37] Parts of this discussion is published in Nisbeth Jensen & Zethsen (2012)

Here, the translators have decided to keep the LB term, but these terms do not add to the receiver's understanding as they are not related to an illness the receiver might have, but are merely the expert term for the lay explanation before the parentheses. Furthermore, translating using both a LB term and a lay explanation does not necessarily help the patients if they do not understand the LB term, because the explanation can be interpreted as extra information and not necessarily as an explanation of the expert LB term. Finally, it may be argued that the segment of patients from the target group who find it difficult to process written information in the first place may be scared off by too large a number of unrecognizable words, even when these are explained, and ultimately this may have a negative impact on the likelihood of them reading the PIL at all.

The findings also showed that the pharmacists are not only affected by their pharmaceutical subject matter expertise, but by introducing more nominalizations than the professional translators, they also seem to be less aware of what makes a text syntactically complex and of the possible deagentivizing effect of nominalization (Halliday, 1994). Especially in cases where the patient is expected to act it may be very confusing that the agent – the patient – is not directly mentioned (Clerehan et al., 2009). In expert language, nominalizations are often used for reasons of precision and condensation and are perceived as positive (Halliday, 1994). Therefore, they may be used more extensively by pharmacists as a result of the pharmacists being more accustomed to the use of nominalizations through their extensive experience in reading expert language and communicating with other experts. A further factor may be their lack of linguistic knowledge about how to adjust the level of formality and accessibility of a text (Askehave & Zethsen, 2002).

Non-significant tendencies

For the category *compound split up*, a tendency was found in the translator corpus to split compounds which were present in the source text more often in the target text than in the pharmacist corpus. This could show that the professional translators are aware that for example *koncentrationen i blodet* [the concentration in the blood] is more lay-friendly than the compound *blodkoncentrationen* [the blood concentration] or the compound *Peripheral blood stem cell mobilisation* is better to translate as *Mobilisering af perifere blodstamceller*[38] [mobilization of peripheral blood stem cells] than the literal translation *perifer blodstamcellemobilisering.*

The category of introduction of officialese expressions was slightly higher in the

[38] There are of course other lay-friendliness problems with the use of *perifere* (LB term) and *mobilisering* (polysemic word)

professional translator corpus than in the pharmacist corpus. The use of such officialese expressions could be explained by the academic background of at least state-authorised translators in Denmark, who might be accustomed to using these expressions.

For the other categories, *more specialized Danish medical term than English source text item* and *accuracy*, no statistically significant differences were found between the two corpora.

So there are statistically significant and non-significant differences found between the two sub-corpora in relation to the results that could be quantitized. The results also showed a large variability across the PILs as witnessed by the standard deviations. For the categories without enough instances for quantitative analysis, a comparison is not possible as such. However, these categories contain many choices relevant for lay-friendliness in PILs in general, and the results show that both sub-corpora make many lay-friendly and non-lay-friendly choices. Therefore, the results of these categories will be briefly presented and discussed below.

Qualitative results

Generally, the qualitative results showed lay-friendliness problems in both corpora; examples of the different categories in both corpora are given below.

Medical register

For the three categories subsumed under lay-friendliness, the first, *LB terms* and the third category, *more specialized Danish medical term than English source text item* had enough instances for quantitative analysis. The second category, *polysemic words* (here common words with specialized meaning) will be discussed below. In some instances, the pharmacists use the Danish term *indgive*, which is specialized in this context, for source text elements such as *administer* and especially *give*.

ST: administered
TT: indgives

ST: given
TT: indgives

The same use of *indgive* is found in the professional translator corpus:

ST: delivery of the injection
TT: indgift af injektionen

ST: administer
TT: indgives

ST: Method of administration
TT: Indgivelsesmåde

The problem of using *indgive* is that it is usually used in a context where it means *lodge* or *submit* (for example an application or report).

Furthermore, a pharmacist uses the Danish term *indlagt* twice, which usually has connotations to admission to hospital, but in this context is related to placing a catheter:

ST: inserted (catheter)
TT: indlagt

Once, the term *administrere* is used by a pharmacist:

ST: administering treatment
TT: administrere behandling

Administrere in this context is problematic because it commonly refers to perform work by taking care of financial matters, manage staff and allocate tasks on the basis of rules and regulations.

The term *spontan* is often used in lay Danish with reference to someone who is impulsive and or something which is unplanned. Therefore, the use of the term *spontan* in the PILs can be a cause of confusion, such as in the following examples:

ST: spontaneous bleeding
TT: spontane blødninger

ST: These symptoms may be seen at the beginning of treatment, but they disappear spontaneously
TT: Disse symptomer kan forekomme i begyndelsen af behandlingen, men de forsvinder spontant

Both the pharmacist and professional translator corpus use *spontaneous* (three times each). In one case, a pharmacist has decided to make a more lay-friendly option for the English term *spontaneous* by using the Danish term *pludselig* [sudden]:

ST: spontaneous bleeding
TT: pludselige blødninger

A last example is the use of the word *local* which occurs in both corpora. *Lokal* in Danish is normally used in a context of something being within geographical proximity. In a Danish study, Thorsen et al. (2012) asked 404 participants from adult learning centres about their understanding of several commonly used medical terms. One of them was *lokal* in the following sentence “Man vil undersøge lokale sygdomsmekanismer i hjertet” [we will examine local disease mechanisms in the heart]. 49.6% said that they do not understand that meaning of *local* in this sentence, and 18.8% of the participants who said that they understand

it gave a wrong explanation of the meaning of the term. Only 29.1% gave a correct explanation[39].

There are not enough instances of the use of the category of *polysemic words* to make any generalizations about their use by the pharmacist and professional translators, respectively. However, this category was found in the translations of both groups, and in the light of the results of Thorsen et al (2012), the use of such terms are detrimental to the skopos of lay-friendliness in PIL and should thus be completely avoided.

Voice

For the use of voice, the translation choices mainly followed the structure of the English source text. However, choices were found relating to three strategies: 1) making the text more lay-friendly by changing passive into active, 2) making the text less lay-friendly by changing active into passive, and 3) changing imperative into passive thus making the text less lay-friendly. The first table, Table 19, shows lay-friendly strategies being used in both corpora, i.e. where the PIL translators have changed a passive voice construction in the source text to an active voice construction in the target text.

Pharmacists – passive voice in source text into active voice in target text		
ST	TT	Explanation
Use the injection technique advised by your doctor or diabetes nurse	Anvend den injektionsteknik din læge eller diabetessygeplejerske har anbefalet	Use the injection technique your doctor or diabetes nurse has recommended
A starting dose is set by your doctor	Deres læge fastsætter en startdosis	Your doctor sets a start dose
If a GnRH agonist has been given	Hvis De har fået en GnRH-agonist	If you have been given a GnRH agonist
Professional translators – passive voice in source text into active voice in target text		
ST	TT	Explanation
Effective contraceptive precautions must be taken by both male and female patients	Både mandlige og kvindelige patienter skal anvende sikre pæventionsmidler [sic]	Both male and female patients must use contraception
The dose prescribed by your doctor	Den dosis din læge har udskrevet	The dose your doctor has prescribed
If you have been told by your doctor	Hvis Deres læge har fortalt Dem	If your doctor has told you

Table 19: Passive voice in source text changed into active voice in target text.

In these cases, the PIL translators have not kept with the source text, but have used their expertise and changed something, thus making the target text more lay-friendly. The second

[39] The numbers do not add up to 100%, because 2.6% left the question blank.

table, Table 20, shows the opposite strategy: the PIL translators have changed a lay-friendly active voice construction to a non-lay-friendly passive voice construction.

Pharmacists – active voice in source text into passive voice in target text		
ST	TT	Explanation
Your insulin will work more quickly if you inject it around the waist	Du vil få en hurtigere virkning, hvis insulinet injiceres i maveskindet	You will get a faster effect if the insulin is injected into the skin on the stomach
They [relatives, friends and close colleagues] must turn you on your side	Skal du vendes om på siden	You must be turned on your side
You can carry them with you…	Kan medbringes…	Can be brought…
Professional translators – active voice in source text passive into voice in target text		
ST	TT	Explanation
You should take XX tablets with meals	XX-tabletter bør indtages i forbindelse med måltider	XX tablets should be consumed with food
Before you begin treatment	Før behandlingen påbegyndes	Before the treatment is commenced
You may require blood tests	Det kan være nødvendigt at få taget blodprøver	It may be necessary to have blood tests taken

Table 20: Active voice in source text changed into passive voice in the target text.

In these cases, the PIL translators have not kept with the source text, but have changed something making the target text less lay-friendly. Finally, Table 21 below shows instances where the PIL translators have changed imperative constructions to passive voice.

Pharmacist – imperative in source text into passive voice in target text		
ST	TT	Explanation
Only use it if the solution is clear	Det må kun anvendes, hvis opløsningen er klar	It must only be used if the solution is clear
Swallow the tablets	Tabletterne skal synkes	The tables must be swallowed
Professional translator – imperative in source text into passive voice in target text		
ST	TT	Explanation
Call the doctor	Bør lægen kontaktes	The doctor should be contacted
Please discuss the matter with…	Bør det diskuteres med...	It should be discussed with

Table 21: Imperative in source text changed into passive voice in target text.

The problem with the translation choices using passive voice is that they potentially make it unclear who the agent of the action is (Askehave & Zethsen, 2000b, p. 21).

There are not enough instances of the use of voice to make any generalizations about their use by the pharmacists and professional translators, respectively. The conclusion is

that in both corpora, instances of the less lay-friendly choices of *active into passive voice* and *imperative into passive voice* and the more lay-friendly choice of *passive into active voice* are found.

Lexical cohesion

Several problems with lexical cohesion were found in the Danish translations, especially in relation to the use of synonyms. The problem is that the lack of lexical consistency could cause the reader to think that they are dealing with two different things. Even though the two terms are synonyms, this may not be clear for the lay receiver.

Pharmacists

The following problems with cohesion were found in the pharmacist corpus:

The use of synonyms

Mix of use of Danish lay and expert term for *injection* in five PILs:

- the term *injektion* (the expert term in Danish) is used 14 times, and then suddenly, towards the end of the PIL, in the section on side-effects, the Danish lay term *indsprøjtning* is used, which may lead to confusion for the receiver.
- the lay term *indsprøjtning* is used nine times, and the expert term *injektion* is used 11 times.
- the lay term *indsprøjtning* or the equivalent verb *indsprøjte* is used 24 times and the expert terms *injektion* and *injicere* are used 10 times.
- The lay term *indsprøjtning* is used in 15 instances and the expert term *injektion* is used 11 times.
- The expert terms *injektion* (noun) and *injicer* (verb) are used 32 times, but once, the term *indsprøjtning* is used.

Mix of use of Danish lay and expert term for *ovary*:

the use of the lay and expert terms for *ovary*, i.e. *æggestok* and *ovarie* are mixed, with the lay term used 16 times and the expert term used seven times.

Mix of use of Danish lay and expert term for *kidney disease*:

the English term *kidney disease* is translated three times using the Danish lay term *nyresygdom* [kidney disease], but once, the translator has opted for *nyreinsufficiens* [kidney insufficiency], which belongs to the medical register.

Mix of use of Danish lay and expert term for *haemoglobin level*:

> in the first half of a PIL, the term *haemoglobin level* is translated using *hæmoglobinniveau* [haemoglobin level], but in the next half of the PIL, the term *blodprocenten* [blood percentage] is used.

Mix of use of Danish lay and expert term for *calcium*:

> the term *calcium* is translated 4 times using the Danish lay term *kalk*, but once, the translator has transferred the term directly using *calcium*, which is the more specialized term.

Lack of repetition of lexical items in Danish translation

Another example of a lexical cohesion problem is in the following pharmacist example:

> ST: XX belongs to a group of medicines called *antiplatelet medicinal products*. *Platelets* are very small structures in the blood which clump together during blood clotting. By preventing this clumping, *antiplatelet medicinal products* reduce the chances of blood clots forming (a process called thrombosis).
>
> TT: XX tilhører en gruppe medicin, der kaldes *blodforyndende* [sic] medicin. *Blodplader* er meget små bestanddele i blodet, mindre end de røde og hvide blodlegemer, og de klumper sig sammen, når blodet størkner. Ved at forhindre denne sammenklumpning nedsætter et *blodpropopløsende præparat* risikoen for, at der dannes blodpropper (en proces, der kaldes trombose).

In the English text, the first sentence ends with *antiplatelet medicinal products*, and the word *platelet* is then taken up in the next sentence. However, in the Danish translation, *blodforyndende* [sic] *medicin* and the next word *blodplader* do not carry a cohesive element. In the third sentence in the English source text *antiplatelet medicinal products* are referred to again, but in the Danish target text, a new word is used *blodpropopløsende præparat*. Thus, for the Danish reader, the cohesive elements of this section are left out, which is likely to lead to comprehension problems.

Punctuation

The use of punctuation in the PILs hampers cohesion as in the example below:

> ST: Make sure there is no air left in the syringe: point the needle upwards and push the air out
>
> TT: Kontrollér, at der ikke er luft i sprøjten. Vend nålen opad, og pres luften ud.

In the source text, it is clear from the colon that the next part of the sentence is the way to ensure that there is no air in the syringe. In the Danish target text, the colon has been replaced by a full stop; it is thus no longer clear that the next sentence is the information on how to ensure that there is no air left in the syringe.

Professional translators

The following problems with cohesion were found in the professional translator corpus.

The use of synonyms

Mix of use of Danish lay and expert term for *injection* in two PILs:

- the terms *injektion* and *injicere* are used 19 times, but the Danish lay terms *indsprøjtning* and *indsprøjte* are used 26 times.
- *injektion* is used 12 times and *indsprøjtning* 4 times.

Mix of use of Danish lay and expert term for *anaemia*:

> the English term *anaemia* is translated using the expert term *anæmi* except for once, where the Danish lay term *blodmangel* [lack of blood] is used.

Two different source text words translated using same word in target text:

> In a PIL, two different source text words, i.e. *bottle* and *glass of water* are both translated using the same word in the target text, i.e. *glas* [glass, both in the sense of the material and a glass of e.g. water].

Lack of repetition of lexical items in Danish translation

In a professional translator PIL, one of the first sentences is "XX is an amino acid which…". The translator chose – maybe to make the PIL less complex – to translate *amino acid* using the more generic word *substance:* "XX er et stof [substance], der…". This creates cohesion problems, because later in the PIL, there is a reference to amino acids.

An identical example to the one found in a pharmacist PIL presented above is also found in a professional translator PIL concerning *platelets* (see page 143). This example is identical to one found in a pharmacist PIL, which gives evidence of a form of intertextuality or borrowing from other PILs.

Both pharmacists and translators

Another lexical cohesion problem found in several PILs is the use of synonyms for lexical items related to medicine. In both pharmacist and professional translator PILs, the translators use *medicin* [medicine], *lægemiddel* [medicinal product] and *præparat* [compound/agent] for the translation of the English *medicines*.

The results show that there are several lexical cohesion problems in the PILs, and they are found both in the professional translator corpus and the pharmacist corpus. It is interesting to see that lexical cohesion problems are especially linked to the mixed use of lay terms and expert terms, which shows a willingness and acceptance of using lay terms, even though they are unfortunately not used consistently. Furthermore, the cohesion problems could be seen as the failure on the part of the translators to produce terminologically consistent translations; however, it could also be a result of the process of PIL translation where updates to small sections of the PIL are needed, maybe without the entire PIL being updated (more on this below). One example also showed that there is some intertextuality between PILs; most likely a result of translators borrowing items and sentences from other PILs, which, unfortunately, can lead to cohesion problems if these are uncritically borrowed.

Pronouns

In both corpora, personal pronouns are deleted in the Danish translations, but this is mainly done where this is a result of Danish language conventions. An example is the English ST:

> Your doctor will check your blood pressure before and during your XX treatment. If your blood pressure is high and cannot be controlled either by appropriate medicines or a special diet, your doctor will interrupt your XX treatment or reduce the dose.

The source text has six personal pronouns whereas the Danish translation below only has maintained the personal pronoun once and in all other cases, the personal pronoun is replaced by a construction using the definite article (e.g. *blodtrykket* [the blood pressure] and *behandlingen* [the treatment]:

> TT: Din læge vil kontrollere blodtrykket før og under behandlingen med XX. Hvis blodtrykket er for højt og ikke kan kontrolleres med passende medicin eller diæt, vil lægen stoppe behandlingen med XX eller sætte dosis ned.

Translation-specific choices - interference

Only the sub-category of accuracy under this category had enough instances for quantitative analysis. The other two sub-categories under translation-specific choices are treated here, i.e. the use of English spelling and un-Danish expressions.

The use of English spelling

Pharmacists**:**

The use of ‘c’ instead of ‘k’:

Cholestasi [kolestase]: 1

Cortison: [kortison]: 2

Glucagon [glukagon]: 20

Chromoblastomycosis [chromoblastomykose]: 1

Lactose [laktose]: 7

English ending ‘-is’, ‘ia’, ‘-xi’:

Aspergillosis [aspergillose]: 1

Thalassaemia [thalassæmi]: 3

Anorexi [anoreksi]:

Chromoblastomycosis [chromoblastomykose]: 1

Cholestasi [kolestase]: 1

The use of ‘ph’ instead of ‘f’:

Epinephrine [epinefrin]: 2

Professional translators:

The use of ‘ph’ instead of ‘f’:

Phosphate [fosfat]: 4

Phosphor [fosfor]: 1

Nephropatisk [nefropatisk]: 1

Lipoatrophy [lipoatrofi]: 1

English ending ‘-is’, ‘ia’:

Cystinosis [cystinose]: 2

Homocysteinuria [homocysteinuri]: 4

The use of ‘c’ instead of ‘k’:

Lactose [laktose]: 8

The use of ‘ch’ instead of ‘k’:

Bronchitis [bronkitis]: 1

The use of ‘th’ instead ‘t’:

Thrombotisk [trombotisk]: 1

The use of English spelling seems to be somewhat widespread in both corpora. The problem in relation to the PIL skopos of lay-friendliness is that such words will look foreign to the PIL receiver.

Un-Danish expressions

In both corpora, the use of un-Danish expressions is found. In Table 22 below, examples of such expressions are given.

Pharmacists – un-Danish expressions		
ST	TT	Explanation
If you experience…weight loss	Hvis du…taber i vægt	The expression “lose in weight” is not idiomatic in Danish
Suddenly stopping XX	Pludselig stop med brug af XX	The expression “sudden stop with use of XX” is not idiomatic in Danish
Your doctor may need to…take other precautions	Det kan være nødvendigt for din læge at foretage andre forsigtighedsregler	The verb used here “foretage” does not collocate with the noun “forsigtighedsregler”
Professional translators – un-Danish expressions		
ST	TT	Explanation
Has led to a loss of effect	Har medført et tab af virkning	The expression “tab af virkning” is not idiomatic in Danish
And leads…to reduced levels of consciousness and to coma	og…medfører nedsatte niveauer af bevidsthed og koma	The expression “medfører nedsatte niveauer af bevidsthed og koma” is not idiomatic in Danish
In the long term, the daily dose usually ranges	Længerevarende strækker den daglige dosis sig sædvanligvis fra	The expression “ Længerevarende strækker” is not idiomatic in Danish

Table 22: Use of un-Danish expressions in both translator corpora.

Summing up qualitative results

For the qualitative results, comparison of the two sub-corpora was not possible. The purpose of this review of the qualitative results was to show that lay-friendly options are found in both corpora, but also many non-lay-friendly translation choices were found in both corpora meaning that the skopos of lay-friendliness has generally not be achieved in either corpora. Furthermore, these results show that there might be problems of translation competence in both corpora. Below, all the results of this study are discussed further.

6.3. General discussion of study 2

Here, the overall results of study 2 are discussed. First, the results are discussed against Translation Studies literature to gain an understanding of the choices made by the translators. Second, the limitations of the study are discussed. Third, the conclusions of this study are presented.

6.3.1. Literal translation choices

Literal translation means to translate word by word[40]. We saw in the results that both groups of PIL translators make many literal translation choices. Some examples are:

1. they transfer many LB terms directly:
    a. *lactose* instead of *mælkesukker* [milk sugar]
    b. *inflammation* instead of *betændelse* [infection]
    c. *anæmi* instead of *blodmangel* [lack of blood]
2. they use English spelling:
    a. English endings *-is*, *ia* and *-xi*
    b. *ph* instead of *f*
    c. *c* instead of *k*
3. there is interference from the source text in the form of un-Danish expressions:
    a. *Weight loss* translated to *taber i vægt*
    b. *Loss of effect* is unidiomatically translated to *tab af virkning*

Below, possible explanations for the many literal translation strategies are discussed.

Literal translation as a result of lack of translation competence

The direct transfer of source texts items could be linked to the lack of translation skills and training. Previous studies have found that novice translators seem to operate on the basis of encoding and decoding processes/literal translation (Jääskeläinen, 1989, p. 94; Tirkkonen-Condit, 1990, p. 393). Gile also argues that non-professional translators are afraid to move away from the meaning, and have a tendency to translate word-for-word, and only professional translators have the competence to write a comprehensible text which is loyal to the source text without being contaminated by the source text (Gile, 1986, p. 28). We saw in Chapter 5, in the PACTE competence model, that bilingual sub-competence involves amongst other things interference control (i.e. avoiding interferences between the two languages used)

[40] Literal translation is also referred to as formal correspondence (Ivir, 1981), direct translation (Vinay & Darbelnet, 2004, p. 128), formal equivalence (Nida, 2004, p. 156) etc.

and knowledge of language registers. Therefore, the literal translation choices could be linked to a lack of bilingual sub-competence possessed by some of the PIL translators. The lack of interference control leads to unidiomatic Danish expressions and the literal transfer of English spelling. The lack of knowledge of different language registers leads to non-lay-friendly LB terms being transferred directly.

The many literal translation strategies can be linked to the lack of translation competence. However, there are other possible explanations for the many literal translation strategies found in the PILs; these will be discussed below.

Literal translation as a result of time constraints

We saw in Chapter 2 that the pharmaceutical companies only have five days to provide EMA with the translation after the medicinal product has been approved. This could be an explanation for the many literal translation choices found in the PILs. Franco argues that the *economy of effort* plays an important role when trying to explain interference in translation (Franco, 2009, p. 80). Because translators usually have very tight deadlines, and because they often work for a modest salary, there is a tendency only to deviate from the source text when it is really necessary, because "conservative translation is the fastest and most economical way of working" (Franco, 2009, p. 80). This also means that, in general, it is easier for the translator to import ready-made words instead of creating new ones (Franco, 2009, p. 80). This can be related to what Tirkkonen-Condit calls the *literal translation automaton hypothesis* (2005). She argues that there is a tendency for both novices and experts to translate word by word, and this is evident in both translation processes and products (Tirkkonen-Condit, 2005, pp. 407-408). Her findings show that literal translation is a default mechanism, which is used until it is interrupted, e.g. when a problem occurs and conscious decision-making is triggered (Tirkkonen-Condit, 2005, p. 408). The same observations have been made by Ivir, who says that the translator starts out by searching for formal correspondents with identical meaning, and only when these are not available, the translator uses formal correspondents with meanings that are not quite identical (Ivir, 1981, p. 58). Therefore, it is suspected that literal translation is the default procedure used as long as there is formal equivalence. We have seen that equivalence is not the ultimate goal in PIL translation. Furthermore, for LB terms, even words that seem equivalent such as *inject*/*injekt* or *oral/oral* or *thyroid hormones/thyreoideahormoner* are not really equivalent because they belong to different registers in English and Danish.

Another explanation could be the influence of the source text: "When the source text is one whose vocabulary includes many cognates of words in their native language […]

translators may use words in meanings they do not have" (Mossop, 2001, p. 26) Translators can thus be influenced by the source text, which could be especially relevant under time constraints.

Literal translation as the ideal way of translating

Some translation scholars argue that literal translation is the default choice in translation in general, and also that it is the ideal way to translate (Newmark, 1989, pp. 118-119; Vinay & Darbelnet, 2004, p. 128). This means that target text-oriented translation strategies on micro level will only be used if the translator is not satisfied with a source text-oriented strategy. Source text-orientation as default is not only supported by some scholars; some translators also seem to think that the translator should translate close to the source text. This is shown by this quote by Wagner: "Translators, too, need to understand why they should translate differently for different purposes. Surprisingly many translators will argue that a translator's duty is to translate accurately…" (Chesterman & Wagner, 2002, p. 44). Some of the PIL translators, potentially both the pharmacists and the professional translators, might have a similar approach to translation. They might see literal translation as the best approach to translation. We have already seen in Chapter 3 (section *3.8. Conclusion - Two diverging approaches to translation*) that there seem to be a difference in the approach to translation between EMA and Translation Studies. The many literal translation choices could therefore be linked to the PIL translators having a non-functionalist approach.

Competing skopoi

Nord argues that a translation error is "a failure to carry out any one of the translating instructions" (Nord, 1991, p. 170); however, this is very difficult to assess if the instructions are not explicit. From the EU legislation, it is clear that the skopos of PILs is linked to lay-friendliness, but from the analysis, it becomes apparent that many translation choices are in breach of this skopos. An explanation for some of the literal translation choices could be the idea of the competing skopoi suggested by Askehave & Zethsen, linked to the fact that:

> the package insert should be approved as smoothly and fast as possible. In the medical industry, development of new products takes many years. The approval procedure is the last step before the product can be marketed and start making a profit. The need quickly to obtain marketing approval means that the approving authority becomes the immediate recipient of the translation. There is no doubt that the two skopoi are in conflict. (Askehave & Zethsen, 2002, p. 24)

Gal & Prigat in their PIL study also found conflicting goals to be problematic for PIL producers who have to balance "requests or pressures of decision makers, experts or partners to add or modify materials" and the production of a lay-friendly PIL which is "comprehensive, current, and satisfactory to initiators, content experts and various internal or external stakeholders" (Gal & Prigat, 2005, p. 489).

Furthermore, in Chapter 2, we saw that when the pharmaceutical company has produced the translations, the national medicines agencies, in Denmark, the DHMA, have 14 days to check the translations and report back to EMA and the pharmaceutical company using QRD Form 1. Clearly, the main focus of these categories is on technical correctness and accuracy and not on lay-friendliness. This could be another reason why the translators stay close to the source text. It might therefore be difficult for the PIL translator to assess his/her loyalty as s/he is being dragged in different directions, in one direction by the sender (and potentially the legislation) (fast and smooth authorisation) and another by the target text receiver (lay-friendly language).

Above, literal translation strategies have been discussed; however, the results showed that the PIL translators have used some strategies that did not literally transfer source text elements, but actual changes which lead to an increased complexity in the target text. Examples include the introduction of LB terms, medical terms, nominalizations, compounds and officialese. Below, possible explanations for this are discussed.

Institutional linguistic usage

Kjærgaard investigated why it is so difficult to actually get people to write in Plain Language, and she proposes that it can be linked to institutional constraints of different kinds (Kjærgaard, 2010). Similarly, Becker Jensen argues that often the lack of Plain Language is seen primarily as a communications problem, which then logically will be solved using linguistic techniques, e.g. short sentences, avoiding technical terminology and writing in concrete terms, using active voice and personal references (Becker Jensen, 2007a, p. 12). However, such an approach can be lacking; for example, it is not fruitful to demand Plain Language if the person in charge values complex officialese, and argues that it should not be changed (Becker Jensen, 2007a, p. 13). Becker Jensen argues that it is difficult for a communication employee to get permission to change the texts of subject matter experts because the linguistic and communicative competences have a lower rank than the other expert competences such as the lawyer or the economist in the institutional system (Becker Jensen, 2007a). The following quote sums this view up well: "We all know the Danish language!, but not everyone knows about law and economy" (Becker Jensen, 2007a, p. 19;

my translation). Similar constraints might be at play in PIL translation. Similarly, Gal & Prigat concluded that the production of PILs is complicated by experts who insist on including additional complex textual elements or technical details to improve medical accuracy (Gal & Prigat, 2005, p. 489).

Curse of expertise

For LB terms and nominalisation, the results show that pharmacists seem to have a different view on the perceived expertise of the PIL receiver, supporting Bromme et al. who state that "[t]here is a good deal of evidence that experts have difficulty in adapting their advice to the information needs of laypersons. One can assume that experts' extensive and highly integrated knowledge of their own domain makes it very difficult for them to comprehend the completely different perspective of a layperson" (Bromme et al., 2005, p. 571). Research from other disciplines such as communication and psychology shows that experts are often unaware of what poses problems for lay people, and therefore, might overestimate the knowledge of their receivers (e.g. de Jong & Lentz, 2007; Hayes & Bajzek, 2008; Hinds, 1999; Lentz & de Jong, 2009; Nickerson, 1999). Pharmacists may thus be influenced by their own expertise, and thus may struggle to distinguish between their own knowledge and that of the receiver; they might be affected by *the curse of expertise* (Hinds, 1999, p. 205). Even though it could logically be assumed that experts are better at judging novice performance, because they used to be novices themselves, and they have extensive knowledge to draw on, research on cognitive heuristics suggests that experts might actually have problems assessing novice performance (Hinds, 1999, p. 205). The study by Hinds is different from this study as her study was based on experts predicting how long time it would take novices to perform a real, physical task i.e. using a telephone and building LEGO; however, the study can still be compared to the ability of experts to assess reader problems as was done by Lentz & de Jong, who studied communication experts' prediction of reader problems (Lentz & de Jong, 2009). They found that communication experts have problems predicting reader problems when producing texts (Lentz & de Jong, 2009, p. 119), and they would therefore have difficulties evaluating their own process. The translators, on the other hand, who are not experts in pharmaceuticals, seem to have a better ability to assess the expertise of the lay person PIL receiver, maybe because they themselves belong to this receiver group, or at least are no more than semi-experts.

However, for example for the use of officialese, it was seen that the professional translator corpus introduced more of these expressions. The translators who are state-authorised translators have an academic background, and might thus be influenced by this.

6.3.2. Limitations of study

This study, as any study, has some limitations. These will be presented below.

Lay-friendliness is standardized

The analysis of the construct of lay-friendliness is a standardized measure which cannot say anything about how individual readers interact with the text where factors such as decoding ability and text topic familiarity become important for understanding (Zakaluk & Samuels, 1988, p. 128). Understanding would be linked to individual factors such as prior knowledge, educational level, the level of relevance of the material etc.

Such an uncertainty is admitted in functionalism: "…it becomes unlikely that one can safely base one's assessment on the (supposed) reaction of 'the reader' who may or may not apply and idiosyncratic mixture of these criteria. It is argued, therefore, that even if assessment is based on functionalist principles, a speculative element will remain and has to be admitted" (Hönig, 1998b, p. 14).

Lay-friendliness items are not created equal

The desire to quantitize something as qualitative as language naturally has some potential limitations. The categories of the lay-friendliness framework are broad categories encompassing linguistic elements at various points of the lay-friendliness continuum. For example, the use of nominalisation is not one thing, some nominalisations are potentially more difficult to understand than others. For example, the nominalisation *behandling* [treatment] might not be as difficult as *indtagelse* [consumption] or febersænkning [fever reduction]; however, the main point is that when translating for the lowest common denominator, there are no good arguments for *inserting* such constructions when the source text uses an infinitive construction.

Similarly, the use of LB terms has extensive variation within. One can argue that the term *cancer* is now so widespread and is well-understood to a similar extent as the lay term *kræft*. The same might be said for *diabetes* versus *sukkersyge* [sugar disease]*;* however, when a term like diabetes is changed to *diabetika*, the lay person is not likely to understand it. In the PIL corpus, it was also found combined with another LB term, i.e. *anti* as *antidiabetika.*

The same is the case with the use of compound nouns in the PIL corpus. Some of the introduced compounds only consist of two compounds such as *koncentrationsbesvær* [concentration difficulty] and *åndedrætsbesvær* [breathing difficulty], and some consist of more such as *mitralklapstenose* [mitral valve stenosis] and *insulindispenseringssystemet*

[insulin dispensation sysmem], which might be difficult to understand to different degrees; however, the main point is again that a lowest common denominator approach would state that such compounds should generally be avoided. Therefore, the analysis shows which PIL sub-corpus contained which number of instances for an entire category; however, these might be qualified differently on a lay-friendliness continuum.

Lack of control of translation process

A further limitation of the study is the lack of control of the translation process that one has to compromise somewhat when doing an ecologically valid study. It is not possible to be certain that the pharmacist or professional translator was the only person involved in the translation process or whether one or several proof-readers have participated as well. Also, because all PILs are now checked by the Danish Health and Medicines Authority (DHMA), it is not possible to know whether the use of certain linguistic elements have been introduced by the two translation quality reviewers. In addition, because the pharmaceutical companies use external translation agencies, it is not possible to know whether they have used a state-authorised translator. The translators used might not be truly professional, trained translators.

Translator groups are standardized

As seen in Chapter 5, PACTE includes psycho-physiological components in their model of translation competence. As a consequence of their inclusion in the model, these cognitive and behavioural psychomotor mechanisms are seen to influence overall translation competence. Such mechanisms are naturally not linked to a specific translator background, pharmacist or translator, and the differences between the translators in relation to these components could be part of the explanation of the results found.

Wide range of medications

This study investigated PILs for a wide range of medications; a future study investigating whether the type of drug influences the translation choices would be valuable. The translator choices might be related to the type of medication and also the type of receiver of the medication.

One coder

Because the coding process was so extensive, with 54 PILs analysed twice and all codes double-checked, and was performed over a period of almost one year, it was only possible to have one coder. This can of course be seen as a limitation as it may potentially be key to

inconsistencies; however, exactly because the process was so extensive, the coding is viewed as optimally consistent under the circumstances. Furthermore, the aim was to make the coding and evaluation criteria as transparent as possible.

Intertextuality

A final limitation of the study is that today, the use of computer-assisted translation tools is extensive, which means that the choices made by the translators might not always based on the translator choice in that unique translation process, but could instead be a choice made by a translator in an earlier version and thus be stored in the translation memory and reused by the translator. The translator should, however, have the competence and expertise to avoid recycling bad translation choices.

6.3.3. Functionalism revisited

According to Katan: "[e]ver since "the cultural turn", over 30 years ago, and the rise of the functional school, belief in the importance of the translator as much more than a (more or less) faithful copier has taken hold" (2009, p. 112). However, based on a survey, Katan found that "the skopos theory functionalist thinking has yet to permeate the profession, and that Gentzler's prediction, "the future of the functionalist approach appears assured", is certainly not (yet) the case" (2009, p. 137). This suggests that viewing translation as a functional activity might not be the prevalent idea in the translation profession. Furthermore, pharmacists, without any translation training, might not approach the translation task functionally. We saw in Chapter 2 that EMA has guidelines and rules concerning the translation of PILs, i.e. the requirement that only English PILs need user-testing, which shows that EMA might have a different conception of translation. As illustrated in Figure 17, in PIL translations, the different agents, i.e. professional translators, pharmacists and EMA might have different conceptions of translation - conceptions which may be different from each other and different from the approach to translation with TS, i.e. the functionalist approach. To be able to investigate the pharmacists and professional translators' conceptions of translation, a study involving these two groups of translators is needed.

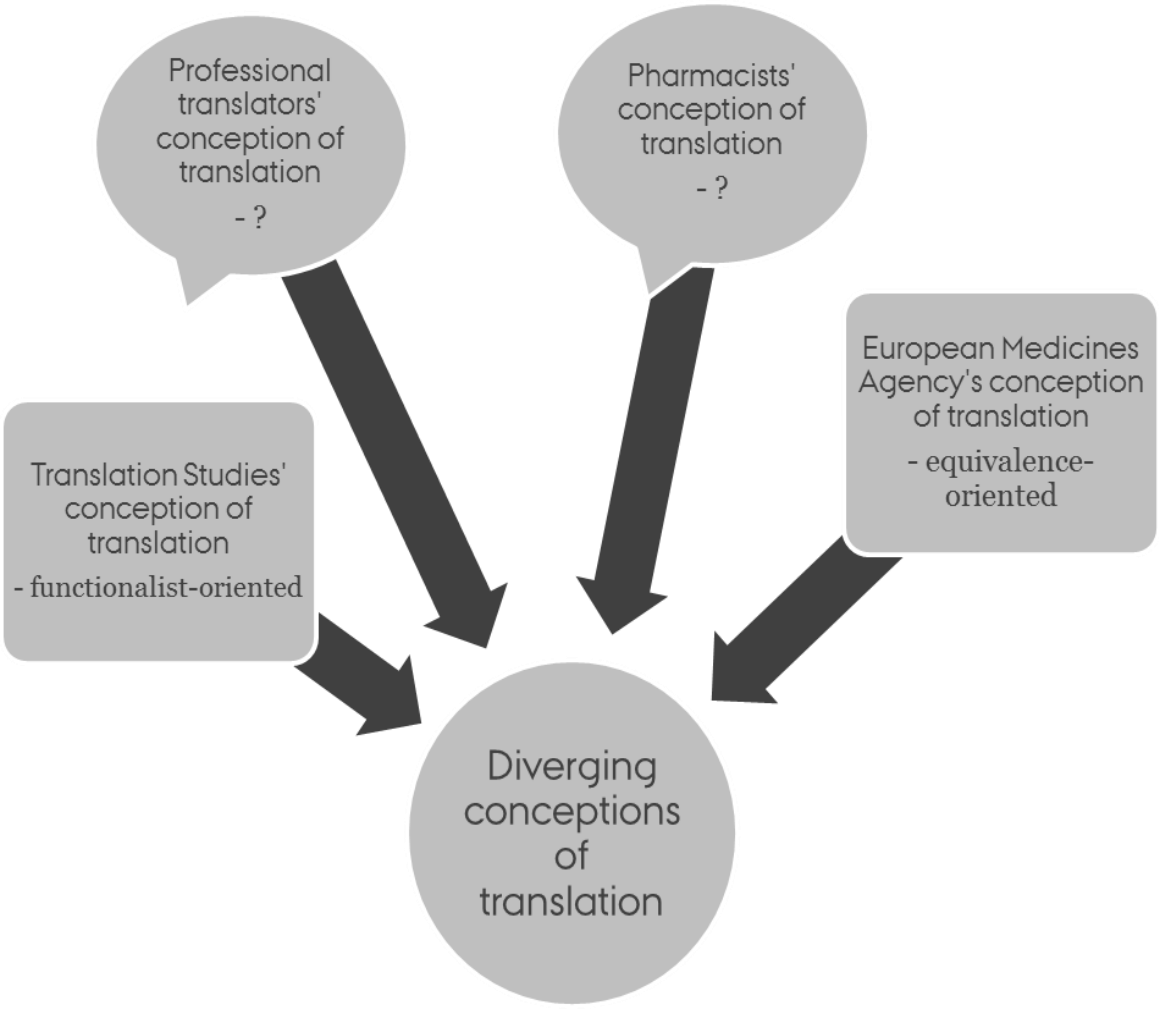

Figure 17: Potentially diverging approaches to translation and the translation process.

6.3.4. Lay-friendliness revisited

Lay-friendliness has been operationalized in this study based on a literature review of what makes a text more or less linguistically complex. This is what is illustrated in the first square in Figure 18 below. However, professional translators and pharmacists might have other conceptions of lay-friendliness (squares 2 and 3), and this could thus be an explanation of the lack of lay-friendliness in the translated PILs. Furthermore, even if the pharmacists and professional translators have conceptions of lay-friendliness which are identical with the literature, they might not be able to and operationalize these conceptions optimally or to the same extent because of lack of translation competence. The same is relevant for the differences found between the professional translators and the pharmacists in relation to LB terms and nominalization. Furthermore, as illustrated in square 4 in the figure, EMA, the legislative authority, might have a different way of conceptualizing and operationalizing lay-

friendliness, and this could also influence the translators' choices as pleasing EMA might lead to a smoother, and just quicker authorization process. These potentially diverging or identical conceptions and operationalizations can only be investigated by interacting with PIL translators.

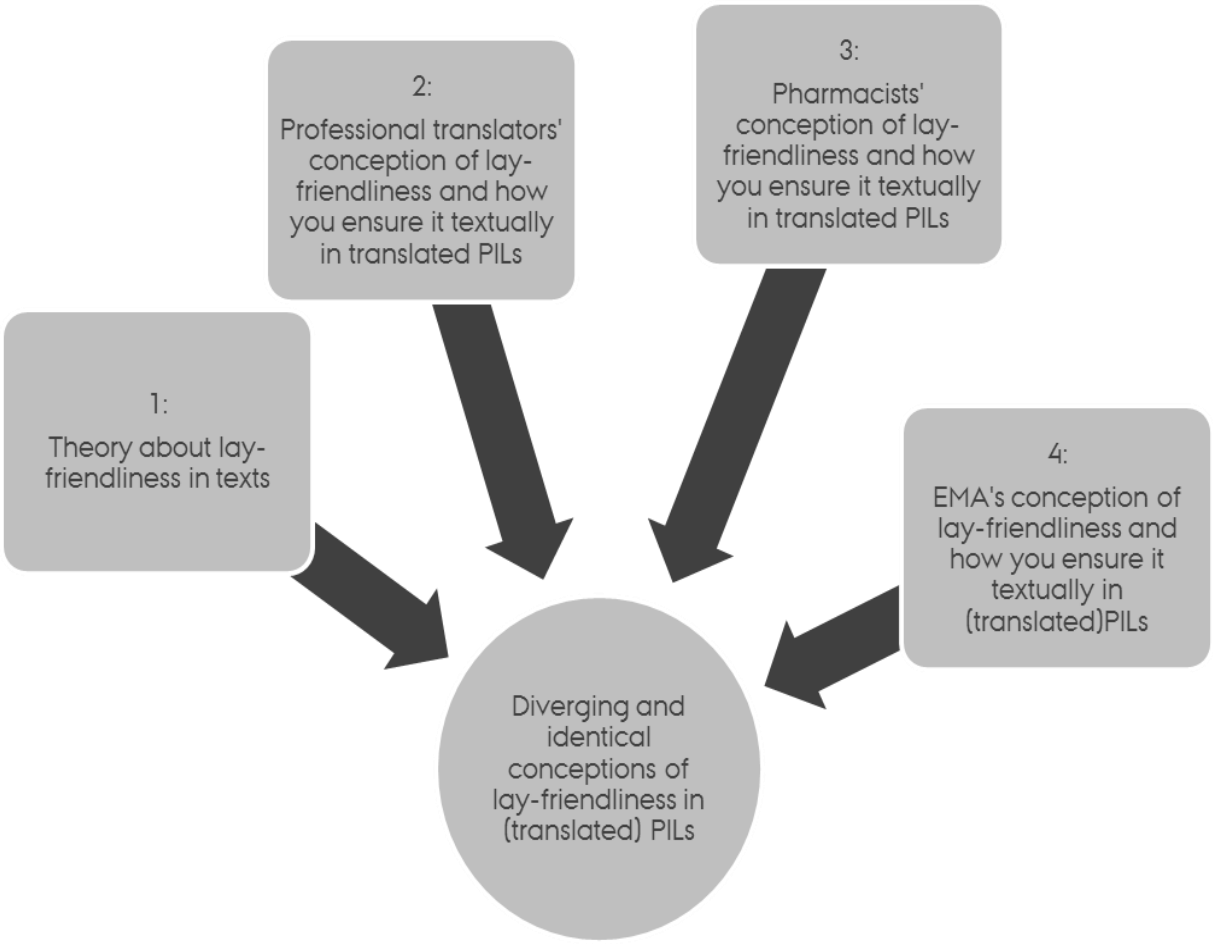

Figure 18: Potentially diverging and identical conceptions of lay-friendliness in (translated) PILs.

6.3.5. Contextual constraints

Finally, an explanation of the many literal translation choices and the choices leading to increased complexity in the translated PILs could be the contextual constraints presented in Chapter 2. The limited time provided for the translation phase might impact on the translation choices, and translator might opt for the fastest, literal choice. Furthermore, there might be competing skopoi in operation where a fast and smooth marketing authorisation process trumps lay-friendly translation. Furthermore, the functionalist approach frames the translator as an expert, but are PIL translators allowed to be experts? A further explanation could be the influence of institutional constraints in relation to different kinds of expertise and thus power relations.

6.4. Conclusion of study 2

The hypothesis generated for this study was:

> *Pharmacists – compared to professional translators – lack translation competence in relation to lay-friendly PIL translation*

Significant differences as well as non-significant tendencies were found in connection with the two groups of translators which were tested. The hypothesis was thus confirmed to some extent. The PILs in the pharmacist corpus were translated differently from the PILs in the professional translator corpus in relation to two lay-friendliness categories, i.e. LB terms and nominalizations. We can conclude that pharmacists generally make use of more LB terms when they translate and that they introduce more nominalizations into the texts than the professional translators. The results showed a large difference in occurrences of lay-friendly and non-lay-friendly options *within* the two groups (seen by the high standard deviations).

The results also showed that for several linguistic elements, no significant difference was found between the PILs from pharmaceutical companies that use professional translators and pharmaceutical companies that use pharmacists. For several elements such as compounds, officialese and accuracy, many translation choices involving these non-lay-friendly elements are found in both corpora. It is of course difficult to assess how many of these choices are too many to call it skopos-inadequate as skopos adequacy should be seen as a continuum, but in a lay genre like the PIL, there should be a minimum of officialese expressions, compound nouns and passive constructions.

Therefore, one could claim that both translator types introduce too many non-lay-friendly elements into their translations. This can be explained in at least three ways. One explanation is that, overall, there are not differences in the translation competences of the two groups in relation to these elements. Another explanation is that the limitations of the study (discussed in section 6.3.2.) have influenced the results. Finally, the explanation may be that other factors have influenced the process. It has been assumed that there is a causal relationship between translator type and final product enabled through the concept of translation competence; however, there could be other factors influencing on the translation process.

In order to understand the reasons behind the translators' translation strategies – both the strategies that showed significant differences and lack of significant differences, the PIL translators need to be actively involved as the above study can only provide information on products, not on the process and argumentation for choices made.

6.5. Transition to next chapter

This empirical study provided information about translation products, and not the translation process and the reasons for the translators' choices. In order to understand the reasons behind the translators' translation strategies, a study involving focus group interviews with professional translators and pharmacists who translate PILs will be conducted to investigate their opinions and conceptions concerning lay-friendliness, translation in general and translation of specific PIL elements.

Focus groups are often used as a follow-up method after other qualitative or quantitative studies; typically to enable explanations for patterns and help interpret the results seen in the previous studies, e.g. as an effort "to clarify poorly understood results" (Morgan, 1996, p. 135). They are used when, like in this case, there is a need to include the relevant social context (Halkier, 2009, p. 19). In the next chapter, the third and final study will be presented. Based on the above discussions and conclusions, it is suggested that the differences and lack of differences found in the contrastive PIL analysis could potentially be linked to three different causes, i.e.

- The approach to translation [also related to competence]
    - Do the translators have a functionalist approach to translation?
    - Do the translators have an equivalence approach to translation?
    - How do they approach the role of the translator?
- The approach to lay-friendliness
    - What do the translators think constitute lay-friendly language?
    - How do the translators operationalize it linguistically [also related to competence]
- The contextual constraints
    - Competing skopoi
    - Time constraints
    - Institutional linguistic usage

These will be explored in the third and final study presented in the next chapter.

7. Focus groups with professional translators and pharmacists

The previous study showed the translation choices made by the PIL translators in relation to lay-friendliness. To further extend the analysis to researching not only what these translators did, but also *why* they do what they do, a qualitative focus group study was conducted. Monacelli argues for the use of qualitative data which report interpreting subjects' perceptions of how they operate in order to gain greater understanding of subjects' strategic intentions (2001, p. 194), and similarly, this study aspires to understand the strategies used in the process of PIL translation, the translators' view of and approach to translation and lay-friendliness. The purpose of this part of the thesis is thus to create a nuanced understanding of the motivation behind the choices, to serve as explanatory material for the results of study 1 and 2 as well as to create further understanding of the phenomenon of PIL translation in general.

In Chapter 2, we saw that lay-friendliness is a legal requirement of the PIL; however, in the same chapter, we saw that the majority of the legal documents and processes related to reviewing the PIL documents do not take lay-friendliness aspects into consideration. Therefore, there seems to be diverging opinions concerning lay-friendliness between the Plain Language literature and the EU authorities. The professional translators and pharmacists might have other conceptions of lay-friendliness than the one advocated by the Plain Language literature, and this could thus be an explanation for the lack of lay-friendly language in the translated PILs. Even if their conceptions are similar, there could also be differences in relation to the translators' ability to operationalize lay-friendliness in the translations, i.e. they might not know which terms and grammatical constructions might be detrimental to lay-friendliness. Therefore, the first research question of this study is:

1. How do the PIL translators approach lay-friendliness and how is their ability to operationalize it linguistically?

In a recent study by PACTE of translation competence, a close relationship was found "between a dynamic concept of translation, a dynamic approach to the translation of a specific text, and a dynamic approach to the translation problems posed in the text… and the acceptability of the solutions found to these problems" (PACTE, 2011, p. 50). This means that the approach a translator has to translation in general is reflected in the approach taken in a particular text. Thus, a dynamic approach (same as the functional approach taken in this study) to translation in general is linked to dynamic (or functional) translation choices. The PACTE group also found that "only expertise in translation enables subjects to convert this overall dynamic approach to the translation of a specific text into a dynamic approach to

translation problems in a text and acceptable solutions within a given context" (PACTE, 2011, p. 50). The ability to operationalize a translation approach in a specific translation situation consequently requires translation competence. The second research question of this study is thus:

2. How do the PIL translators approach and conceptualise translation and how do they operationalize it? Do they have a functional approach?

We also saw in Chapter 2 on the legal requirements and PIL research that the PIL as a mandatory genre is extensively constrained by the institutional environment, which affects the translation process. However, to my knowledge, no studies involving the perceptions of the PIL translators themselves have been conducted. Such a study could serve to understand the constraints from the PIL translators' point of view and could provide explanatory material to understand the processes of PIL translation and the choices of PIL translators in more detail. The third and final research question of this third study is:

3. What are the contextual constraints and helpful tools perceived by the translators which might influence the translation process?

To answer these research questions, the focus group method is presented and argued for as a suitable method for the third study of this thesis.

It should be noted that relevant ethics approval for this phase of the mixed methods research design was granted by the Macquarie University Human Ethics Committee (see Appendix 6 for ethics approval and Appendix 7 for ethics amendment).

7.1. Research design of study 3

7.1.1. The focus group method

One of the definitions of focus groups widely agreed upon is formulated by Morgan, who defines focus groups as a "research technique that collects data through group interaction on a topic determined by the researcher" (Morgan, 1996, p. 130 ; same definition is adopted by e.g. Halkier 2009, p. 9). This definition emphasizes that it is the interaction in a group discussion, which is the source of the data, and also that the researcher is important for the creation of the data as s/he determines the topic of the group discussion. Dahler-Larsen & Dahler-Larsen (1999) have a similar focus, but they also include the number of participants in their definition of the focus group as a "semi-structured group interview typically with 6-10 participants, in which a moderator seeks to initiate a group process which leads to multilayered perspectives on a focused topic" (Dahler-Larsen & Dahler-Larsen, 1999, p. 1; my translation).

Focus groups are often used as a follow-up method after other qualitative or quantitative studies, typically to enable explanations for patterns and help interpret the results seen in the previous studies, e.g. as an effort to clarify poorly understood results (Morgan, 1996, p. 135). In this third study, the focus group method is used to gain an understanding of the choices found in study 2, to learn from the actual PIL translators why they choose different translation strategies.

The focus group method has not been used very extensively within Translation Studies (Koskinen, 2008, p. 85) even though a study by Schjoldager & Zethsen (2003) found that:

> The focus group method seems an excellent tool for **the exploratory study of translators' self-perception, norms, and working conditions:** it elicits data in a less controlled way than more traditional methods and **encourages subjects to react to other people's views, thereby making information available that might otherwise have remained unarticulated**; it seems to reduce the risk of researcher interference; and it seems to help researchers keep an open mind. (2003, p. 150; my emphasis)

This quote clearly demonstrates the usefulness of focus groups as a method to investigate translators' norms and working conditions, two elements which are relevant for the purpose of this study. Furthermore, according to Koskinen, who is one of the few people who have conducted focus group interviews within Translation Studies, the focus group method is seen as a suitable method to produce qualitative data on translators' shared attitudes, beliefs as well as their group dynamics and group norms (Koskinen, 2008, p. 83). As PIL translation occurs in a context characterized by legislation, multiple agents and knowledge asymmetries, to understand the translation process behind the translation choices, there is a need to include the relevant situational context, which is made possible through focus groups (Halkier, 2009, p. 19).

Strengths and weaknesses of focus groups

The focus group, like any other method, has strengths and weaknesses. One of the strengths of focus groups is that the participants both ask each other questions and explain themselves to each other thus making the discussion in focus groups more than the sum of individual interviews (Morgan, 1996, p. 139). The focus group interaction leads to data which show consensus and disagreement among the participants (Morgan, 1996, p. 139). Focus groups can thus provide "the occasion and the stimulus for group members to articulate normally

unarticulated normative assumptions" (Bloor, Frankland, Thomas, & Robson, 2001, p. 5),which means that in order to function as a group, the participants are forced to be "discursively explicit" (Halkier, 2009, p. 10). In focus groups, the researcher has the ability to ask participants to compare their experiences and views, instead of trying to compare individual data from different interviews and trying to speculate whether or why the interviewees differ (Morgan, 1996, p. 139). During a focus group, two processes are happening at two different levels. On the one hand, a specific topic is discussed based on the experiences and attitudes of the participants. On the other hand, a group process is happening in which the participants talk or stay silent, are inspired, form an opinion, dominate or are dominated based on their impressions of the other participants (Morgan, 1997, p. 20). The group dynamics are thus seen as an instrument to assist the data collection. The experiences of some participants can inspire other participants to engage in the discussion. Some argue that data from groups are more valid than interviews as the participants inspire each other to give broader answers and activate forgotten details, but also because the presence of others can correct a person's most idealized statements (Morgan, 1993, p. 232). This argument concerning the heightened validity of focus group data is, however, criticized by Dahler-Larsen & Dahler-Larsen, who argue that the group dynamics can also lead to social desirability bias as the participants might wish to present themselves in the best possible light (1999, p. 6).

This social desirability bias can be viewed as a weakness of the focus group method. Another weakness is that focus groups naturally do not say anything about individual practice or individual understandings and there might be a tendency to conformity and polarization (Halkier, 2009, p. 14). According to Morgan, the weaknesses of focus groups are, like their strengths, related to the production of focused communications, which means that both the role of the moderator in generating the data and the impact of the group itself on the data need to be taken into consideration (Morgan, 1996, p. 139). The group format also impacts the data, because there might be a limit to what participants disclose in the group setting. Finally, in focus groups, the moderator has less control than in traditional interviews, and also, each informant has less time to share than in an interview (Morgan, 1997, p. 10).

The advantages of the focus group method for the purpose of this study are seen to outweigh the weaknesses, and thus, this method was decided on for the third study for the following reasons. For the purpose of investigating the translation strategies and constraints in the translation process of PILs, focus groups seem highly suitable as they are said to be favourable at producing data, which shed light on norms for the practices and interpretations of groups (Bloor, et al., 2001, pp. 4-8). Furthermore, with the focus group method, it is

possible to access direct data about potential similarities and differences in the focus group participants' opinions and experiences. With single person interviews, such conclusions would need to stem from post analyses of separate statements (Morgan, 1997, p. 10). On the basis of this introduction to focus groups and their strengths and weaknesses, the research design of the third and final study of this dissertation is presented below.

7.1.2. Planning the focus group

Selection of participants

The selection of focus group participants is naturally linked to the research interest and questions. As a rule of thumb, the group should be as heterogeneous as possible to get optimal broadness and variation; however, it must be sufficiently homogenous for the participants to share a common understanding of the topic (Dahler-Larsen & Dahler-Larsen, 1999, p. 7). Morgan argues that focus groups often use homogenous strangers, i.e. people who do not know each other, but who share certain traits. Most of focus group literature suggests 6 to 12 participants per group (e.g. Morgan, 1997, p. 34).

For the PIL translator focus groups, it was decided to have one focus group consisting of professional translators and another focus group consisting of pharmacists. Mixing the two groups was purposefully avoided to ensure that this heterogeneity did not lead to conflict and repression of views (Bloor, et al., 2001, p. 20) especially because some of the pharmacists might know some of the professional translators from previous translation projects, which could lead to problems with power and status relations.

Most of the literature on focus group recruitment emphasizes the importance of group composition and selection of participants (e.g. Bloor, et al., 2001, p. 20); however, for this study, it was a luxury that could not be afforded because the PIL translator population is quite small. As for sample size, focus groups of 5-8 participants were planned (according to Morgan, 1997, p. 42, small groups work best when the participants are likely to be interested in the topic as in this case). The population of professional translators and pharmacists that translate PIL is quite small, and therefore, two main recruitment criteria were used:

1. the participant had to be either a professional translator or a pharmacist
2. the participant had to have PIL translation experience

A recruitment email was sent out to translation companies, freelance translators with listed medical translation expertise and pharmaceutical companies who in study 1 had listed that they use pharmacists as translators of PILs. The recruitment email can be seen in Appendix 8.

The translator email was sent out to 11 translation agencies and seven freelance translators. The pharmacist email was sent out to 12 pharmaceutical companies.

Eight translators and six pharmacists agreed to participate. For one translation agency and one pharmaceutical company, three people from the same company agreed to participate. As three participants from one company could influence the group dynamics negatively, these two companies were asked to send two participants of their own choice (it was suggested for them to send the two participants with the most PIL translation experience). In the translator focus group, one participant cancelled due to sickness and another participant was abroad on the date, which left five participants in each focus group. Tables 23 and 24 below show the participants and their background information based on the completed background question sheet (see Appendix 9 for translators and 10 for pharmacists). Apart from the five participants and me as the moderator, a colleague (Line) attended the focus group to help with potential technical problems, and take general notes on group dynamics and non-verbal behaviour.

Focus group 1 – translators					
Name[41]	**Educational background**	**Medical/pharmaceutical training**	**Other relevant training**	**Years of experience**	**Number of PIL translated**
T-Jonas	State-authorised translator Cand.ling.merc[42]	-	-	15	50
T-Torben	State-authorised translator Cand.ling.merc	Only through translation	-	14	25-50
T-Annika	State-authorised translator Cand.ling.merc	-	-	5	10-20 (but primarily reviewing)
T-Cathrine	State-authorised translator Cand.ling.merc	Course in medical terminology	-	12	1000 (translation and review)
T-Lone	Translator Cand.mag[43]	Two years' medicine, minor in sports science.	Translated medical texts for 30 years, participation in project on systematized Nomenclature of Medicine for three years	30	1000-2000

Table 23. Participants in translator focus group.

[41] The names used here are pseudonyms.
[42] Master's degree programme in International Business Communication, Translation and Interpreting Profile. This master's degree gives access to the title of *state-authorised translator*.
[43] Master's degree programme in English (Arts).

Focus group 2 – pharmacists					
Name	**Educational background**	**Translation training**	**Other relevant training**	**Years of experience**	**Number of PIL translated**
P-Hanne	Pharmacist (Cand.pharm)	-	23 years in pharmacy, customer contact, communication about medicine	23	500-1000 (has produced the same amount in Danish based on SPC)
P-Louise	Pharmacist (Cand.pharm)	-	-	14	200+ (partly)
P-Katja	Pharmacist (Cand.pharm)	-	15 years of experience, 2½ day course	35 (regulatory experience 22 years)	200 + (fully + partly)
P-Kristine	Pharmacist (Cand.pharm)	-	-	6.5	50
P-Vibeke	Pharmacist (Cand.pharm)	-	Six years of experience in Regulatory Affairs with translation/reviews	8	50

Table 24: Participants in pharmacist focus group.

Structure of the focus group

As for the structure of the focus group, Halkier (2009, pp. 38-40) describes three models:

1. Unstructured focus group with a few, broad questions and low moderator control
2. Structured focus group with specific questions and high moderator control
3. Funnel model focus group starting with open questions, and moving on to more structured questions.

Models 1 and 3 are suitable for exploratory studies or for studies where the researcher does not know enough about the understandings and practices which characterize the field and therefore want the participants to say as much as possible from their perspectives. Model 2 is more suitable for projects where the researcher has relatively comprehensive knowledge about the field and there is more focus on the content than on the interaction between participants. The third model, the funnel model, was chosen as it has the advantages of both the structured and the unstructured model by starting with open questions and finishing with more structure.

The role of the moderator

The "interviewer" in focus groups is often called the moderator or the facilitator, because of his/her role in steering and facilitating the process of the discussion rather than actually asking the participants questions (Krzyzsnowski, p. 164). Therefore, the moderator also oversees the general development of the communicative dynamics taking place in the course of a focus group (Krzyzsnowski, p. 164). According to Morgan, the moderator must ensure the following four points, which I aspired to fulfil as the moderator of the focus groups (1997, pp. 48-49):

1. make sure the focus group is characterized by informality
2. make the participants participate actively and interact
3. make sure participants respond to the topics and express opinions and experiences
4. make the participants produce varied opinions and experiences

7.1.3. Conducting the focus group

One week prior to the two focus groups, the participants were emailed (see Appendix 11 for email to professional translators and Appendix 12 for email to pharmacists), with information about focus groups in general, the study, a consent form to be signed (see Appendix 13), the above-mentioned sheet with background questions and travel guidance to the venue.

Interview guide – procedure and content

In order to be able to compare across the two different focus groups, the discussion topics were organised into a guide to be followed by the moderator in the same order in each group (Morgan, 1997, p. 47). An interview guide was elaborated based on the research questions developed after study 2, i.e. to investigate whether the differences (LB terms and nominalization) and lack of differences (all other lay-friendliness elements) found in the contrastive PIL analysis could potentially be linked to the three reasons presented in the introduction to this chapter.

The elaboration of the interview guide is based on Halkier (2009, p. 54) Dahler-Larsen & Dahler-Larsen (1999, p. 10) and Morgan (1997, pp. 48-53).The interview guide can be found in Appendix 14. The main content is presented below. The funnel model involves having a specific question guide with a few open questions, which make the participants speak from their own experiences and then more specific start questions as well as focused follow-up questions.

In the introduction to the focus group, the study was explained in broad terms, and it was explained why the participants were selected. The focus group rules were explained to the participants including the guidelines for interaction (encouraging talking to each other, self-management and the sharing of concrete experiences), emphasizing the expert status of the participants, that the goal of the focus group was not to reach consensus and that no right or wrong answers exist.

After the participants had introduced themselves, a broad discussion-starter question was asked in order to present the basic topic for the sessions and to open the discussion for the group (Morgan, 1997, p. 49). In this question, the participants were asked about their experiences with the translation of PILs, what they found interesting, easy, difficult, whether they meet challenges or constraints etc. After about 10 minutes of open discussion, I introduced the first of the three substantive topics in the guide (following Morgan, 1997, p. 51).

The three main topics were:

1. Translation of PILs, the process
    - purpose, instructions, translation brief, tools

This topic was introduced to gain an understanding of the translation process of PILs as conceptualized by the translators to investigate what they see as the purpose of PILs and PIL translation, and to understand the context, i.e. whether the translators receive instructions and whether they use any tools.

2. The receiver group of PILs
    - The importance of the receiver, who the receiver is, how to tailor for the receiver

This topic was used to investigate the translators' perception of the PIL receiver and to investigate their conception of lay-friendliness and what they do to ensure it and tailor for the receiver. Also, this topic was introduced to prompt the participants to talk about their approach to translation.

3. The role of the translator

This topic was introduced to have the focus group participants share their opinions about the role of the translator in relation to PIL translation, among other things to gain an understanding of the expertise of the translator and the degree of power or freedom the translator finds that s/he has.

After these broad general questions, following the funnel model, the focus group moved into more specific questions. For this purpose, specific examples taken from the analysis in study 2 were provided to the participants (see Appendix 15). These included discussing the possible translational choices for English source texts elements (e.g. osteoporosis, menopause, oral, nominalisations etc.) and discussing different Danish target text options. The focus groups were audio-recorded to make them possible to transcribe for analysis purposes.

Pilot focus group

Prior to conducting focus groups, a pilot focus group was conducted with four colleagues with translation experience and training. The introductory part of the focus group was carried out and some of the general questions were discussed. In addition, a few of the specific examples were discussed. The pilot focus group led to the realization that the three broad topics needed to be introduced in a different way to ensure that the participants would be able to remember which topic was under discussion at a specific time during the focus group. Therefore, posters with key words were made to be placed on the table during the focus group (see Appendix 16).

Location

According to Halkier (2009, p. 36), the location of the focus group can influence the data production, and therefore, a neutral, institutional place was chosen for both focus groups. The professional translator focus group was held at Aarhus University in Aarhus, and the pharmacist focus group was held at Aarhus University's campus in northern Copenhagen.

7.2. Analysis

7.2.1. Transcription

Following Halkier (2009, p. 70) and Kvale & Brinkmann (2008, p. 202), I transcribed all recorded speech based on the audio files. It should be noted that I am aware that all transcription forces a processing and reduction of the data (Halkier, 2009, p. 70; Kvale & Brinkmann, 2008, p. 200), which thus means that the analysis and interpretation of data start already at the point of transcription (Kvale & Brinkmann, 2008, p. 199). The transformation of oral data into written data is also seen as a translation process (following Kvale & Brinkmann, 2008, p. 200). Like Koskinen in her transcription of translator focus groups, I tried to balance analytic needs and readability, keeping transcription conventions to a minimum (Koskinen, 2008, p. 88). This means that pauses and overlaps are roughly marked,

but their durations are not calculated and phonetic features such as pitch and intonation are unmarked. The transcription symbols used are based on Halkier (2009, p. 72) and Koskinen (2008, p. 89), and they can be found in Table 25 below. Both focus groups were transcribed by listening to the tapes three times. The transcribed focus groups can be found in Appendices 17 (translators) and 18 (pharmacists).

Transcription symbols	
Emphasis	Bold
Overlaps in speech	[ ]
Interrupted speech	--
Short pause	…
Longer pause	(pause)
Shared laughter	(laughter)
Indecipherable talk	( )
Unidentified speaker	??:
Non-verbal	* *

Table 25: Transcription symbols.

7.2.2. Analysis procedure

The analyses were carried out using an method inspired by a qualitative approach to content analysis (Baxter, 1991). Content analysis is defined by Krippendorff as "a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use" (2013, p. 24). Traditionally, content analysis has been noted to be of a quantitative nature, here, however, an interpretative qualitative approach is taken. Content analysis is said to provide new insights, increase a researcher's understanding of particular phenomena, or inform practical actions (Krippendorff, 2013, p. 18). Creating categories is the core feature of qualitative content analysis. A category is a group of content that shares a commonality (Krippendorff, 2013, p. 106).

The focus groups were analysed using NVivo, and to ensure stringency in the analysis, it followed the procedure outlined by Halkier (2009, pp. 72-77) consisting of coding, categorization and conceptualization.

Phase 1: Coding

In the first phase of analysis, each focus group was coded. According to Coffey & Atkinson, coding means applying preliminary labels to small pieces of textual data (1996, p. 28). Miles & Huberman (1994) describe codes as:

> tags or labels for assigning units of meaning to the descriptive or inferential information compiled during a study. Codes usually are attached to "chunks" of varying size – words, phrases, sentences or whole paragraphs, connected to or unconnected to a specific setting. They can take the form of a straightforward category label or a more complex one (e.g. metaphor). (1994, p. 56)

Following Miles & Huberman, I view coding as an integrated part of the analysis and not as a mechanical processing separated from the analysis (Miles & Huberman, 1994, p. 56). For the analysis, synthesis of induction and deduction was sought as an iterative process. Thus, a strategy that acknowledged existing literature and the research questions sought answered while simultaneously remaining open to possible new findings was applied. This follows Barbour who argues: "One would expect the discussion to reflect the questions put by the moderator, but the coding frame should be flexible enough to incorporate themes introduced by focus group participants as well" (Barbour, 2007, p. 117).

In the first phase of analysis, a provisional coding scheme was developed while coding the data, which was then constantly applied, developed and further adjusted. It should be noted that text segments can contain more content subjects, and therefore, the same sequence in the data can be given several codes at once (Barbour, 2007, p. 123).

Phase 2: Categorization

After the first round of coding, in the second phase, categorization, the codes were structured into overall categories (Halkier, 2009, p. 75); the codes were related to each other, to see if they were linked or contradicted. The categories were also based on the literature as well as the empirical data After this categorization, I started the coding procedure again for both focus groups based on these categories.

Phase 3: Conceptualisation and presentation of the analysis

In the third phase, conceptualization, codes and categories are discussed against the theoretical concepts of translation and lay-friendliness, and related to the two previous studies. In the following, the results of the analysis will be presented. To present the analysis, the emerged categories will be the structuring element instead of presenting one focus group

at a time (following Miles & Huberman, 1994, p. 183). Within these emerged categories, the discussions from the two focus groups will be presented and compared where comparison is relevant. When presenting the focus groups, Kvale & Brinkmann's recommendations concerning interview quotes have been followed (2008, pp. 306-308). The quotes are thus presented in written style (Kvale & Brinkmann, 2008, p. 307), and language mistakes deemed to be unimportant have been eliminated. The aim has been to create a balance between text and quotes (Kvale & Brinkmann, 2008, p. 307). All the quotes have been translated by me, and a functional approach to the translation has been taken. The main skopos was to ensure that the meaning of the quotes is carried across to the reader. Therefore, target-oriented translations have been made.

7.3. Results

The three research questions of this study will serve as structuring elements for the results section.

1. How do the PIL translators approach lay-friendliness and how is their ability to operationalize it linguistically?
2. How do the PIL translators approach and conceptualise translation and how do they operationalize it? Do they have a functional approach?
3. What are the contextual constraints and helpful tools perceived by the translators which might influence the translation process?

The first question to be explored was thus to investigate potential differences between the two translator groups in relation to what constitutes lay-friendliness and the participants' ability to operationalize this linguistically, i.e. linguistic challenges. The results in study 2 showed that for Latin-based terms and nominalization, differences exist between professional translators and pharmacists in the analysed corpus. This third study explores the potential explanations for the differences between the two groups in relation to Latin-based terms and nominalization, and also attempts to gain an understanding of the reasons for the lack of differences between the two groups in relation to the many other lay-friendliness parameters investigated in study 2.

7.3.1. Lay-friendliness

Latin-based terms

In the second half of the focus groups, specific examples were presented to the participants, and they were asked to discuss them (see also Appendix 15). To gain an understanding of the

translators' approach to the lay-friendliness or non-lay-friendliness of LB terms, the participants were asked to discuss potential Danish translation choices for the LB terminology below taken from the corpus analysis in study 2:

1. osteoporosis
2. acne
3. inflammation
4. incontinence
5. menopause
6. injection
7. oral

Latin into Danish

In both groups, the participants agreed that they would translate osteoporosis using the Danish lay term *knogleskørhed* [bone brittleness], and they would then add the LB term in brackets. They would choose this option with reference to the receiver, who might need this information as this might be what the doctor has called it, or the receiver may meet the term in future interactions with health professionals or texts. In the translator focus group, T-Jonas[44] argues for this choice as a help to the receiver, and he also emphasizes that the Danish lay term should be placed first:

> T-Jonas: Also because we have sometimes discussed that if you are having a conversation with your doctor, or if you hear some doctors talk to each other in the hall way, then they would use that term, and then it would be a nice little language guide. That you get…but I can remember that for a while we chose the opposite solution until we found out that we should actually focus on the Danish expression…but I don't know…can you get away with that in a PIL?
> T-Lone: Yes, you can. I have been allowed to do so. But I have sometimes had to fight for it.
> T-Jonas: Yes.
> T-Lone: Most of them accept that in Danish, we don't use the Latin terms as lay people. You can't expect that the patients know Latin.

[44] In the following, the professional translators can be recognized by the *T-* in front their names and the pharmacists by the *P-* in front of their names.

We see that T-Jonas is then unsure whether it would actually be allowed to put the Danish term first, but T-Lone argues that this has been possible for her, albeit not without having to justify it at times. The pharmacists also all agreed that they would opt for the Danish lay term *knogleskørhed* with the LB term in parentheses. I then asked them whether they would get away with deleting the expert term *osteoporosis*, or whether they were afraid that it would not be authorized if they deleted the LB term. They all agreed that this would not be a problem. Two of the pharmacists also emphasized the importance of placing the Danish lay term first in the sentence:

> P-Hanne: If it is… the English text has the expert term and then they have some explanation after, then we swap them.
> P-Louise: Yes.
> P-Hanne: Then we take the explanation, and then we put the strange word in parentheses if we do it.

This quote by P-Hanne also shows awareness that the LB term might look *strange* to the receiver. In both focus groups, all participants agree that the terms *menopause*, *inflammation*, *vagina* need to be translated using Danish lay terms with reference to the receiver and his/her need to be able to understand the PIL, here exemplified in the professional translator focus group:

> Matilde: What about "after the menopause"?
> T-Cathrine: After the transition age [overgangsalderen].
> T-Lone: After the transition age [overgangsalderen].
> Matilde: Not "the menopause" [menopausen]?
> T-Lone and T-Cathrine: No.
> T-Jonas: No, I think it will be too technical.
> T-Lone: In the Summary of Product Characteristics, I would maybe talk of "menopausal women" and "after the menopause" or after…I think I would do that. But not in…not for the patients, no.
> Matilde: I am asking because sometimes you see it in the PILs, that it is maintained…
> T-Lone: Yes and then Mrs Smith would say…
> T-Torben: Which pause?
> (laughter)
> T-Lone: Yes, exactly, right.

T-Jonas: It is the long pause…

(laughter)

This humorous exchange between the professional translators shows the potential of misunderstanding when foreign-looking terms are used in PILs, and that the translators are aware of this potential. The professional translators also showed awareness of the different degrees of technicality of LB terms. As mentioned above, the translators agreed that they would translate osteoporosis using the Danish lay term *knogleskørhed* and put the LB term in parentheses. They chose this option with reference to the receiver, who might need this information as this might be what the doctor has called it. However, for the term *inflammation*, they suggested translating using the Danish lay term, but deleting the expert term completely. Similarly, the pharmacists also suggested that *vagina* and *inflammation* should be translated using Danish lay terms (*skede* and *betændelse*), and deleting the LB terms. For these terms, both groups of PIL translators thus seem to be have a preference for the Danish lay terms, with the LB term in parentheses if it is likely to be used by the doctor or in other communication and without the LB term if this is not seen as providing needed information to the receiver.

However, some of the PIL translators argue for maintaining some LB terms for various reasons, which can be related to the following factors:

- the background of the translator
- the legal requirements
- the LB term is likely to have been used by the doctor
- the perception that the LB term has crossed over into lay terminology
- the Danish lay term is too direct or impolite

These possible explanations for the maintenance of LB terms will be presented in the following.

Background of the translator - Pharmacy experience

In the pharmacist focus group, the translation of the term *injection* is discussed quite extensively. P-Hanne starts out by saying that she would translate using the Danish lay term *indsprøjtning*, and P-Katja first suggests the expert term *injektion* until prompted again by P-Hanne:

P-Hanne: I would not write “injektion”, we don’t use that.

> P-Katja: The injection site [injektionsstedet]?
> P-Hanne: Not “injection”, we don’t use that. Only “indsprøjtning”.
> P-Katja: Indsprøjtning, oh yes.

Also P-Louise says that they always use *indsprøjtning*. Two of the pharmacists from the same company, P-Kristine and P-Vibeke, say that they would translate it using the expert term *injektion*. In this connection, the role played by the background and profiles may serve as an explanatory factor as to why LB terms are maintained. Earlier in the focus group, I asked the pharmacists whether they thought it could be difficult as an expert to estimate the level which a lay person can understand. The two pharmacists who opted for the LB term *injektion* (P-Kristine and P-Vibeke) say that they have not had any actual pharmacy experience where they had face-to-face contact with patients contrary to the other three pharmacists:

> P-Kristine: I think it is very difficult because I came straight from the pharmacist school where it is very specialist-focused. So I have some great challenges adapting to language that normal citizens understand, and especially when you have been translating the Summary of Product Characteristics first where it is okay that it is medically specialized and then into a PIL where you have to be at a whole other level. That jump I find difficult because I am so influenced by my background, you know?

P-Kristine here argues that her expert background hampers her ability to tailor PILs for lay people. These perceived difficulties in relation to translating for lay people are further exacerbated by the fact that the PIL is often translated after the expert-to-expert text, the Summary of Product Characteristics. Shortly after, P-Kristine goes on to say that she feels more competent in translating for experts:

> Matilde: So it is easier to translate the Summaries of Product Characteristics than the PILs? Because it is easier to find the right level or?
> P-Kristine: Yes, because I am used to the expert terms. I find it difficult with the PILs to adapt it so lay people can understand it.

Also the other pharmacist without pharmacy experience, P-Vibeke, expresses her difficulties translating for a lay audience and her preference for translating for experts as she can then translate more directly:

> P-Vibeke: I have a lot of hospital products where the PIL does not go out to the patient…where it is only a health professional who … so I think about them and

> then I think: "Okay, then it is not as important that it is translated so an average citizen or patient can understand it". That makes it a bit easier… there you can translate it more directly…

This quote also shows P-Vibeke's preference for translating literally as she finds this to be easier. The other three pharmacists have experience working at pharmacies:

> P-Hanne: …I have been so many years in the pharmacy, so I think I have a very, if I have to say so myself, good feeling for what people understand from when I had to go to the counter and explain something to people.
> …[45]
> P-Louise: I have like you been at a pharmacy so I think about all the customers I have had at the counter with the PIL in hand and explained to them what it said.
> …
> P-Katja: … when I worked in the pharmacy. There were no PILs in the packages.

The pharmacists with experience of working in a pharmacy find themselves more equipped to assess lay person knowledge because they have discussed PILs and medication directly with various patients. This experience could be one of the reasons they would opt for the lay term of *injection*.

Legal requirements

It also became evident in the focus group that some LB terms must be maintained in Danish and not be translated using the Danish lay term because of the legal requirements:

> P-Louise: And we are not allowed to translate…I mean we must translate it as *lactose*. We are not allowed to explain what it means.
> P-Hanne: Milk sugar [mælkesukker] and things like that …
> Andre: No.
> Matilde: Oh.
> P-Hanne: You wanted…You would have thought: "Arhh they have not written milk sugar".
> Matilde: Yes, I would probably have thought that.
> P-Hanne: But we are not allowed to do that. So that's why we don't do it.

[45] In this results section, the three dots (…) on an otherwise blank line signify that the quotes are taken from different places in the focus group or from different focus groups.

Matilde: Okay.
(laughter)

The same is the case for the term *oral*, at least for the wording on the packaging:

P-Katja: But you actually run into…for *oral solution*, the requirements of the Danish Drug Standards where it is called *oral opløsning*.

The focus group participants were also presented with examples of terms with English spelling instead of Danish spelling such as the word *lactose*, usually spelled with a *k* in Danish (*laktose*). When the pharmacists discussed this example, they argued that according to the Danish Drug Standard, they must translate it using the English spelling:

P-Hanne: But *lactose* is not with a *k* at the moment. It goes back and forth.
Matilde: Okay. And it is what…?
P-Louise: That is what it says in that the Danish Drug Standards. It says there how we should translate the English words.

PILs thus sometimes contain non-lay-friendly expressions such a LB terms – not because the PIL translators are not aware of their potential detriment to text complexity, but because there is legislation in place dictating the use of certain expressions. Not only the use of LB terms is required by legislation, also the use of English spelling is dictated despite its potential harm to lay-friendliness.

Term used by doctor

Some of the participants argued that they would use the LB term *akne*, because this would be the term used by the doctor in the doctor-patient interaction:

P-Hanne: Because some of those birth control pill are actually for girls who have been at the doctor because they have pimples, but the doctor has said that they have *akne*.
P-Kristine: I have written *akne*.
P-Vibeke: Yes, so have I. I do that too.

This is similar to the quotes by T-Jonas on page 175 concerning the use of *osteoporosis*.

The use of euphemisms – akne versus pimples

The translators also discussed the use of the term *acne* as a euphemism, because the lay term *pimples* might be a bit direct or impolite:

> T-Jonas: Also because, I think that *akne*, I mean if it was to be pimples. It becomes a little, you know…it is a bit broader. There is a little too much Coca Cola and chips about it.
> Others: Yes. That's right.

Here T-Jonas argues for maintaining the LB term, still with reference to the receiver, not as a lay-friendliness strategy, but to avoid representing or constructing the receiver negatively.

The LB term has crossed over into lay terminology

For two of the LB terms, *acne* and *incontinence*, both groups argued for their maintenance in the Danish target text:

> P-Katja: *Inkontinens*, on the other hand, that is a completely normally used word.
> (Line makes a note that all agree that *inkontinens* is maintained).
> …
> T-Lone: People know *akne* I think.
> Others: Yes.
> T-Lone: And they also know *inkontinens*
> …
> T-Torben: There are some words that are used so much, like *inkontinens*, people would know that by now.
> T-Lone: Yes.

These quotes show a perception in both groups that these terms not only belong to expert register; they have crossed over into lay terminology and can thus be maintained in the Danish PILs. There seems to be agreement about this and no one contests the lay-friendliness of these LB terms. One explanation of this could be the expert status of the pharmacists and the potential semi-expert status of the translators, the latter hinted at by T-Annika in the translator group:

> T-Annika: It is actually true what T-Jonas also said, it is difficult to frame for the right target group because you also have Summary of Product Characteristics and clinical trial protocols for example where you are allowed to write at a fairly high technical level, and it is okay that it is very complex and then you know that in PILs you must make it more digestible – you know that – but as T-Jonas also said, it is a very large group and then you can say, yes it is

> for lay people, but then after all you have an academic background. So you also write a little from your own level maybe. And there are a lot of people who are not educated or are dyslexic…

T-Annika here argues that sometimes it might be difficult as a translator with an academic background to tailor for lay people. Furthermore, the translation of the Summary of Product Characteristics can also influence the translator's ability to tailor for the lay receiver. This was also discussed in the pharmacist focus group as seen above.

Nominalization

The results of study 2 showed that there was a significant difference between the professional translators and pharmacists in relation to the introduction of nominalizations in Danish PILs. To investigate this, both focus groups were presented with the following example to see if they would prefer the infinitive or the nominalization:

- Source text: It is used to treat vitamin E deficiencies.
- Target text 1: Det bruges <u>til behandling af</u> mangel på E-vitamin.
    - Nominalization
- Target text 2: Det bruges <u>til at behandle</u> mangel på E-vitamin.
    - Infinitive

The participants were asked to discuss the two translation choices and state which translation they would choose.

Translators

All the participants in the translator focus group agreed that they would choose target text 2:

> T-Jonas: But I would also. I would…prefer, what is it called, the infinitive.
> Others: Yes.
> T-Cathrine: Number two.
> Matilde: Instead of the nominalization?
> T-Jonas: Yes.
> …
> T-Cathrine: That is also a question of, again, decreasing the level of formality [T-Jonas: Yes] by using infinitives instead. That it becomes easier to read.
> T-Lone: It is easier to read, yes.
> T-Jonas: Mmm.

The translators thus show agreement about option 2 arguing that the infinitive would be the less formal option and easier to read. They thus show awareness that this option is often the better option for the lay person.

Pharmacists

Four of the five pharmacists agree that they would choose the example with the introduced nominalization. Interestingly, P-Hanne contests this, which forces the other participants to be "discursively explicit" (Halkier, 2009, p. 10) about their reasons for choosing the nominalization:

> P-Katja: Yes, I would choose one.
> P-Louise: So would I…
> P-Hanne: Why would you choose number one? I think I would choose number two. ..I think that technically, number one is probably more correct, but… it is not an expert who will read it. They get exactly the information they need.
> P-Katja: My point of departure is to make the language more expert term-based. I think that is probably the easiest to handle when it becomes more expert term-based instead of being…it becomes too much like a novel. So that is my background for thinking "for the treatment of"… that's it. But I don't know how it will be perceived actually. I don't have any... What does your translator use? What would you use? [talking to P-Kristine and P-Vibeke].
> P-Vibeke: For the treatment of…
> P-Kristine: Yes, I would say that too.
> P-Katja: For the treatment of?
> P-Vibeke: Yes.

These quotes show that all pharmacists, except P-Hanne, would choose the nominalization. P-Katja argues that she would choose it to "make the language more expert term-based" instead of "like a novel". This is interesting because it shows that her translation strategy is not necessarily functional with focus on the skopos of lay-friendly language for the lay receiver. Instead, her strategy is to maintain the expert language. She admits that she is unsure of how it will be perceived by the receiver. Similarly, P-Louise argues that using the nominalization is more "correct":

> P-Louise: I think that number one is more correct Danish. I don't know if that is what you [P-Katja] are also saying, but then the question is whether correct is the right thing to use for the patients? [P-Katja: Yes] And that is where, that is

> those dilemmas, I think these are good dilemmas, because that is exactly what one is dealing with when translating. I have had these exact dilemmas and thought: "I will write it like this because I think it is more correct Danish to write it like this".
> Matilde: Do you mean more grammatically correct Danish?
> P-Hanne: No, but it is also more correct from an expert point of view, right?
> Others: Yes.
> P-Katja: Yes. I think so. Yes.
> P-Hanne: But I don't know…I think the other one [infinitive option] sounds better.
> P-Louise: For the treatment of…Because that is… how … "one" says it … Sorry I say it in that way …
> Others: Yes.

Most of the pharmacists thus agree that the nominalization is the expert way of writing, and thus the more correct one. In the above, the patients are not referred to explicitly, and it could be interpreted as if the pharmacists (except P-Hanne) do not know that nominalizations might be detrimental to patient understanding, also underlined by P-Louise's comments that "but then the question is whether correct is the right thing to use for the patients?". However, as this conversation goes on, it becomes evident that P-Louise is aware that nominalizations might not be the ideal choice for patients:

> P-Louise: But I am aware that if you have to try to write in more patient-friendly language, then I have to choose number two [infinitive option]. So that is a dilemma I think one has sometimes, right? Because it is supposed to be written like this, but that is maybe just not…

It shows awareness that nominalizations are not patient-friendly, but it is still seen as a dilemma, which is difficult to solve. P-Katja then goes on to argue for more expert-oriented language to enable patients to distance themselves:

> P-Katja: I am also thinking that if you are a patient, yes, that then you can, maybe wallow too much in it and maybe become a little depressed by what is it that is wrong with me, what kinds of side effects can I get, and do I then need to be treated, and with the other one [the nominalization], it can maybe be a little distanced, that it is something, it is maybe not me, but just my body …
> ??: Oh, I see.

> P-Katja: That it is more the expert knowledge, that you can more easily get into it.
> P-Louise: Then it gets a bit more serious.
> P-Katja: Yes, in some way. A little bit more…That one shouldn't have to involve oneself so much, because I don't think that patients necessarily should have to involves themselves in a sickness in that way, that…

P-Katja here also argues for the nominalization as a way to take some responsibility off the patient. P-Hanne keeps contesting this viewpoint arguing that the infinitive option would be easier to understand for the lay people, especially taking into consideration the wealth of other information in the PIL:

> P-Hanne: I just think it would sound easier when you read it that…now we are just reading a few sentences, but this it in the middle of a billion pieces of information.
> Others: Yes.
> P-Hanne: So I am thinking, the easier you can make it, the better…the easier it is to grasp. And then you might manage to read all of what you need. That you don't get overwhelmed half way through.
> Matilde: So you think it is easier to read "to treat"?
> P-Hanne: Yes. I feel that it is more straightforward to say that it can be used to treat lack of vitamin E …that's it. But…I can easily have written the other one. (laughter)

In conclusion, for nominalization, all the professional translators prefer the infinitive option, whereas the majority of the pharmacists prefer the nominalization with reference to maintaining correct expert language even if the infinitive is seen to be more patient-friendly. In other parts of the focus groups, the two groups show differences in relation to arguing for linguistic choices and making informed decisions; these will be presented below.

Metalinguistic competence

One noticeable difference between the two groups was how language competence was expressed, especially metalinguistic competence, i.e. the ability to identify and discuss the elements of language. The professional translators showed that they possess the terminology for discussing linguistic issues in the PILs. The pharmacists, on the other hand, sometimes showed that they had a feeling a choice would be preferable compared with another choice, but were not able to express the exact nuances and provide argumentation for a choice.

Furthermore, some of the pharmacists expressed the problems they sometimes have making an informed decision about certain linguistic choices.

Showing language expertise by using linguistic terminology

The translators show that they possess the terminology to discuss different linguistic decisions as well as their potential impact on the lay-friendliness of a text (my emphasis):

> T-Torben: When I started, often it was the formal version of "you" used for the receiver and a lot of passive sentences. And then after a while – concurrently with officialese being abandoned by the authorities in general, it is found that we can actually talk normally to people, then it becomes more informal "you" and **imperative** sentences where that is relevant. Then it is easier to figure out what is actually happening – you are the one who has to do something. The things don't do something themselves. That can be confusing to some people – what is it actually I have to do?
>
> …
>
> T-Jonas: I think I can remember that it is very much **imperatives**, which are used in English, but whereas in Danish, they have chosen to use **passive constructions** and then if it is a slightly higher level then it becomes dense terminology combined with **passive constructions** – then I think that Mrs Smith, she …
>
> …
>
> T-Cathrine: It is also a question of, again to get the formality level down a little by making **infinitive** forms instead. Then it becomes easier to read.

The pharmacists did not use terminology related to different linguistic decisions and their consequences for lay-friendly communication. In a few instances, the pharmacists do use terminology or describe linguistic decisions, but in these few instances, they show a lack of understanding of these terms, which will be seen below.

Showing lack of linguistic competence

In a few places, the pharmacists show that they have a lack of linguistic command:

> P-Katja: …The golden goal is to cut all those empty words. Like "which" …Yes… There are many introductory things, which you could, when you are working with the text, could write using more direct speech.

Cutting relative pronouns such as “which” (“som” or “der” in Danish) is normally said to actually make a text more difficult to understand. Another example is when both groups were presented with the following example and asked to discuss it:

Source text: Where your body does not produce enough insulin

- Target text 1: hvor **kroppen** ikke danner **tilstrækkeligt** insulin
    - Back-translation: where **the body** does not produce **sufficient** insulin
- Target text 2: hvor din krop ikke danner nok insulin
    - Back-translation: where **your body** does not produce **enough** insulin

When discussing this example, P-Louise argues that the guidelines say to write directly to the patient and not in passive form; however, she has misunderstood what passive voice entails:

> P-Louise: But I often, when I am translating and then I am thinking: “Should I follow the English one and write it like “your” or “yours” or what it is or should I actually write what…
> P-Hanne: What sounds right?
> P-Louise: Passive form, right? But it is because you want to talk directly to the patient. I think that it is also what many of these readability tests have shown, and it says in the guidelines that you should ensure that you write directly to the patient and that you should not write passive form. So if you take sentence number two, then you write directly to the patient, right? But in Danish I think that you… you don’t use that…

P-Louise here uses the term *passive form*, but it is not in the sense in which it is usually used in linguistic register. She is referring to passive giving the example of “the doctor” versus “your doctor”.

Difficulty making a professional decision for linguistic options

The pharmacists sometimes express difficulties making an informed expert decision on various elements related to language:

> P-Louise: … and then I might write one thing and then be looking at it. And then write the other one and then be looking at it … Then I might ask a colleague, I mean it could easily be examples like these that I would consider. And then suddenly I find out that, oh God, time is running, and then I just write something.

This shows that P-Louise spends time choosing between different options, and that she has difficulties making an informed decision. P-Hanne also states how they, at her company, change their mind concerning different options, which is then seconded by P-Katja:

> P-Hanne: We have the opinion of the day. And one day we think one thing and the next day when we read it again, we think something different.
> P-Katja: Yes. It is horrible. It is sometimes like that. And then you alter back and forth, out and in.
> P-Hanne: Yes. And then, again, no, it was actually better like that. What was it that **you** said?

One of the problems with the lack of expertise to make an informed decision is that it is very time-consuming and can thus have consequences for the final product as illustrated in the following quote by P-Louise:

> P-Louise: That is actually a really good example of how you actually work with it. Actually sometimes you consider it very very much whether you write one thing or the other. But the decision can sometimes be made very quickly, because you are… Sometimes I think you get so immersed in it if you understand what I mean? In the end, you become completely blind.

Language understanding – lay-friendliness and tailoring for lay people

Even though the pharmacists do not use the terminology related to different linguistic choices, some of the pharmacists show awareness of Danish linguistic conventions, for example for the use of pronouns in the example "Where your body does not produce enough insulin":

> P-Louise: In Danish, we don't say "your body".

Also, they show awareness of which choices potentially make a text difficult to understand for lay people:

> P-Louise (discussing the translation of localised swelling): it is also about the comprehensibility of it, that it is a swelling, which is limited to one place, right? And then one might translate it to "local swelling", but in principle that does not make any sense for a patient. I don't think my mother would understand what local swelling was…
> …

> P-Hanne: Because it sounds more… "where your body does not produce *enough* insulin". That is more common than "where your body does not produce **sufficient**".
>
> …
>
> P-Hanne… "indsprøjtningsstedet" [the injection site] can be a little long, so you could write something like "the place where you get the injection" … If you want to make it really good then you think about what sort of message they should get out of it. …you know - so it contains the same, exactly these things instead of it being word-for-word and you end up with "indsprøjtningsstedet" [the injection site], which is a bit long.

The first quote by P-Louise shows her focus on the comprehensibility of the translation. The last quote by P-Hanne shows her awareness of the non-lay-friendliness of compound nouns. It also provides evidence for her approach to translation: "then you think about what sort of message they should get out of it" which shows a meaning-based approach to translation as opposed to a source text-oriented approach. This quote also leads to the next research question to be explored: the approach to and conceptualisation of translation and the translators' ability to operationalize it.

7.3.2. The approach to translation and the translators' ability to operationalize it

In Chapter 6, after the discussion of the analyses, it was hypothesized that the two types of PIL translator may have differing approaches to the translation task, and that this could potentially explain both the differences and lack of differences in the PIL corpus. We saw in Chapter 3, the translation-theoretical chapter, that functionalist approaches to translation see translation as a communicative task, with focus on the function of the target text and its receiver and on the role of the translator as a responsible expert. Despite the strong focus in functionalism on these three elements, this might not be the approach taken by actual PIL translators. The three dimensions to be explored in the focus group interviews are thus:

- Translation as a complex, communicative act
- The function of the target text and the role of the target text receiver
- The role of the translator as an expert

Translation as a complex, communicative act

Even though the pharmacists do not have any translation training, they seem to have awareness of the demanding and complex nature of translation:

> P-Katja: And I think it is really really difficult to keep the spirits up, and straight away be able to look at an English sentence, how is it it should be in Danish? And turn it around…because often you start with the end of the English sentence and have to build it up from there.
> P-Hanne: You also have to spend a lot of time on the fact that the English sentences are very long.
> Others: Yes.
> …
> P-Louise: … we spend a lot of time breaking up sentences in an attempt to make it more understandable. But it is actually demanding because when you break up a sentence, I think that you have to read it over a lot of times to ensure that you do not change the meaning.
> Others: Yes.
> …
> P-Louise: As soon as you change a sentence, you might change the meaning slightly. I think you need to be quite careful.
> P-Katja: You have to be a little sharp, yes.

The first quote by P-Louise sounds like she finds translation to be a bit overwhelming. These quotes also show that the pharmacists find translation complex, especially because of long sentences in the English source text, and also because of a fear of changing the meaning of the source text in the translation process. It could be argued that the elements they focus on would probably not be perceived as problematic for a trained translator.

We saw in Chapter 2 that EMA's translation policy is that if the English source text is of a good quality then the target will also be of a good quality. However, P-Hanne in the pharmacist group shows awareness that a good source text does not necessarily lead to a good target text – in line with the functionalist approach:

> P-Hanne: …it might be understandable in English, but because it has been rubber-stamped, it is not synonymous with even a good translation of it being meaningful in Danish.
> Others: No.

The professional translator focus group did not explicitly discuss translation as a complex act, but it was implied in their comments concerning other parties' lack of understanding of the intricacies of translation:

> T-Cathrine: There are also some instances where a technician has realized that there is money in putting words into codes. A word like "printer" for example, which is called the same in many languages. They had just not realized that e.g. in Danish, we don't use "a" and "the" printer, but need the definite form...

Function of target text and role of target text receiver

In both groups, the PIL receiver was very often mentioned as the most important factor to take into consideration. The categories related to the PIL receiver can thus be related to the approach to PIL translation. When asked about the receiver of PILs, some participants in both focus groups showed awareness of the broad and heterogeneous nature of the receiver group:

> P-Hanne: I find that the people who write, at least the ones in my company, do not think about the fact that the people who will get the medication are very different.
>
> …
>
> P-Louise: It is probably very dependent on who you are as a reader whether you want all those explanations or if they just confuse more than they benefit, right?
>
> …
>
> T-Lone: Yes, but the target group is…most often patients… I don't think it is difficult to figure out who the target group is, really. I think sometimes you have to think about it…this is for elderly people primarily. Then we should formulate it in a different way if it is possible. This is parents of children, because it is not the children who will read it even though it sometimes is written like that.
>
> …
>
> T-Jonas: But again, parents of children, or parents in general, that is also, that can also be a very very vague concept because parents is a vague term, right...

Because of this broad, heterogeneous audience, one of the pharmacists and one of the translators argue for what could be interpreted as a lowest common denominator approach to PIL translation:

> P-Hanne: But I am thinking that people who want to be educated in it, and are able to, that is often people who go on the internet anyway and search information about their illness. I was at a course at the DHMA where they said that we should think about writing the PIL for the ones that couldn't do all that themselves. The ones who need a piece of paper to get exactly the "aha

> experiences" they need…Instead of writing to educate people who already are well-educated, and what is it called, have the resources to find all kinds of information themselves, then we should try to keep it in a language that people who are maybe not as used to reading and understanding written material, and who maybe do not have the need to be educated as a mini-pharmacist when they read it. So they understand what to do and what not to do. When to contact the doctor, what to expect, that it is okay to get a little dizzy or something…

P-Hanne also argues that PILs must be optimally simplified as this would also lead to a higher likelihood that the PIL receivers read it:

> P-Hanne: So I am thinking that the more you simplify it, the easier it is to cope with. And then you might get to read everything you need. That you don't get sick of it in the process.

T-Jonas in the translator group expresses a similar view that PIL receivers are not necessarily well-educated and could also have poor reading skills. Furthermore, because of the nature of the PIL genre, the receiver might not be feeling well in the reception situation:

> T-Jonas: …you mention challenges in PILs – I think that it is also the linguistic challenges where you think about who will actually use [T-Lone: yes, yes] the medication, right. That is usually not someone who is a doctor or a PhD student, right? It can also be a person who reads really poorly, besides being sick or not feeling well, maybe. This is where we have been allowed to put our fingerprint on it sometimes.

Even though both groups discuss the importance of tailoring for the lowest common denominator, the translator focus groups discusses the problem that often PILs "shoot over the target" linguistically:

> T-Lone: Plus, in some places, they suddenly start mixing Latin and Danish. For example for side effects. Then suddenly something which is complete gibberish for most people, like half-doctor-Latin. And that will probably not be changed. No matter how many times you try to explain to them that people do not **understand** it! They can't know what stomatitis is, right?
>
> …
>
> T-Jonas: …as we talked about on the way here (T-Jonas and T-Torben), we actually think that often one shoots over the target linguistically --

> T-Lone: Yes, that is true.
> T-Jonas: It becomes way way too bombastic, right.
> Others: Yes.
> …
> T-Jonas: So if people have thought about reading the PILs, they drop it as soon as they start.

This shows awareness from the translators that PILs are translated above the acceptable complexity level (expressing as "shooting over the target"), and not skopos-adequately. T-Lone's comment above shows the opinion that the causes for this high level of text complexity are contextual, and linked to the client or authorities (expressed as "they"). T-Jonas' comment, on the other hand, could be perceived as the high complexity level being caused by the translator (expressed as "one"). Therefore, I asked the following clarifying question:

> Matilde: But T-Jonas when you say shooting over the target. Do you think that it is the source text which shoots over the target or is it in the translation where it gets shot over the target or where does it lie…?
> T-Jonas: But I think it is – at least in English – it is that there is a spillover effect from Latin on the English concepts and that results in the British and the Americans and other English-speaking people being used to the Latinised expressions, and we are not so used to them in Danish. So you could say that if you match that style in Danish then you shoot over the target, right. So you can say that it is maybe a slightly higher level in English as a starting point, but because they are used to the language, then it actually isn't higher. And there, you would typically… I think I can remember that it is very much imperatives, which are used in English, but where they in Danish have chosen to use passive constructions and then if it is slightly higher level then it becomes dense terminology combined with passive constructions – then I think that Mrs Smith, she …

This quote shows that T-Jonas attributes the increased difficulty in the target text to two factors: first, the differences between English and Danish medical lexis and second, the fact that some translators have chosen to change the imperatives in English to passives in Danish. He also argues that the combination of LB expressions with passive constructions makes the text too difficult to understand for the average receiver (here personified as Mrs Smith).

The pharmacists also argue that PILs are too complex for the average receiver:

> P-Hanne: I think that often she [her mother-in-law of 82] doesn't understand a word of what it says in PILs.
> Others: No.
> P-Louise: Where I think it becomes very difficult, it is where you go into that section where if you take other medications what you need to be attentive about… I mean it is a very high expert level. And it mentions a lot of… diseases with some long complicated names which I think are very difficult …
> P-Hanne: …and that is what I am afraid of, when too much information gets onto a piece of paper like that, you lose the thread. You give up.

In the translator focus group, it was further emphasized that the PILs actually need to be very easy to understand because PIL receivers are potentially sick and vulnerable in the reading situation:

> T-Jonas: And you also have to remember that depending on how serious the illness is which they are getting the medication for, you read things differently when you have some sort of serious illness than if you are just translating. I think it should be even easier to understand when you--
> T-Lone: Yes, it should be.
> T-Jonas: are sick than if you read a text just to read it.
> T-Lone: In many circumstances you are extremely vulnerable…
> T-Jonas: Yes.

Both groups thus seem aware of the importance of tailoring for the lay receiver who might be vulnerable in the reception situation, which means that optimally simplified language should be used in PILs so the people who really need the PIL are targeted.

T-Torben argues that it is the responsibility of the translator to ensure that the receiver can understand the translation:

> T-Torben: In that situation, it can also be our role to make it easier to understand by going back to the customer and saying: "This sentence can be understood in several ways. It is correct that it is like this?" This is a very important role *everyone nods in agreement*, especially when you are vulnerable. That they get the correct message and take the correct medicine at the correct time. We have a responsibility in some way. That is an important part of it I think.

This last quote by T-Torben also opens up another important subject discussed in both groups, the role of the translators and the expertise of the translator.

The role of the translator - the translator as a responsible expert

The PIL translators' perception of their role in the translation process could have consequences for the final product; depending on their perceived degree of expertise and responsibility, important target text choices could be left to other parties. The translator focus group had several conversations concerning the role of the translator and the exercising of expert competences. T-Cathrine and T-Lone in the translator focus group construct the translator's role as one linked to communication:

> T-Cathrine: I think that as translators, our role is often to communicate, or it is to communicate… [T-Lone: It is to communicate] what it says in the source. But often we also have to, I mean you have to interpret …
> T-Lone: Yes.

The translators also seem comfortable exercising their expertise by educating clients on non-lay-friendliness choices made in previous translations:

> Matilde: What would you do in practice with these words if there was a translation memory in which it said *osteoporosis*, *menopause*, *an oral solution*…
> T-Lone: If I get one that like that, then I inform the client that this is not good enough. Am I allowed to change? That is what I usually do at least…and sometimes they say yes, sometimes they say no. Then you get the classic one with – "but we have always called it that", and "that version is authorized so you can't change it".
> T-Torben: The earlier in the process you make them aware about something like that, the easier your work becomes because if you are told that you are allowed to change something, then that's good, but if you are told that you need to use what it says, then you are helped quite a bit and then you can let go of responsibility in a sense, because then they get it the way they want it. Then no matter whether you are dissatisfied with the result, the clients get what they want.

T-Torben here shows the responsibility of the translator to contact the client if something is not ideal in the translation. He prefers to be allowed to change it as this would give him the most satisfaction with his final product. He also shows that until he has contacted the client,

the text is his responsibility, but if the client does not want him to exercise his expertise by improving the text, it becomes the client's responsibility that the text is sub-optimal or skopos-inadequate.

T-Lone states that she once went a step higher in the hierarchy when she grew frustrated with other people's lack of expert competences and awareness:

> T-Lone: I contacted Haarder when he was Minister of Health and Prevention. I contacted him then because I had just received something back from the DHMA with corrections via an agency. That "it should not be called that, it should be called like this", and then it was corrected to something linguistically wrong. Then I got a little hot-headed, and I contacted Haarder and said "can't you put your foot down with your people in there and say that they have to *hits the table* use some proper Danish. They can't send such a mess out and ask us to make mistakes in something which is correct". And I know that he did it. It **is** better now.

T-Jonas in the translator group states that depending on who the translation client is, he as a translator is allowed the freedom to exercise his expertise:

> T-Jonas: …I think it depends on who you have as your end client. Because I think that sometimes we have translated some PILs in which we actually had quite free reins. And quite a lot of authority to put our mark on it, where we could actually get a step further and think about [the receiver]…we have been allowed to put our fingerprints on that sometimes.

This is seconded by T-Torben:

> But I feel that I meet receptiveness from the clients, that they are prepared [T-Lone: Yes] to, they are aware that something is problematic and they really want to change it to more fluent language--

However, there are more instances in the translator group where the translators express their frustration with trying to exercise their expertise, but not being able to because of the client:

> T-Lone: We are allowed to change too little I think *everyone nods in agreement*. Haha. In general. I would like to be allowed to simplify them more than we are allowed actually.

It seems to be very client-specific whether the translators are allowed to change something:

> T-Cathrine: I think that it makes a big difference whether it is something you get from a foreign client or it is in Denmark [T-Jonas and T-Lone: Yes]. Especially because you have the possibility of arguing for something and say "have a look at this, your final product will actually get better if we change these things". Whereas if you meet Chinese, Czechs or Americans, they just take one-to-one what it says.
> T-Lone: Yes.

This quote by T-Cathrine shows that the lack of understanding of translation and the complexity of functional translation on the part of the client makes it difficult for the translators to unfold their expertise. The same is the case for the next quote by the translator T-Torben:

> T-Torben: And then we get the problem I mentioned before: you send it back to the client who then makes some changes and then says thanks for the work, and then sends it on to the manufacturer, and then you don't know what has been changed. That means that the next time you get something from the same client you risk making the same mistakes, or at least things that the client is not satisfied with again. And then you risk that they say "can't you understand what we want", and there is nothing to understand, because you have not been informed.

Here the expertise and the status of the translator can actually be harmed because the client does not see the need to give feedback to the translator on what has been changed. Some of the professional translators seem to feel that for their clients, they are sometimes a very insignificant part of a large process:

> T-Lone: It is about time that we make a document which we send out to our customers every time. When we take on a job. "Have you remembered to think about this?"
> T-Jonas: We are such a--
> T-Lone: These are our conditions. But we put up with everything!
> T-Jonas: Yes, but we are such an insignificant piece in the process, because it is not only the PIL which comes after a long process, there are also sometimes someone who has been fiddling with a nice profile brochure for years and then oops, then it all needs to be translated for tomorrow, right. And it must just fly from the start, right…There is not much respect…

Especially the translators comment that they feel overruled by other parties in the PIL process; parties who might not have the sufficient linguistic knowledge and skills:

> T-Annika: And what is often the problem is that some people want to follow it [the source text] stringently, and then there are others who suddenly want to go in and make their own rules and "it should be like that and that and that, because we don't think it sounds nice when it is written like that or that".
> T-Jonas: I can also remember once we made some…I can't remember if you have also tried it T-Torben. It was something to squirt into the eyes or something. But there was a grammatical mistake. A word which was neuter or common gender where it consistently had to be called the wrong one (laughter). And it made no sense, but it just had to be like that. It is a little irritating when you point it out and then are told that you shouldn't interfere in that.

Sometimes the translators also feel overruled by people with medical expertise:

> T-Annika: And then there are also the doctors – they are the ones with the expert competence, but they might not be so good at the linguistic things and it all just clashes.
> …
> T-Torben: And then again you can come across situation where the client comes back saying "but we have always called it that."
> T-Jonas: Or, some doctors have said that it is called like that, right.
> Others: Yes.
> …
> T-Torben: And then you can pull as many search results out as you want which show that this is actually used a lot more in this way, but it can be like talking to deaf ears sometimes.

The pharmacists primarily feel overruled by the reviewers at the DHMA:

> P-Hanne: But I would also say that one of them [one of the two reviewers] is very… intense at correcting all kinds of places where it isn't exactly…
> Others: Yes.

Translators with insufficient translation competence

Even though there seems to be consensus that translators are experts, both the translator group

and the pharmacist group argue that there are PIL translators who do not have sufficient translation competence:

> T-Cathrine: …the translations that you meet sometimes, if they stay very close to the text then it can be because it is a translator who does not completely understand the source text and then choose to stay extremely close to the source text to avoid writing something wrong.
>
> …
>
> T-Lone: That is where you can see if it is an inexperienced translator who has had it earlier--
>
> T-Cathrine: Yes that the English sentence structure has been maintained.
>
> T-Lone: Yes.
>
> T-Cathrine: That is a **real** give-away.

The pharmacists who send PILs out to translators say that they struggle to find competent translators:

> P-Katja: What we often do, or not often, sometimes, is that we send a PIL to a translator, and I find it is really difficult to find a translator who can write Danish, understood in the way that often you get it back where it is more or less like the English sentence in Danish, and the sentence structure has not always been changed so it becomes an appropriate sentence structure…
>
> …
>
> P-Hanne: There are big differences, right? How those translation agencies are I think.
>
> P-Louise: Yes, there is.
>
> P-Hanne: Yes, because we have just bought another company and taken over a lot there, and they used a translator. And now we are getting the all the rubbish in, and I mean…it is inconsistent all the way through and I think it is…There has not been made a proper review of it before it has been passed on. I don't think it has been very good. So we haven't been so impressed.
>
> P-Louise: I have also heard from some of the people at the DHMA who are reading them that they can see a difference. When it has only been with a translator.
>
> P-Hanne: Yes, haha.

This conversation shows that the pharmacists sometimes struggle to find competent translators, and that even the DHMA is able to see when the PIL has been with a translator. To understand exactly how this lack of competence manifests itself, I prompted the pharmacists to elaborate on this:

> Matilde: How can they see the difference you think?
> P-Hanne: Because they have not filled out all the secret codes all the way through.
> P-Louise: That is one of the things, but also clinical terms that are not translated correctly like **we** want it to be translated.
> P-Hanne: Yes, because they have a language approach then it is maybe not always combined with the specialist clinical understanding for the translation of the words. I mean there are some concepts where you cannot translate the words one by one. We have also had some of them. It is not a medical expert term in Danish, it might be in English, but it is called something completely different in Danish. That is those mysterious code words…

These quotes show that these two pharmacists have clear understanding of what the role of the translator should be: the translator needs to translate clinical terms according to the pharmaceutical company's requirements (however, it is not explicitly stated whether the translators have been informed about these) and they need to have specialist-medical knowledge. The latter is supported by P-Louise and P-Katja elsewhere in the focus group:

> P-Louise: And it is also…if we get a good translator, then we think that it is valuable to have a good starting point which is translated by a professional translator, but we cannot be without the specialist check afterwards, both the pharmacist-specialised or the technical things in relation to the requirements of the DHMA for standard sentences and things like that. These Danish Drug Standard requirements about how the various pharmaceutical substances should be translated and things like that. And maybe also something medicine-specialised**.** We can't get that. We have not succeeded in finding a translator who can do all of it.
>
> ??: No.
>
> P-Katja: No. Neither have we.

Furthermore, the pharmacists argue that the translator needs to know all the so-called secret codes determined by the DHMA such as whether *lactose* should be written with *k* or *c*:

> P-Hanne: But *lactose* is not with a *k* at the moment. It goes back and forth.
> Matilde: Okay. And it is what…?
> P-Louise: That is what it says in that the Danish Drug Standards. It says there how we should translate the English.
> P-Hanne: That is one of the codes, the secret codes.
> Matilde: Yes, okay.

Interestingly, I had actually asked the translators in their focus group (which was conducted before the pharmacist focus group) whether they receive information about spelling conventions or rules:

> Matilde: In relation to what we talked about before about spelling, for lactose, whether it is with a *k* or with a *c*. Do you receive any instructions about what you should do?
> T-Lone: Never. I have chosen to say: for the patients I write Danish, for the experts, I write Latin because they have asked us for that.

T-Lone thus chooses Danish spelling, because she has not been informed otherwise. She does so with reference to the patient receiver. I also asked the professional translators whether they get any translation brief or instructions about purpose or target group:

> Matilde: I would like to hear if you get any instructions before you start translating. I mean do you get information about the purpose or the target group or? What some might call a translation brief. Do you get any form of instruction?
> ??: Not always.
> T-Lone: No. It has been a long time since I have seen it. We are expected to know what it is.
> T-Cathrine: Often they don't even send the templates. You are expected to go in and find them yourself. And find the right version…

So the pharmacists find that some translators are not sufficiently competent; however, the needed information might not have been passed along to the translators, which shows disagreement between who is responsible for this task in the PIL translation process. P-Louise also states that the translator might not be aware of the legislation suggesting that the

pharmaceutical companies fail to inform the translators of the existence of such in their translation briefs or reference material:

> P-Louise: And it can also be things like ingredients and medications…I mean all these…there is a clear legislation from the DHMA about what things should be called. But if you don't know that legislation exists…and we have used many different translators…It is one of those places I almost always catch them. I mean where the translation might be great, but there are some places where it has slipped. And they catch that at the DHMA. They see that…and then there are some of us specialists who might not be super good at making the really good formulations which the translators can do better. What you do [to P-Kristine and P-Vibeke about them having both pharmacists and translators in-house to translate PILs] is in reality extremely good because you get both angles on it. We try to do it a little in what we send it out of the house, and then we take the review internally.

Here, P-Louise introduces the possibility of the translator not knowing that specific legislation exists; however, it does not seem like she finds it to be the pharmaceutical company's responsibility to inform the translators about it. In the end of this quote, P-Louise emphasizes the value of PIL translation being a cooperative process between trained translators and pharmacists, a solution that the company represented by P-Kristine and P-Vibeke and P-Hanne's company have chosen, and which they find has a positive impact on the PIL translation process as well as products:

> P-Kristine: Before it was only us pharmacists who translated. So it is quite new. To get some actually educated translators, who do it…
>
> …
>
> P-Katja: It makes the process easier or what do you think …?
>
> P-Kristine: Yes.
>
> P-Vibeke: Yes.
>
> P-Kristine: It is also nice that it is only two people who then agree on which terms they use and are very consistent in their translation. Whereas if we employed many people with product responsibility, then five different people would be translating in their own way.
>
> P-Katja: Yes.
>
> …

P-Katja: So you have two professionals, I mean educated to make those translations?
P-Kristine: Yes.
P-Katja: That's clever.
P-Kristine**:** It works really well.
P-Katja: Yes.

There is also consensus in the translator focus group that PIL translation ought to be a cooperative process between trained translators and pharmacists, ideally with the translator responsible for the first step in the process:

Matilde: There are several of the Danish pharmaceutical companies that use pharmacists as translators…What do you think about that?
T-Lone: In an ideal world, cooperation would be ideal.
Everyone nods in agreement
T-Cathrine: Yes, it would.
T-Lone: And let the pharmacist check our translation. Because I think we should go first.
T-Jonas: Yes, I would think the same.
T-Lone: Because it is us language people who are best able to communicate what the text says using understandable language. Then they can afterwards check whether the specialized content is correct…We are not experts in medicine, and none of us can be experts even though we are medical translators…and therefore, it would be practical if experts went through the translations to check expert terminology.
T-Torben: And ideally in dialogue with the translator …
T-Lone: Yes, definitely.
Others: Yes.
T-Lone: Yes, definitely.
T-Torben: So they don't change expressions where we have arguments that "this is Mrs Smith who will read it. It must be more understandable".
Others: Yes.

Even though the pharmacists argue that some of translators they have used previously have deficient competences in relation to PIL translation, P-Louise argues that translators possess some competences which pharmacists lack:

P-Louise: But in return, they sometimes can do something with wordings where we fall short. They can do the specialized stuff and something with wordings, and therefore we sometimes think that it is a very good starting point to send a completely new text out because then we get something back, which we can proceed with.

The fact that the pharmacists have struggled to find competent translators could be explained by their inability to distinguish between translators and state-authorised translators:

Matilde: And is it… Do you know - is it translators [oversættere] you use or state-authorised translators [translatører]? I know don't know if I know …
P-Katja: Is there a difference?
Matilde: Yes.
P-Hanne: Now it is becoming a bit nerdy, right?
??: Yes it does.
Matilde: I am just interested in knowing whether you know the difference, because a translator…anyone can call themselves a translator. Whereas *state-authorised translator* is a protected title. You need a master's degree…
P-Hanne: The two people we employ are state-authorised translators.
P-Louise: Yes I would say the same thing. That we use them too. We use them through agencies.
Matilde: Yes.
P-Louise: So we actually don't know directly who it is. Because we do it through an agency. But they can often say what kind they use, right?
Matilde: Yes.
P-Louise: And I have the impression that they are state-authorised translators.
P-Katja: Yes… The company we use they also use state-authorised translators.
Others: Yes.

So after the difference between the two types of translators was explained to the pharmacists, they seem to be able to identify the type they use. P-Katja goes on to argue that they have both had issues with translators and state-authorised translators:

P-Katja: Yes. It is true that it is very diverse. But sometimes we have…we have also used translators sometimes successfully, but also sometimes less successfully. But we have also used state-authorised translators with a less successful outcome when it comes to the specialist knowledge. It has been too

difficult and too complicated to correct some of their texts. So…You have to be a little lucky or select the right one to get a good translator I would say.

P-Louise: You have to try quite a few different ones before you find one…well, I think...We are using an agency right now, and I think they are quite good, but there are large differences. So, I think that is what they see at the DHMA. They might see some of the ones which…

P-Hanne: Don't use reviews.

P-Louise: Does it all the way through with a translator and maybe …And it also has something to do with the staff you have in the different companies and things like that, right?... So…I think that over time I have realized that it is the combination which gives the best result.

We saw above that the pharmacists view translation as a complex activity. However, it could be argued that the elements they find challenging such as breaking up the long sentences in the source text without changing the meaning might not create similar problems for a trained translator. Both groups of PIL translators have the PIL receiver in mind when translating, and they are aware that because of the broad, heterogeneous receiver group, the text must be optimally simplified to be skopos-adequate. Some of the pharmacists do not seem to know enough about translation, exemplified by their lack of awareness of the importance of a translation brief and reference material, and they seem to think that it is the translator's responsibility to know about legislation and find templates and other standards. Furthermore, the pharmacists lack knowledge about the difference between a translator [oversætter] and a state-authorised translator [translatør], and therefore, they are not able to choose a professional state-authorised translator when outsourcing the translation of PILs.

Especially the professional translators talk about the translator as an expert whose role it is to take responsibility of the target text and inform the client if something is not ideal. However, we also saw that because of the client or the DHMA, sometimes they are not allowed to exercise their expertise. Also the pharmacists feel constrained by the DHMA. Finally, both groups stated that their own profile has some limitations in relation to PIL translation, which is why both groups argue for the translation of PILs to be teamwork involving both a professional translator and a pharmacist, and there should be a dialogue between the two experts in relation to specific choices.

The constraints linked to clients and reviewers were only a very small part of the reasons that PIL translators feel constrained their expertise; an extensive part of the focus groups concerned other contextual constraints, which will be presented in the following.

7.3.3. Contextual constraints which might influence the translation process

Early in the course of the focus groups, it became clear how extensive the contextual constraints surrounding PIL translation are, and how limited the PIL translators feel by these. Even though the participants were only explicitly asked about constraints in the opening question (I asked about their experiences with the translation of PILs, what they found interesting, easy, difficult, whether they meet challenges or constraints etc), the results show that the translators feel primarily constrained by contextual factors and not so much by intratextual, translation difficulties. The contextual constraints discussed by the two groups of PIL translators will be presented below.

Procedural constraints due to legal authorization process

Many of the constraints discussed by the focus group participants are linked to the authorization process. Some are linked to the fact that small segments of the PIL are amended often, which has consequences for the cohesion of the text. One participant, P-Katja, states: "Sometimes we are up to amendment number 87 for a product which has had a life time of only 10 years". Some of the participants said that they had in fact never translated a PIL from the beginning but had mainly translated amendments. These amendments cause several problems for the translation process and product as will be discussed below.

Only amendments

Several participants in the translator focus group mention that sometimes they are not able to change for example an expert medical term into a Danish lay term because of the amendments:

> T-Cathrine: I am also thinking…that often, it is an update to a PIL we get, and then we are limited by the fact that we have to follow what is translated already and sometimes you then come into conflict with, I mean, would you continue something where you are thinking "this is not very good, but at least it will be consistent" and you are sure that they can get it authorized when they send it in…Or should you improve it and run the risk of getting it back and be told that this is no good, because you have not been consistent in your terminology?

Therefore, when the translators are given only amendments, they find that their expertise is constrained, because they might have to give good text quality and lay-friendly language a lower priority than consistency and a quick authorization process.

The focus group participants also mention that the extensive number of amendments poses challenges to the fluency of the text:

> P-Katja: And then there are many, small segments in the Summary of Product Characteristics [which then have to be implemented in the PILs], which are changed from time to time. And that makes it very difficult to have a flowing text, because at the same time, you receive very strict rules that you are only allowed to change the text segments which are in red in English in the Danish text.

This quote shows the extensiveness of amendments, but another pharmacist, P-Hanne, also argues that the amendments are time-consuming without having a positive impact on the text in relation to the receiver:

> P-Hanne: I think sometimes that the PILs with amendments…that is one of the things that we spend a lot of time on, and also that the template is changed, and suddenly someone has chosen that something has to be described in a different way …But for the end user, all of the work generated here, I **don't** think it gives a very big aha-experience for them. Unfortunately.

This frustration is shared by P-Louise, who argues that the amendments take focus away from the lay-friendly language of PILs:

> P-Louise: And I would say that we actually spend a lot of time on nitty-gritty things. What we are describing here in reality has nothing to do with translation a lot of it. A lot of this is nitty-gritty things. And because we have these very strict deadlines. That is what we spend our time on instead of spending our time on looking at the language…

Templates

The templates are mentioned by both focus groups as a constraint in the translation process, both because they are always bound in their formulations, but also because the templates are in some parts written using non-optimal language:

> P-Katja: But we are very bound by some locked-in sentences, which have been authorized through the European registration process which means that there are some expressions and sentences…and it can be pretty challenging translating it into Danish and fluent language.

…

T-Lone: We are extremely locked-in given that EMA's texts must be…more or less be maintained. That constrains us a lot in our choice of words and in our way of expressing ourselves…

Both PIL translators here show that they would like to have an influence on the target text and change expressions in the PILs, but they are not able to because of the templates. T-Annika in the translator group argues that some clients follow the templates blindly:

T-Annika: Often it is just some strange process it has entered, because it is almost a little bureaucratic, because there are templates you have to follow, which only some of them want you to follow and then there are some who are just so keen on us following them, and then they look at the template, but they don't even see what it actually says.

T-Annika also states that the templates create unnatural language which would not have been used otherwise:

T-Annika: You stay with certain expressions. That you wouldn't use otherwise. And which maybe **are** targeted at lay people, but which are still not exactly how you would write it otherwise.

National guidelines

Not only EMA's templates are seen as problematic and constraining for the translation process and hence product. The pharmacists also mention national guidelines as constraining for their process:

P-Katja: But you actually run into…for *oral solution* in the requirements of the Danish Drug Standards where it is called *oral opløsning* [oral is the expert term in Danish].

…

P-Hanne: But lactose is not with a *k* at the moment. That one goes back and forth.

Matilde: Okay. That is what it says in…?

P-Louise: That is what it says in the Danish Drug Standards. It says how we have to translate from English.

The problem with having to follow these European and national standards is that sometimes the language is not of great quality, which means that poor linguistic choices are recycled in PILs. Both groups of translators are aware of the problems these create.

Poor language in templates and national guidelines

T-Lone in the translator group finds that EMA's texts are very problematic, and even when they are revised, they become worse:

> T-Lone: EMA's texts are – excuse me – by God not the best language I have seen (laughter). There are typos. There are…hopeless expressions, totally incomprehensible sentences, which just, for every time they change them, become worse and worse, I think.

Both groups say that the main problem of being restricted by the templates is that the language in the templates is not good. One example is a spelling mistake, which according to T-Lone has been in the Danish template for a long time despite several comments about it from her:

> T-Lone: I think that I have called attention to a mistake at the bottom of the PIL at least 20 times where it said *indehold* [correct Danish spelling *indhold*] [T-Jonas: mmm]. I have been correcting it for three years, every time. And every time they say "yes, we have said it to the client". But you know – what to do then? I do it every time anyway.

T-Lone is trying to exercise her expertise and her role as a translator, but she finds that nothing is changed. Another example related to lack of idiomaticity in the templates is the use of the personal pronoun *you*:

> P-Louise: And what "your doctor" has said you should do. We don't say it like that.
> P-Hanne: No, we say "the doctor".
> Others: Yes.
> …
> P-Louise: But that is what the QRD-template would write: "your doctor".
> P-Hanne: That's modern right now.
> Others: Yes.

The pharmacists are also frustrated by the fact that the newest template dictates that they

should use the term *lægemiddel* [medicinal product] instead of the more straightforward *medicin* [medicine]:

> P-Louise: *Medicine*. We use *medicine* in PILs.
> P-Katja: Oh yeah.
> P-Louise: But the funny thing is that in the newest template, the word *lægemiddel* has come into the PIL in the central QRD-template.

One translator, T-Torben, argues that the constraints do not necessarily lie in the legal regulations, but in the client's interpretation of the constraints:

> T-Torben: I also think that we have met that wall sometimes, but we are maybe not so bound by EMAs regulations, but by the client's interpretation of these regulations.

This indicates that there might actually be more freedom within the regulations than what the clients at the pharmaceutical companies assume.

Source text

Both groups express their views concerning the problem of having an English source text, which must be translated very literally, because this is the text that has been authorized. The participants express their concerns that the English PIL is written within an English context, which makes it difficult for it to function in a Danish context. Several participants argue that it would lead to better texts if the Danish text was to be produced from scratch:

> T-Annika: …if you were to do all of it from scratch, and you didn't need to think about the fact that it was a PIL and translate what it said, you would definitely write in a completely different style and combine the sentences a little differently, and it would look completely different, so you are still a little constrained by some things…
> …
> P-Hanne: I think that the national PILs – where we write them almost exclusively ourselves based on the Summary of Product Characteristics without an English source. That is much easier. It is easier keeping it to language suitable for the common citizen, who needs this. My mother-in-law for example.

P-Louise also argues that it is obvious that the English source text is often not produced by a person with translation competence or knowledge, which makes it difficult to translate it:

> P-Louise: I think that one of the biggest challenges with the central PILs or when you are not the creator of these PILs, and you have to stick very stringently to an English text. It is my perception - and I don't know how the rest of you feel who are in subsidiaries - that the people who write them, I mean in my parent company, that is not people who are used to translating. It is people who do not have any idea as to how you translate a text, because they have English as their mother tongue and they never experience that the text has to be translated. And I think that in reality that is the greatest challenge, because it is written as **you** [P-Hanne] say. It is written from an English perspective and maybe based on how you live life in English or where they are…

Thus, in both the pharmacist and the translator group, the participants mention that the Danish PILs would be better and more lay-friendly if they were to be produced from scratch, without the existence and thus constraints of an English target text. In line with P-Louise above, P-Hanne also argues that the problem is that the English PIL is written with an English mentality, and therefore, it would not be possible to produce a Danish target text which lives up to Danish expectations of such a genre:

> P-Hanne: But I think that the challenge with the central one is that the source is English and an English mentality as to how things should be described, and that is also where they are readability tested. They have a completely different idea of writing much more into the PILs than we have here in Denmark. Over there, they write lay language which contains lots of expert terms, which is not the case for Danish. We would always translate it into something totally common like "ache in the belly" and things like that. They don't use that over there, they use a more expert expression. So it is a little difficult with the central ones, I think, because they write the same information 17 places, and you would never have done that if you were to do the same PIL nationally, where you had, free reins to interpret what it says in the Summary of Product Characteristics and write it in the PIL. Here, someone else has done it, someone who has a **completely** different perception of the world. And then these PILs are readability tested in English, and then they say that they are good enough to be translated, because then people can find things, and they can understand what it says, because it is structured in this way. And then you just have to get it into Danish and then you can choose if you translate … We try to translate a little based on meaning … You know that it is the same meaning in several

> paragraphs, but you will still repeat yourself in 117 different ways in those standard paragraphs which have to be there. That's why I think that the central PILs are the most frustrating PILs to spend time on, because I don't think that they are ever really good. I don't think that they ever turn out the way they would if you had made them from scratch yourself.

This quote by P-Hanne shows that even though she tries to have a meaning-based approach to translation, it is not possible to make a functional translation because the extensive repetition has to be maintained even though it might be detrimental to lay-friendliness. P-Louise argues that because of the legal status of the source text, it can be really difficult, even after several years of experience, to assess how much it is possible to deviate from the source text:

> P-Louise: And it is obvious that the Danish translations are translations. I mean, it is not how we would have written those standard sentences here in Denmark, I think, and I don't think that is just me, it might as well be the people at the DHMA. But people who speak Danish. We would never have chosen to write the sentence in that way. But it is because it comes from something English, and we are actually very bound by the fact that we must not deviate from the English text because it is the one that is authorized by the European health authorities. And therefore, we are not allowed to deviate at all. Because then we suddenly have something in our PILs that is not authorized. And that's where the fine balance comes in, and I still find that difficult *everyone nods in agreement*, even after seven years in this job. Knowing when, how much I can deviate, you know, when is it actually okay the deviation I make, because this I cannot translate into something which is understandable in Danish.

Temporal and financial constraints

Both focus groups discussed the strict deadlines as a constraint of the PIL translation process:

> P-Katja: I think we all have to do with products which are authorized through a central registration procedure, and there you are very bound by the text to be translated. And there are very short time deadlines, so it is a massive challenge to write some proper PILs, because as I said they are authorized through a central registration procedure where we receive the English and text and in, yes, Friday to Monday morning or Monday afternoon, we have to have a final text.

These strict and short deadlines mean that time is a factor leading to potential problems for

the optimal tailoring for lay people:

> P-Hanne: Of course, you have the possibility of talking to the person who does the review. The problem is just, as you say, that you get them Friday afternoon and then it has to be delivered Monday at 12. You don't have time to ride it to death, and agree on anything. But if you have some issue where you really think "no I can't live with that", then we can do it of course. But we don't have much time.
> P-Kristine: No often I think one just yields, you know because --
> P-Hanne: Yes, it is the quickest option.
> P-Kristine: You don't have time to take the discussion and to--

Because of the very limited time for both translation and review, the pharmacists here feel that they often yield in certain translation choices. P-Louise argues below that she likes the opportunity to play with the language, but this is often not possible as the consequences of time delays can have financial and embarrassing consequences for the local companies:

> P-Louise:…I think that playing around with the language is extremely interesting, and trying to see how I get something to be comprehensible based on this strange English text. But the challenge is that there is not always time for it. And then it has to be sent off. And those deadline are of extremely high importance, especially in the European procedures, because if you don't submit your things on time, then you risk that it is Denmark, who is delaying some important authorization and you don't want to be responsible for that, so we all try to live up to those deadlines.

As was seen above, both groups are very aware of the importance of tailoring for the receiver; however, they expressed frustration with the fact that the limited time often needs to be spent on other factors due to the legal requirements:

> P-Louise: For many of our ones [PILs], it is probably the same with yours, that if there are different strengths, then you have to copy all the amendments into all the different strengths too. Because an amendment is often the same for all the elements … It is very different how the texts are structured. And this process of making sure that you get it all incorporated correctly into all these strengths you have, that is… that is also very time-consuming. That can sometimes be more time-consuming than the translation itself, at least for some of the texts we have.

> [Others: yes]. Because we have so many similar ones where everything is repeated. So that…only adds to the time pressure which results in the translation sometimes being one of the things you need to make fast, because you need to have time for all your quality assurance also.

P-Louise shows that time is spent on other issues than tailoring for the receiver, and that the translation phase thus needs to be finalised as quickly as possible. When talking about the reference material that translators sometimes get, T-Torben and T-Lone also mention the short deadlines:

> T-Torben: Yes, if it is an amendment which has to be done, it is a little intense receiving 17 PDFs, which you don't really know if you have to read or if you just need to look at quickly or how to use them.
> T-Lone: And then 24 hours to do it …
> (laughter)

Above we saw that both groups say that a cooperative process between a translator and a pharmacist would be the ideal situation. When asked why the process is not already in place, the translators replied that time is an important factor:

> Matilde: Why do you think it doesn't already happen?
> T-Cathrine: Money.
> *Everyone nods in agreement*.
> T-Lone: Time.

Only the participants in the professional translator group mention some of the issues concerning financial constraints in PIL translation. At one point, the translators were discussing problematic terms in PILs, and I asked them what they do about such terms; whether they have the possibility of talking to their client:

> T-Jonas: But it is – there is also the financial angle on what we do, right? When you are young and idealistic then you want to point out everything – at some point, then you realize – but if no one wants to pay for it, then you can, as you say, in the end actually live with actual mistakes, because if you have pointed it out several times, then in the end, you get fed up.

Thus, if the client does not want to pay for the expertise of the translator or listen to the advice given by the translator, s/he can only expect to get what they pay for.

Lack of language awareness from client

The translators also expressed a lack of language awareness on the part of the clients which leads to constraints in the translation process, especially if the translator and the client have different conceptions of quality:

> T-Cathrine: Yes, that it is authorized, and they have called it that before and it is written in the versions that have had for many years …It can also be because they want it to be called that and then of course you just have to say: "hmmm, that is fair enough", and then you have to use that term. It can also be that they don't understand the reasons why we want it changed. And they can't…you know it comes back to the question of what is linguistic quality? If you tell them "but it is because we would like to increase the quality, change the quality", then they say "but this is good enough for us like this". Then you can only say "but okay". There are of course many times where they listen if they want it changed.
> T-Lone: Yes, that happens.

Long communication chain

The translator group mentioned the long communication chain in PIL translation as a procedural constraint. This is especially when there is another translation company between the translator and the pharmaceutical company:

> T-Jonas: And if you have another translation company between you and the client…then there is such a long way to the client and then you don't know if it is the other translation company who has fiddled with it [the translation memory], or whether it is the end client who has done it. And then translation memories are swapped and yes…in the end, you just grab a cup of coffee.
> …
> T-Torben: And then we get the problem I mentioned before: you send it back to the client who then makes some changes, and then says thanks for the work and then send it on to the manufacturer, and then you don't know what has been changed. That means that the next time you get something from the same client you risk making the same mistakes or at least things that the client is not satisfied with again. And then you risk that they say "can't you understand what we want" and there is nothing to understand, because you have not been informed.

In the latter situation, the translator is not informed of required changes and thus continues to make the same translation choices which can potentially be damaging for the translator-client relationship and translator reputation.

Linguistic review at the Danish Health and Medicines Authority

In Chapter 2, we saw that all Danish PIL translations are linguistically reviewed by the DHMA prior to authorization. The focus group participants expressed several concerns about this part of the authorization process. Both groups expressed concerns about the quality of this linguistic review. The pharmacist group discussed this review process more extensively, probably because they are much more in direct contact with the DHMA whereas the translators would not be in direct contact with them; the process would proceed through the pharmaceutical companies after translation. Two main concerns were voiced, both relating to consistency and quality.

Flavour of the month and of the person

The expertise of the people in charge of the linguistic review at the DHMA is called into question by T-Lone in the translator focus group:

> T-Lone: Sometimes you risk when you…the client sends it to the DHMA, and there are very often some medical students who do the linguistic review. I have tried it that someone very stubbornly informed me that it could not be called *stof* [substance] because then we were referring to narcotics.
> (laughter)
> T-Lone: And that is not very fortunate. Haha. They are not always completely conscious about what they are doing the people who do the linguistic reviews. And sometimes it also comes back just to send it back to delay a process. That also happens.

The lack of linguistic expertise of the people at the DHMA is supported by the pharmacist focus group:

> P-Hanne: But I would also say that one of them is very… intense at correcting all kinds of places where it isn't exactly…
> Others: Yes.
> P-Hanne: Sometimes you are not crazy about changing it and having to go into a discussion where it becomes a good idea…yes, but it has a different meaning at the other end.

> Matilde: So when you get it back the person has changed some things?
> P-Hanne: Yes.
> Matilde: Okay.
> P-Louise: That is actually very common.

This sequence shows the linguistic expertise of the people doing the reviews being called into question as the pharmacists feel that sometimes unnecessary elements are corrected, or elements are even changed resulting in a changed meaning. In another sequence, the pharmacists express their frustration about the linguistic review process, one of their main concerns being what is expressed by P-Louise as "the flavour of the month":

> P-Louise: …the consequence of the translations we make will change depending on – I would almost say "the flavour of the month" at the DHMA. And they are actually two people in there who do their linguistic reviews very differently. You have probably noticed the same in your companies? *Everybody nods or exclaims affirmatively*

This quote shows the pharmacist, P-Louise's frustration with the lack of consistency in the review process, both expressed by a time-wise inconsistency ("flavour of the month") and a person-specific inconsistency (the two people in there who do their linguistic review very differently). At a later stage, the person-specific inconsistency is exemplified by P-Hanne:

> P-Hanne: Yes. One of them wants us to translate "fatal" [fatal] with "letal" [lethal], and the other one wants "fatal"[46].
> P-Katja: Yes.
> P-Hanne: And it can be a little difficult if you have products in both groups, because then you need to remember – oh that one, she wants "lethal" oh, and that one wants "fatal" – okay…and that seems totally inconsistent that those two people cannot agree on what they think.

Directly after this sequence, P-Vibeke argues for the time-wise inconsistency:

> P-Vibeke: And also, sometimes she says that something must be changed and then the next time it must be changed back again.
> (laughter)

[46] These could be in relation to the Summary of Product Characteristics, but still shows that lack of consistency in the review process.

Person-specific

Both groups focused on the PIL production process as a large mechanism with decisions being made far from the Danish context; however, the pharmacist focus group show that person-specific, local circumstances also influence the PIL process extensively. The pharmacists mentioned the person who used to be in charge of the linguistic review process at the DHMA, NN[47], several times:

> P-Hanne: It depends on who has the linguistic review of the PIL and who decides – the people who do the review of our PILs. Because before, there was a person who said: "But, if the meaning is exactly the same, then it doesn't have to be so exact". She is not there anymore, you know. Now, it has become more rigid.
> Matilde: Someone at the DHMA?
> P-Hanne: Yes at the DHMA. Who had … it actually resulted in PILs that were at bit better when she looked at them. She is not there anymore. She has her own translation firm now, I think.

This quote shows that P-Hanne found that the PILs became better then as the rules were less rigid. It seems that NN also educated the pharmacists on translation-theoretical knowledge and procedures such as the concept of *localization* or target text-orientation:

> P-Katja: You mentioned another person, who used to be at the DHMA. From her, we learned that there was something called that you actually had to convert the language to a local …I mean a local language so to speak, so you get, so the many English expressions that we don't use at all in Danish, where you then maybe just use two words or a whole sentence depending on the situation. We have done that several times successfully, but it was easier before than it is now. And it is true that there are some diverging…yes, what they think at the DHMA.
> P-Hanne: It is opinions of the day…

P-Katja here states that there used to be more acceptance of target text-orientation then there is now at the DHMA. Also P-Louise argues that there used to be more freedom to make functional translations even when problematic elements were found outside the text segment which was being amended:

[47] This person was named in the focus group, but will here be referred to with the initials *NN*.

P-Louise: … Also from the person who used to be at the DHMA, I learned that if we found something in our previous translations which did not necessarily have to do with a current amendment, then we should just correct it. Because it was after all, if it was just a language thing, then it is better to make it better. And I have actually still used that and I have not had any problems with them not being accepted as long as it is a linguistic correction.

Several of the pharmacists argue that NN also inspired them by providing them with various linguistic choices suitable for PIL receivers:

P-Louise: We always use *indsprøjtning* (lay term for *injection*). That is actually something NN taught me. Haha.
…
P-Hanne: Yes, she was actually really good.
Others: Yes.
P-Louise: At giving you those little...
P-Hanne: We got some good hints.
P-Louise**:** I remember when I was pretty new in registration and there were some training sessions at the DHMA I participated in. She gave many really good tips about all this …
P-Hanne: Yes.
P-Louise: Use that word instead of this word and things like that.
Others: Yes.

NN also educated the pharmacists on the role of the translators and the purpose of PIL translation:

P-Hanne: … I think that the translator's role is to try to make it make sense in Danish, because I have actually been at the course with NN. But we have not always succeeded, have we? Because she is not there anymore.
Matilde: No. So you miss her? It sounds like that.
P-Hanne: Yes, we miss her.
P-Hanne: But she was actually very skilled. So it is such a shame. Very inspiring.
Others: Yes.

Finally, we saw in Chapter 2 that a DHMA document (Lægemiddelstyrelsen, 2008) states that the PIL translations are checked based on the expectation that they fulfil seven standards where the last two are related to lay language:

- Phrasing and choice of words are adapted to the user, PILs are always written using readable language
- In the PIL, technical terms are only used when they are known by the user

This document is authored by NN, so it would be interesting to investigate how the two reviewers, who presumably do not have any translation or linguistic training, check these two elements.

The contextual constraints were not only linked to constraints resulting from the PIL translation process, but also because the translators found it difficult balancing different interests in the PIL process. These will be presented in the following.

Balancing acts and paradoxes of PIL translation

Both groups discussed the problems of balancing different interests in the PIL translation process. The pharmacists discussed the difficulty maintaining a balance between consistency and good, lay-friendly language. Both groups mentioned the non-transparency concerning the degree of freedom in the translation process, such as how much could be changed or deleted in the process of translating the English source text into Danish. These difficulties were further exacerbated by unclear quality criteria. Finally, participants from both groups discussed the legal status of the document versus the need to inform patients.

Consistency vs. good language

Both groups mentioned the problem of balancing consistency (with previous PILs) against lay language. The problem is that the PIL lives up to the legal requirements, but it does not live up to the skopos of lay-friendliness:

> P-Louise: And sometimes you think “okay, this is what we send out to our patients”, right. Then you focus on living up to the legislation. And in some way you know in your stomach that these might not be suitable for the patient.
> Others: No.

The problems experienced by the participants in the translator group are linked to the client’s fear that changes, even though they lead to better quality texts, might not be authorized:

> T-Cathrine: …we have also experienced some clients who…have been a little afraid to deviate from the source text, and who have said "but you have to stick to what it says as closely as possible" even though you have said "but it doesn't really make sense in Danish to do a one-to-one translation". Of course it has to be coherent, but they are afraid to deviate too much or that you have made interpretations of some sentences…because again, they don't think that they can get it authorized. Then they would rather be able to follow--
>
> …
>
> T-Cathrine: …often it is an amendment to a PIL we get and in that you are very limited by the fact that you…quickly have to follow what has been translated already and sometimes you get into conflict with, you know, continuing something which you think "this is not very good, but at least it will be consistent" and you are sure that they will get it authorized when they submit it…or should you improve it and potentially risking getting it back and being told that it does not work because you haven't been consistent in your terminology…

This fear of non-authorisation might, however, be somewhat unwarranted. According to P-Louise in the pharmacist group, NN at the DHMA taught them to it was possible to combine consistency and good language:

> P-Louise: … Also from the person who used to be at the DHMA, I learned that if we found something in our previous translations which did not necessarily have to do with a current amendment, then we should just correct it. Because it was after all, if it was just a language thing, then it is better to make it better. And I have actually still used that and I have not had any problems with them not being accepted as long as it is a linguistic correction.

The last part of this quote also shows that even with the new people in charge of review at the DHMA, this approach is still unproblematic.

Unclear quality criteria/whose quality criteria

In the pharmacist focus group, I informed the participants that the European Commission is currently elaborating a report concerning the quality of patient information, showing awareness of necessity of improving the process and product. P-Hanne argues that one of the problems is that there is no agreement on what our ultimate goal is:

> P-Hanne: But the question is, goodwill yes, but we would probably struggle to agree on what good means. I mean it would be interesting to know what the people in the Commission, what they look at. What do they think is good?
> P-Katja: I think that one of the points of criticism has been, I haven't kept up completely, but in the beginning, there was talk that the template which we need to use for our translations has not been validated or been readability tested…before we start there, none of it matters.

According to T-Annika in the translator group, the problem is not only unclear quality criteria, there are also different quality criteria from client to client:

> T-Annika: And often, the problem is that some people want to follow it stringently and then there are others who suddenly want to go in and make their own rules and "it should be like that and that and that, because we don't think it sounds nice when it is written like that or that". So some of them have their own…more or less good rules and others just want that you follow the templates and there are so many different templates you have to follow. So when you use a TM [translation memory] if you use a joint TM then it is suddenly a mishmash…

The other translators also expressed their frustration with differing quality criteria from client to client:

> T-Torben: But I feel that I meet receptiveness from the clients, that they are prepared [T-Lone: Yes] to, they are aware that something is problematic and they really want to change it to more fluent language--
> T-Lone: Yes, as long as it is not the Americans.
> T-Torben: Yes, that might be.
> T-Lone: Then there is no room to manoeuvre; it must be the way it is. And that is awful really. It is really a pain.
> …
> T-Cathrine: I think that it makes a big difference whether it is something you get from a foreign client or it is in Denmark [T-Jonas and T-Lone: Yes]. Especially because you have the possibility of arguing for something and say "have a look at this, your final product will actually get better if we change these things". Whereas if you meet Chinese, Czechs or Americans, they just take one-to-one what it says.

T-Lone: Yes.

Matilde: …You said – T-Cathrine – that sometimes then you get just a small part which needs translation where you find some things which could be improved. Some terms which might be translated in a better way. What do you do then? Do you have the possibility and time to try and talk to the end client?

T-Cathrine: I would say that it depends on the day, the task and the client….based on the experience you have with the client, then you might "this is not worth it going back and saying something". But of course if you find something where you think, this is something we **have** to point out, then we usually write an email to the client while we are doing the translation to say "listen, this we would actually like the opportunity to change". Sometimes we are allowed and sometimes we are not.

T-Lone: Exactly.

Legal document vs patient information

The pharmacists discuss how the PIL is legally supposed to be information for the patient, but that it is also a legal document for the authorities and companies:

P-Louise: But the official purpose is that you are to inform the patient, right? So the patient has the possibility to know what they are getting and what they should be aware of, when to contact their doctor if they experience certain things, how to take it etc. That is information for the patient. But there can still easily be other things in it. Exactly that both authorities and companies are able to…what to say…legally, can document that now we have--

P-Hanne: We **have** told you.

P-Louise: Got this information. So if you get a stomach ache then it said so in the PIL, right?

Matilde: Yes.

P-Louise: And that goes both ways for both authorities and companies…And therefore, sometimes when the big machine is running and who, who is…do they even think about in the end, what is this actually? And what should it be used for?

P-Louise here discusses the PIL as a way for the companies and authorities to obtain an exemption of liability, which unveils the PIL as a legal document instead of patient information. P-Hanne supports this:

> P-Hanne: The text sounds a lot like a text just … to check off that you have been informed that there is eosinophilia and rash because of the medication. Bam! Then no one can come back and say that we haven't told them. And no one really understands what it is you are informed about.

P-Louise also says that the PIL in its current format cannot be an information document:

> P-Louise: …because what we have now is maybe good enough if the purpose is something else [than the patient].
> Matilde: Yes.
> P-Louise: But if it is the patient we address then we need a different format
> *Everybody nods*.

P-Louise also addresses the problem of balancing the interests of patients versus the interests of pharmaceutical companies:

> P-Louise: …and hopefully we get a different end product which is directed at the needs of the patient and not the needs of the authorities and the companies. Both how on earth do you find that balance? I am happy that I am not the one who has to do that (laugther), because I think that would be a really difficult task…

T-Lone in the translator group also agrees to this when prompted, but this is not further discussed in the translator focus group:

> Matilde: Some might say that a lot of the things in the PILs are …I think that some patients state that they think it is more of a legal document because--
> T-Lone: But it is. I mean, it is! That is evident.

Helpful tools in PIL translation

The focus groups did not only discuss the constraints in PIL translation; they also introduced tools they found helpful in their process. Three of the pharmacists discussed their extensive use of the tool *Lægemiddelkorpus* [Medicinal Products Corpus] in which previously authorized PILs (and other medicinal product information) are compiled. This tool is seen as a helper in the translation process, both as a guarantee for consistency across PILs and as a source for inspiration. One problem of using such tools could be that bad, non-lay-friendly elements are recycled. The pharmacists using the tool seemed to be aware of this potential problem:

P-Louise: … And you know that the ones… the PILs in there have been through opinion. The only thing you have to consider is that they are not as such validated, I mean just because they are in there doesn't mean that they are correct.

P-Katja: No.

P-Hanne: No. You have to use your head.

P-Louise: You have to really consider the choices.

P-Hanne: You can actually get some good ideas in there.

P-Louise: Yes you can.

P-Katja: Sometimes you can see that the linguistic review has not been so good because there are PILs from many years back. Then there can be English-ish Danish translations. So you have to look through many examples sometimes to find it. It is not **the** solution you find there.

Matilde: You have to be critical of it?

P-Louise: Yes you have to. I mean, you have to remember all the time that it is not necessarily correct what it says. It can easily be wrong…

P-Hanne: You have to use your head.

P-Louise: You can use it as inspiration; it is really good for that. If you get stuck on some expression or word or something.

P-Hanne says that her company not only uses the Medicinal Products Corpus as inspiration; they also use other, best-case PILs:

P-Hanne: XX has actually been really good at making PILs.

Andre: Yes?

P-Louise: Who?

P-Hanne: XX. What are they called now? XX. I don't know if they are good anymore. But when they were called XX, you could always get some inspiration by looking at how they had treated an area because I don't know who they had employed to make them, but they were always written…crystal clear where I thought "Oh of course"…Especially birth control stuff. They have had some where they have just cut down to business and then you think "of course, it should be like that", where you have been trying to move around the words forever, right?

The translator focus group did not discuss the use of other PILs, instead they discussed the use of computer-assisted translation (CAT) tools such as translation memories; however, they did not discuss these tools as helpers in the PIL translation process, but instead their potentially constraining nature:

> T-Annika: …some of them have their own…more or less good rules and others just want that you follow the templates and there are so many different templates you have to follow. So when you use a TM [translation memory] if you use a joint TM then it is suddenly a mishmash…
>
> …
>
> T-Jonas: And if you have another translation company between you and the client…then there is such a long way to the client and then you don't know if it is the other translation company who has fiddled with it or whether it is the end client who has done it. And then TMs are swapped and yes…in the end you just grab a cup of coffee.
>
> …
>
> T-Lone: Yes, but if you translate and there is another proofer somewhere else, I mean if it is from an agency, then there is a proofer somewhere and you don't always get any feedback as to what has been changed. And then we get those chaotic TMs where all kinds of things are pieced together. It is not good. It is definitely not good.

These excerpts show that the translators find that the translation memory tools can potentially be detrimental to the lay-friendliness in PILs. Jonas goes on to give an example of how problematic they can be, especially for translation between English and Danish:

> T-Jonas: But I actually have a good example of how broad English is, I mean how broad it is as a source text, both for experts and lay people. That is when you translate clinical trial documents. I remember that there was some kind of description of a trial and then it was repeated exactly again in the end with the informed consent for the participant. It said the exact same thing again and it came up in the TM as a 100% match. Exactly the same, but it was the expert text tailored for doctors, but here it was suddenly for the trial participant who might be there with a coarctation of the aorta where you would need to go down a level, but it was formulated in the exact same way in English.
>
> T-Lone: Yes, that is the problem.

T-Jonas: Then you actually need to go in and scrap everything you have made in that part of the text. So that is actually the disadvantage, you are sometimes lead in a direction which it too complex and expert.

This concludes the results section. Below, the results will be discussed.

7.4. Discussion and conclusions

This third study had three main purposes: first, to investigate why there were differences between translators and pharmacists in relation to Latin-based terms and nominalization in study 2, the PIL corpus study, second, to investigate why the many other linguistic factors said to be detrimental to lay-friendliness were found extensively in both the professional translator corpus and the pharmacist corpus, and third, the focus groups served to create further understanding of the phenomenon of PIL translation beyond what was found in studies 1 and 2. The focus group study provided knowledge on all three of these purposes.

7.4.1. Lay-friendliness

Participants in both groups argued that in general LB terms should be avoided in Danish PILs. One exception was the use of the expert term *injektion*, which two of the pharmacists said that they would use (instead of the lay term *indsprøjtning*). These two pharmacists were also the only ones without pharmacy experience, who had entered PIL translation straight from pharmacist school, which they themselves argue is linked to their problems translating PILs. They find that it is easier to translate the expert Summary of Product Characteristics, because they can use a more source text-oriented translation strategy and maintain the expert language. The reasons for choosing *injection* were unfortunately not discussed further; however, it is problematic that these pharmacists would maintain the LB term, because a suitable Danish lay term exists, which carries the same semantic content as the LB term.

In her MA thesis, Ottzen tested 10 Latin-based terms using a questionnaire answered by 44 non-medically educated Danes at a pharmacy (Ottzen, 2012). Even though a small-scale study, some of the results are interesting for the discussion here. The verb *injicere* [inject] was understood by less than half of the participants. The verb *injicere* might be more difficult to understand than the noun *injektion*, but the fact that two of the pharmacists want to maintain it is likely to lead to comprehension problems. The decision to use such a LB term could thus also mean that similar decisions are made in relation to maintaining other LB terms.

For the other LB terms, the two groups agree that LB terms should be avoided; however, there are some situations where the LB terms should be maintained, which can serve

as explanation for the many LB terms still existent in PILs. The participants argue for the maintenance of the LB term along with the Danish lay term if there is a chance that the doctor might use the LB term. For some LB terms, there are legal requirements in place which dictate their use. Sometimes the Danish term might be too impolite and patronizing, such as the word *pimples* and therefore *acne* is used as a euphemism. And finally, for some LB terms, the groups argue that the LB term has crossed over into lay terminology and therefore can be used, which is the case for *akne* and *inkontinens*. The participants do not state what they base this conception on. The danger of arguing that *akne* and *inkontinens* also belong to lay terminology is that both groups might have too much of an expert status to assess the knowledge of lay people; something which was expressed both by the two pharmacists without pharmacy experience and one of the translators who says that state-authorised translators have an academic background, which might affect their ability to assess the level of lay knowledge. Furthermore, even though the term *inkontinens* was not tested in the above-mentioned small-scale study by Ottzen, another term which could be argued to be equally wide-spread was tested, i.e. *intolerans* [intolerance]. Just over 25% of the participants understood the meaning of *intolerans* even though 32% (14 out of 44 participants) more said they that understood it, but their explanations showed that they did not. Therefore, the use of such a term, even though it is widely used, might create problems of comprehension, but could also potentially have even worse consequences, because the receiver might think they understand it, but have a different meaning in mind.

Study 2 concluded that the pharmacist corpus introduced significantly more nominalisations than the translator corpus. The qualitative focus group study provided explanatory material for this result. All the translators agreed that they would avoid the nominalization and prefer the infinitive showing knowledge that this option is often the better option for the lay person. The majority of the pharmacists on the other hand preferred the nominalization. Only one pharmacist contested this. The pharmacists seem to refer back to their expert background when arguing for the nominalization, i.e. to “make the language more expert term-based” instead of “like a novel”, because it is more “correct” and “how one says it”. In the discussion of nominalisation in study 2, I argued that the pharmacists “also seem to be less aware of what makes a text syntactically complex and of the possible deagentivizing effect of nominalization” as a result of their “lack of linguistic knowledge about how to adjust the level of formality and accessibility of a text”. However, the focus group showed that pharmacists actually show awareness that the nominalization is the less less-friendly option: “But I am aware that if you have to try to write in more patient-friendly language, then I have to choose number two [the infinitive] (P-Louise). However, they still want to maintain them

in the PIL. One pharmacist also argues for more expert-oriented language to enable patients to distance themselves from the text and thus the disease.

There might be some limitations to this result. The focus group participants were only presented with one example of nominalization versus infinitive. It is possible that other examples may have elicited different responses. However, the translators were very explicit about their preference for the infinitive as this was the less formal option for lay receiver. The pharmacists, except P-Hanne, were also clear in their preference for the nominalization.

There is a clear difference between the two groups in relation to metalinguistic knowledge. The translators show language expertise by using metalinguistic terminology to argue for their various preferences. The pharmacists did not express any metalinguistic knowledge explicitly. A few times, a few of the pharmacists showed a lack of linguistic competence in their utterances about linguistic choices such as the deletion of relative pronouns and a misunderstanding of what passive voice entails. Some of the pharmacists also expressed sometimes having difficulties making a professionally informed decision for different language options. Maybe as a consequence of this, they value the expertise of other specialist groups, like translators, some of whom they say have more linguistic ability. These problems making an informed decision also make the translation process very time-consuming for the pharmacists, and sometimes, they end up just choosing some option. Despite these difficulties, the pharmacists do show a certain understanding of language and lay-friendliness.

7.4.2. Translation

We saw in Chapter 3 that the functionalist approach frames translation as a complex expert activity, the function and the receiver of the target text as the leading yardstick in translation, and the translator as a responsible expert. We saw in Chapter 2 that EMA seems to have a different conception of translation than Translation Studies, i.e. that one-to-one translation is possible, and in the PIL context even desirable, which is expressed in their legislation by the fact that the English source text is the approved and readability-tested text. But how do PIL translators see translation and their role as translators? Even though the pharmacists do not have any translation training, some of them seem to be aware of the demanding and complex nature of translation. P-Hanne in the pharmacist group shows awareness that a good source text does not necessarily lead to a good target text. In both groups, the PIL receiver was very often mentioned as the most important factor to take into consideration. However, when nominalization was discussed in the pharmacist group, four of the five participants prefer their expert language, which shows that they do not have a fully functional approach to translation.

The translator focus group had several conversations concerning the role of the translator and the exercising of expert competences. T-Cathrine and T-Lone in the translator focus group construct the translator's role as one linked to communication. T-Torben argues that the role of the translator is to make the text easier to understand by going back to the client as asking for clarification if necessary. The translators also seem comfortable exercising their expertise by educating clients on non-lay-friendly choices made in previous translations (e.g. T-Lone: "then I inform the client that this is not good enough" and T-Cathrine: "but it doesn't really make sense in Danish to do a one-to-one translation").

The problem does not seem to be only linked to the translation competence of the PIL translators, but their contextual environment which sometimes does not allow them to be experts. In several instances in the translator group, the translators expressed their frustration with trying to exercise their expertise, but not being able to because of the client, and it seems to be very client-specific whether the translators are allowed to change something. One example was given in the translator group where the client makes changes in the translation without telling the translator, and then the next time, the translator makes the same choices to the dismay of the client. The professional translators also feel constrained in their expertise by clients who lack the linguistic understanding of what translation entails.

Especially the translators comment on the fact that they feel overruled by other parties in the PIL process, parties who might not have the sufficient linguistic knowledge and skills such as doctors who have the expert competence, but who lack linguistic competence. The medical expertise is also sometimes used as an argument against the translators' expertise: "some doctors have said that it is called like that", no matter how many times the translator argues for something different: "And then you can pull as many search results out as you want which show that this is actually used a lot more in this way, but it can be like talking to deaf ears sometimes" (T-Torben). The pharmacists primarily feel overruled by the reviewers at the DHMA.

The pharmacists argue that some translators do not have sufficient PIL translation competence; however, the focus group showed that this might be caused by the long communication chain as the needed information might not have been passed along to the translators, which shows disagreement between who is responsible for this task in the PIL translation process. One example is that the pharmaceutical companies fail to inform the translators of the existence of regulations and standards in their translation briefs or reference material. Another example is P-Louise's comment "…but also clinical terms that are not translated correctly like **we** want it to be translated", which shows that the pharmaceutical companies have specific preferences, but they do not seem to realize the importance of

briefing the translators on skopos and rules to be adhered to (e.g. lactose). According to Vermeer, it is important that the commissioner is aware "that the translator is the commissioner's partner who works for him and collaborates with him in order to achieve and optimum result of their joint efforts and therefore needs the commissioner's confidence and goodwill and collaboration" (Vermeer, 1994, p. 14). Vermeer thus sees that lack of communication with the translator as problematic, but goes on to argue that it often happens: "How often do people deny the translator the necessary information about documents, for example, because they are considered top secret. Can a lawyer or a doctor work efficiently if you hide important information from them? Would they work under such conditions?" (Vermeer, 1994, p. 14). This quote shows the lack of acknowledgement of the expertise and the status of the translators, something which also seems to be a problem in PIL translation.

The pharmacists do not seem to be aware of the distinction between translators (oversættere) and state-authorised translators (translatører), and when asked about the difference, one pharmacist says "now it is becoming a bit nerdy, right?", which shows that they are not aware of the extensive educational background of state-authorised translators. Moreover, if they think such a distinction is nerdy, what would they think is pedantry linguistically? The lack of knowledge about this distinction also makes it difficult for them to choose a good translator, exemplified by one of the pharmacists: P-Katja: "So…You have to be a little lucky or select the right one to get a good translator I would say".

Some of the pharmacists make comments that there might be some rivalry between pharmacists and translators. P-Hanne twice mentions "secret code words", which are words for which there are specific rules (such as the fact that *lactose* must be spelled with a 'c'). The pharmacists argue that the reviewers at DHMA are able to see which PILs have been translated only by translators, because they have not used these secret code words:

> P-Louise: I have also heard from some of the people at the DHMA who are reading them that they can see a difference. When it has only been with a translator.
> P-Hanne: Yes, haha.

Similarly, P-Louise mentions that for some specific rules that the translators might not know, she always "catches" them. "But if you don't know that legislation exists…and we have used many different translators…It is one of those places I almost always catch them". It was not clear from the pharmacist focus group why the translators are not informed about the legal regulations for such specific terms.

Some of the participants said that they had in fact never translated a PIL from the

beginning, but had mainly translated amendments, which could mean that they do not have a holistic conception of what translation entails.

In conclusion, we see that pharmacists know the skopos (ability to establish skopos); however, the fulfilment is likely to be problematic because of the three following factors:

- Inability to make informed decisions concerning (lay-friendly) translation choices
- Unwillingness to use lay-friendly translation choices, e.g. "make the language more expert term-based" instead of "too much like a novel" and "more correct Danish"
- Curse of expertise, e.g. not knowing what terms might be difficult for lay people, e.g. *injektion* and *inkontinens*.

The last bullet is also relevant for the professional translators, who argue that *akne* and *inkontinens* are commonly known words.

When asked about the receiver of PILs, some participants in both focus groups discussed the fact that the PIL receiver group is very broad and heterogeneous and therefore, a lowest common denominator must be adopted and everything be optimally simplified. However, both groups still wanted to maintain some LB terms, showing a non-optimal approach to lowest common denominator.

Both groups of PIL translators do not only feel constrained in their expertise by other parties in the translation process; they are also frustrated by the many other contextual constraints which limit their translation choices.

7.4.3. Contextual constraints

Very early in the focus group analysis, it became obvious that intratextual lay-friendliness and translation challenges of PILs played a minor role for the focus group participants compared to contextual challenges and constraints. Only few categories emerged related to linguistic challenges whereas an extensive amount of categories were contextual; often categories outside the PIL translators' power, mainly categories which were consequences of the extensive legal authorization process. Examples include the translation of small amendments, which lead to inconsistent language use, the limiting nature of the templates and national guidelines, which contain poor language, and the status of the source text as the authorized text, results showing that the majority of the translators would prefer to produce the Danish PIL from scratch. All the PIL translators expressed their frustration with the time constraints of the translation part of the authorization process and the pharmacists especially expressed exasperation at spending time on other issues which might not benefit the PIL receiver. The

strict deadlines sometimes result in the PIL translators yielding even though they would have preferred arguing for a different translation choice.

According to one of the pharmacists (P-Louise), the English originals are produced without consideration of translation. This thus means that EMA's requirement that "during the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way" (see also pages 23-24) has not been fulfilled. It could be argued that this should not cause problems because a trained translator would be able to translate any source text. The problem with PIL translation is, however, that the source text is the authorized text and therefore, the translator cannot delete sections - as P-Hanne argues: "you will still repeat yourself in 117 different ways in those standard paragraphs which have to be there".

The professional translator group discussed the financial constraints of their work and how this might influence the final products. The pharmacists discussed the linguistic review at the DHMA extensively and how the two people responsible for the reviews seem to disagree with each other on quality criteria, there criteria change from one day to the next. These discussions also showed the importance of the gate-keeper function of the person responsible for the reviews. NN, who used to be in charge, allowed more functional translation choices than what is currently allowed. She also educated the pharmacists on linguistic and translational choices and knowledge.

The long communication chain between the authorities responsible for legislation and the translators has previously been acknowledged in the literature: "The communication chain from the legislators and sensible reflection papers to the organization that is franchised to write the new texts, its medical writers, and finally, the translators is a long one and as a result the ideals of the reflection papers are not fully implemented in the end texts" (Askehave & Zethsen, 2008, p. 187). The consequences of the communication chain just between pharmaceutical company and translator became evident in the focus group as information and feedback sometimes get lost in the process.

Another interesting finding was the issues of balancing different interests in PIL translation such as consistency vs. good language and whether the PIL is supposed to be a legal document or patient information. The PIL translators were also frustrated by unclear quality criteria sometimes provided by clients with lack of language and/or translation awareness. One of the professional translators explains attempting to argue for a choice which would increase the quality, but is told by the client that "this is good enough for us like this".

Sometimes it is not the constraints themselves, but the perception of constraints. One translator, T-Torben, argues that the constraints do not necessarily lie in the legal regulations, but in the client's interpretation of the constraints. This perception of constraints can be said to equally relevant as actual constraints, following Scott & Briggs "If people in a given social setting…perceive something about it to be true that is not, it is their perception rather than the actuality that will govern their behavior" (2009, p. 231). The focus groups also showed that the fear of non-authorisation if the translation deviates from the source text might be somewhat unwarranted. According to P-Louise in the pharmacist group, NN at the DHMA taught her that it was possible to combine consistency and good language, and even though NN is not at the DHMA anymore, P-Louise has successfully changed sections in the PIL without problems. P-Katja argues that target text-orientation used to be easier in the past when NN was at the DHMA. In general, both focus groups expressed their frustration with the non-transparency concerning the degree of freedom in the translation process showing that there is a need for more communication about this.

Intertextuality

Intertextuality in PILs is not a new idea – legally there must be intertextuality between the SPC and the PIL; however, it is a new finding that this is not the only form of intertextuality. The focus groups revealed that a high degree of PIL intertextuality exists because pharmacist translators use previously authorized PILs, either directly from other companies or through the tool *Medicinal Products Corpus*. The use of this tool could be the reason why some strange translation choices are made in some PILs (see for example lack of lexical cohesion on pages 142-145) as previously authorized choices might be recycled. The pharmacists in this study were aware of the potential danger of recycling poor translation; however, other less aware translators might argue that the choices made in an old PIL could be perceived as validated, functional translation choices even though this might be the case just because of the fact that these PILs are authorized.

The forced degree of intertextuality can also be a constraint. In the translator group, the high degree of intertextuality is perceived as a potentially limiting, because it has become an excuse used by the pharmaceutical company to maintain expressions that are not ideal for the receiver ("but we have always called it that", and "that version is authorized so you can't change it"). Also, some translation memories might be inconsistent because the client might have made changes to the document after the translator has delivered it, and these changes have then not been implemented in the translation memory.

7.4.4. Limitation of focus group study

Naturally, the focus group can only say something about the topics discussed by the participants who agreed to participate, which means it is possible to speculate whether those professional translators and pharmacists who did not take part would have had different opinions and comments. One could argue that the participants in these focus groups – as is probably the case with any focus group – are the ones who are most interested in the topic of PILs and PIL translation. This may mean that they are the ones who are most aware of the potential issues in PILs, and thus, they are maybe not the PIL translators who make the most non-lay-friendly choices. However, the recruited participants are argued to be well-chosen as they must be some of the most experienced PIL translators with several of them having translated between 200 and 2000 PILs.

Another potential issue is of course the relation between attitude and action. It is not possible to know what the relation is between what the participants say in the focus group interview and what they do in practice. As mentioned in the introduction to the focus group method, the group dynamics assist the data collection; however, the group situation can also have several effects on the group participants. According to Morgan, the following group effects can happen in focus group (1997, p. 15):

- Conformity processes: participants adapt to each other and to the dominant consensus in the group.
- Polarisation processes: different opinions in the group are made extreme or polarised.

Whether and in which way any of these group effects have influenced the two focus groups is a speculative question. It is impossible to give definite answers to this question, but some factors are relevant to mention. It is difficult to know whether dominant views or participants override any minority opinions; however, it should be noted that in the pharmacist group, two of the pharmacists were younger and more inexperienced with PIL translation than the three other more experienced pharmacists. These two pharmacists did not share as much information as the other three. In the translator group, all four state-authorized translators knew each other, and only the translator with the Arts background did not know anyone else. It is difficult to say whether their knowledge of each other influenced the group processes; as the state-authorized translator business is quite small in Denmark, there might be issues that were not revealed in the focus group.

New limitations of study 1 and 2 found

Through the focus group in study 3, some results were found that might have an impact on the results of study 2. It was seen in study 3 that there is a degree of intertextuality in PILs, both because of the translation memories used by the translators in which previous choices might have been recycled. Furthermore, the pharmacists stated that they borrow choices from other PILs, either through the tool Medicinal Products Corpus or from PILs found at EMA's website. Therefore, some translation choices might not be original choices made by the PIL translators. However, if professional, the translators should be at an expert level enabling them to only implement lay-friendly choices.

A potential limitation in study 1 became evident in the pharmacist focus group. In study 1, pharmaceutical companies were contacted and asked what type of translator they use of the translation of PILs. Choices were given of both translator [oversætter] and state-authorised translator [translatør]. In the focus group, it was seen that some of the pharmacists did not know the differences between these two kinds of translators. This uncertainty of the difference between translator types might also be present in the answers provided by the pharmaceutical companies in study 1.

This sums up the third study of the dissertation. In the following, final chapter, the overall results are synthesized and discussed.

8. Discussion and conclusion

Following the iterative sequential research design, the discussions and conclusions relevant for each study have been presented in their respective chapters. The aim of this chapter is thus to synthesize the findings from the three studies in the dissertation with a view to addressing the main research question, i.e.:

> *Do the profiles and thus translation competence of PIL translators influence the linguistic complexity of translated PILs?*

The dissertation started out with the main aim of investigating why translated Danish PILs are more linguistically complex than their English source texts as concluded by Askehave & Zethsen (2002). Based on a literature review of previous PIL research, it was suggested that this increase in complexity could be linked to the PIL translators and their pharmaceutical background and novice translation status. To provide empirical backing for this, the main aim of this thesis was to investigate PIL translators and their competence in relation to PIL translation and lay-friendliness – one of the skopoi of PIL translation. The synthesized findings cover the following four themes:

1. Translation competence
2. Translation approaches
3. Contextual constraints
4. Expertise and power

After the discussion of these four themes, the overall conclusions are drawn. Finally, the theoretical, methodological, professional as well as social and policy-related contributions are presented before relevant future perspectives are outlined.

8.1. Translation competence

Based on a review of the contextual environment of PILs and of previous literature (Chapter 2), the first aim was to identify Danish PIL translators. Askehave & Zethsen's study from 2000, which states that PILs were generally translated by pharmacists at that point in time (Askehave & Zethsen, 2002, p. 27) was only supported to some extent as study 1 shows that many pharmaceutical companies also use professional translators; however, the majority of EU PILs are from companies that use pharmacists as translators. The results of this first study form the basis for the title of the thesis: Translators of Patient Information Leaflets: Translation experts or expert translators? On the one hand, we have professional translators who are translation experts, and on the other hand, we have pharmacists, who are

pharmaceutical experts and de facto (novice) translators. The hypothetical competences of these two kinds of PIL translators were mapped against the PACTE competence model and a literature review of research on medical translators. Chapter 5 concluded that there are likely differences in translation competence between professional translators and pharmacists especially in relation to the translation-specific sub-competences *knowledge about translation sub-competence, instrumental sub-competence* and *strategic sub-competence*. It was concluded that the hypothesized lack of sub-competences on the part of pharmacists could lead to differences of detriment to lay-friendliness in PILs translated by pharmacists compared to PILs translated by professional translators. This hypothesis was investigated in study 2 in translation products and further qualified in study 3 in the focus group. The overall discussions and conclusions about the translation competence of PIL translators are presented below.

As for the first sub-competence, bilingual sub-competence, the corpus analysis in study 2 showed extensive interference control problems in both sub-corpora such as the use of English spelling and unidiomatic Danish expressions, but there were not enough instances for quantitative comparison. In the focus group, it became evident that extensive metalinguistic knowledge is possessed by the interviewed professional translators, but that the interviewed pharmacists lack metalinguistic knowledge. As this sub-competence also includes knowledge about different language registers and knowledge about which pragmatic conventions are acceptable in the specific context, it can be seen that the significantly larger number of LB terms and nominalisations in the pharmacist corpus gives evidence to a lack of bilingual sub-competence. The use of nominalisation was also argued for by four of the five pharmacists in the focus group showing a lack of register knowledge. Similarly, two of the pharmacists argued for the use of the LB term *injection.* Thus, some of the pharmacists show a lack of knowledge that these elements belong to expert register and be avoided in PILs. It could be argued that both PIL translator groups lack this bilingual competence to some extent as they argue for the use of the LB terms *inkontinens* and *akne.* Finally, this sub-competence also includes knowledge about the use of cohesion, for which problems in the corpus analysis were found with both sub-corpora containing cohesion problems in the form of inconsistent use of specific terminology; however, this result can be explained by the focus group results which showed that PILs are amended quite extensively, which means that only a small section of the PIL might be changed and new terminology might be used – either because of new legislation in the area or because the translator might not see the rest of the PIL, because when the PIL is sent to professional translators, they would only receive payment for the small

amendment. Therefore, the lack of cohesion is not necessarily a result of lacking bilingual competence.

In relation to the extra-linguistic sub-competence, the corpus analysis found a few instances related to the lack of accuracy of some specialised expressions such as *hives* (translated as *gasping for breath* in pharmacist corpus), and *choke* (translated as *go into shock* in translator corpus). However, in general, in relation to pharmaceutical and medical knowledge, the corpus analysis displayed very few instances showing a lack of this sub-competence. This could be a consequence of both PIL translator groups having sufficient extra-linguistic sub-competence. When looking at the profiles of the professional translators included in the focus group, it was seen that all five professional translators had specialised in medical translation through translation experience, and one of the translators has translated or reviewed 1000 PILs and another between 1000 and 2000 PILs. The latter had also studied medicine for two years. So it might be argued that some of these translators actually are a kind of semi-experts. However, another explanation could also be related to accuracy not being the main focus of the analysis, which mainly focused on lay-friendliness. The lack of problems found in relation to this competence could also be linked to the extensive legal review mechanisms we saw in Chapter 2. QRD form 1 mainly checks accuracy of content and therefore, any problems with medical or pharmaceutical knowledge might have been changed already. The only indication of a lack of extra-linguistic knowledge in PIL translators is some of the utterances from the pharmacists in the focus group. Some of the pharmacists blame some of the translators they have used previously for not having sufficient extra-linguistic knowledge, e.g. specialist clinical understanding needed for the translation of some words. This could be explained by the fact that some translators of PILs might not be professional, trained translators. The pharmaceutical companies might not have been able to distinguish between different translator types and their competences as some of them are unaware of the distinction between translators and state-authorised translators. Another explanation could be that the translators have not been optimally informed about which terminology is required as the focus group showed that some of the pharmacists, when acting as translator clients, are unaware of what information and material translators need to make an optimal translation.

Knowledge about translation sub-competence is difficult to assess in a product study; however, as it includes knowledge about translation units, strategies and problems, it overlaps somewhat with bilingual sub-competence and similar conclusions can thus be drawn. The sub-competence includes knowledge of translation briefs, clients and audiences, and the corpus analysis shows that both sub-corpora struggle to tailor for the PIL audience optimally, though this is especially the case for the pharmacist corpus. Based on the focus group, it can

be concluded that this sub-competence was not possessed by the pharmacists, who lacked the terminology and knowledge to discuss translation choices. There also seems to be a lack of knowledge by some of the pharmacists in relation to the translation profession. An example is that some of them do not seem to be aware of the information required by translators to perform optimal translation. Finally, when asked in the background question sheets about translation training, all the pharmacists wrote that they have no translation training; therefore, they cannot be expected to have extensive knowledge about translation. This could of course be different for other pharmacists-cum-translators.

Instrumental sub-competence can only be assessed in the focus group. The pharmacists do not seem to use translation memory tools, but they use other tools such as the Medicinal Products Corpus and other PILs and are aware of their potential weaknesses, such as using them critically and thus ensuring that bad translations are not recycled. It could be argued that even though they are aware of these potential dangers, they might not be able to fully assess the previous translation choices because they lack several other translation sub-competences. The interviewed professional translators use translation memories and are aware of their limitations; they discuss the problems in relation to lay-friendly translation of such tools several times.

As for strategic sub-competence, the results of the corpus analysis showed that both the pharmacist corpus and the professional translator corpus included many translation choices where it could be argued that the translator has lacked the ability to identify translation problems and apply suitable procedures to these problems; both because of the extensive amount of literal translation choices as well as the choices which lead to increased complexity in the translated PILs. The pharmacist corpus could be said to lack this strategic ability more than the professional translator corpus, at least in relation to the two parameters of Latin-based terms and nominalisation. This supports Askehave & Zethsen's results that pharmacists "lack the ability to down-grade their special language to accommodate the non-specialist target group" (2000b, p. 68), and that they are not able to lower the level of formality in a text (2003, p. 39). Thus, based on study 2, it was seen that the pharmacist corpus had more problems applying suitable procedures than the translators; however, also many non-lay-friendly choices were found in the translator corpus. When these results were qualified in the focus group, it became clear that the pharmacists generally seemed to have more problems with this competence as they found it difficult to make informed choices in relation to micro level translation problems. According to Alves & Goncalves, such insecurity concerning decision-making is a characteristic of novice translators compared to expert translators who tend to be more daring and prepared to take responsibility for the changes

they implement in target texts (Alves & Gonçalves, 2007, p. 16). Finally, it could be argued that some of the interviewed pharmacists might lack this competence and a holistic overview of translation because they have never translated a PIL from start to finish, but have only translated amendments.

In conclusion, the pharmacists seem to lack more of the sub-competences making up overall translation competence than professional translators in relation to PIL translation and in relation to ensuring lay-friendliness. However, Chapter 7 also concluded that many other factors than translation competence are relevant for the increase in complexity in translated PILs. First of all, the approach to translation can influence the final PIL product. Translation approaches is thus the second theme to be discussed below.

The focus group study revealed that translation competence is difficult to measure in a study of PIL translation because of the constraints listed in Chapter 2, such as the status of the source text and time constraints. Many additional constraints were presented by the focus group participants, and therefore, the importance of constraints in PIL translation is discussed as the third theme. Closely linked to these constraints is the fourth theme, which involves expertise and power in PIL translation.

8.2. Translation approaches

The PACTE competence model as presented in this dissertation does not include the approach to translation explicitly in a sub-competence; only the sub-competence *knowledge about translation* can be said to touch upon the subject (knowledge about professional translation practice such as how to work with different types of briefs, clients and audiences). In one of PACTE's latest studies (PACTE, 2011), however, they found that the approach to translation also affects and is affected by translation competence. PACTE argues that a dynamic concept of translation and approach to translation is a characteristic of translation competence and determines the acceptability of translations (PACTE, 2011, p. 50). They define a *dynamic* concept and approach to translation to be textual, communicative and functional (like the functionalist approach in this dissertation) as opposed to a static concept and approach, which may be defined as linguistic and literal (related to an equivalence approach) (PACTE, 2011, p. 31). A close relationship has been found between an overall dynamic concept of translation, a dynamic approach to the translation of a specific text, and a dynamic approach to the translation problems posed in the text, and the acceptability of the solutions found to these problems. Even though not stated explicitly, PACTE thus seems to extend their model of competence to also include the approach to translation as part of competence. The approach

to translation taken by the PIL translators can thus be a function of translation competence as well.

The professional translator focus group showed a functional approach to translation evidenced by their approach to the translator's role as one linked to communication and tailoring for the receiver group. The same seems to be the case for the pharmacists in that they (generally – exceptions are listed above, i.e. LB terms, nominalisation and sticking to expert language) focus on the needs of the receivers and the function of the target text. Some of them also explicitly say that they have a meaning-based approach to the translation task. However, as seen by PACTE, an overall dynamic, functionalist approach to translation is not sufficient; the translator also needs to have a functionalist approach to a specific text and to the specific translation problems in that text:

> [r]esults obtained to date, however, have shown that only expertise in translation enables subjects to convert this overall dynamic approach to the translation of a specific text into a dynamic approach to translation problems in a text and acceptable solutions within a given context. (PACTE, 2011, p. 50)

This could thus be seen as a three-step ladder of 1) skopos establishment, 2) skopos operationalization and 3) subsequent fulfilment of a skopos. In Chapter 7, it was concluded that some of the pharmacists are able to establish the skopos of PIL translation, and they see the target text function and audience as the purpose of PIL translation; however, one could argue that they might have difficulties with 2) operationalization, because for some lay-friendliness elements, they are unaware what makes a text difficult (nominalisation and some LB terms). They might have difficulties with 3) fulfilment, because they seemed to struggle to make informed decisions and would struggle to argue for translation choices made because they lack metalinguistic knowledge and terminology. It could, however, be argued that the translators have some problems with fully operationalizing a lowest common denominator approach as they argue for the maintenance of the LB terms *acne* and *inkontinens*.

The main problem with the PACTE competence model for the purpose of this study is that it does not take the contextual, social world into consideration. In the focus group, it became apparent that especially the professional translators' competence was not able to fully unfold in PIL translation. The professional translators argued that they try to exercise their expertise by discussing issues with clients, but sometimes, they find that it is like talking to "deaf ears". Such contextual constraints of the translators' expertise and their consequences in relation to lay-friendliness are discussed below.

8.3. Contextual constraints

Based on the above, we can conclude that translation competence including the approach to translation plays a role when discussing why Danish PILs are less lay-friendly than their source text; however, they are not the only relevant factors when investigating why translated PILs are more difficult to understand than their English source texts. The importance and potentially negative influence on the translation product of contextual factors became very clear in the focus groups as such contextual constraints were discussed much more extensively in both groups than intratextual, translation issues. Based on the literature review in Chapter 2, some contextual constraints were already known, such as:

- The templates, which must be followed
- The status of source text as the authorised text
- The limited time for producing translations and checking translations

The focus group provided further evidence for the impact of these factors on lay-friendliness in PILs. These are discussed below.

8.3.1. PIL templates

Some of the previously suggested constraints were confirmed in the focus group, such as the constraining nature of the PIL templates, which limit PIL translators in their formulations, force the translators to use sub-optimal expressions (because they contain typos, incomprehensible sentences and words that could be expressed in more lay-friendly ways), and even though the translators sometimes argue against the templates, some clients want to follow them blindly.

8.3.2. Status of source text

Also the status of the source text was found by the PIL translators to be of detriment to lay-friendliness because – as the pharmacists argue – sometimes the source text is written from an English linguistic reality; it seems to be produced by a person with limited knowledge about translation who would hence not know whether or not the text can be easily translated. This thus goes against the readability guideline introduced in Chapter 2, which states that “during the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way”. One could argue that this is not relevant as the translator should have the competence to deal with any source text. However, for PILs where the translation must be quite source text-oriented, this can be problematic, especially because the PIL

translators do not find the degree of acceptable change to be sufficiently clear and transparent. Even one of the pharmacists with many years of experience within the field states that it is difficult to assess how much deviation from the source text is accepted. Therefore, most of the PIL translators would prefer to produce the Danish PIL from scratch as this would result in a more lay-friendly text.

8.3.3. Time constraints

We saw in Chapter 2 that limited time is provided by EMA for the translation of PILs into all EU languages. Because of the strict deadlines, the PIL translators said they have to live with some sub-optimal choices because there is not sufficient time to talk to translation clients or with the reviewers at the DHMA. One of the pharmacists also explains that there is pressure not to be the country responsible for delaying the process.

Based on the results of Chapter 6, the following potential contextual constraints were added to the list:

- Competing skopoi, which involves balancing a smooth and fast authorisation vs. lay-friendliness (based on Askehave & Zethsen (2002, p. 24)
- Institutional linguistic usage (based on Becker Jensen (2007a) and Kjærgaard (2010))

These two constraints were explored in the focus group, and the results are seen below.

8.3.4. Competing skopoi

The competing skopoi explanation suggested by Askehave & Zethsen (2002, p. 24) was also found in the focus group in that the status of the source text and the subsequent literal translation of detriment to lay-friendliness was discussed. Another variant of the competing skopoi was found, i.e. balancing consistency vs. good language. Both groups of translators indicated that they find it difficult to balance consistency (with previous PILs and source texts) with lay-friendly language. There seems to be diverging perceptions in play in relation to this: The translators say that the clients fear that changes, even though they lead to better quality texts, might not be authorized. However, one translator argues that the constraints do not necessarily lie in the legal regulations, but in the client's interpretation of the constraints. Also one of the pharmacists has tried to change elements in the PIL without any problems in the review process whereas another pharmacist states that there is not as much freedom to make target text-oriented translation as there used to be when NN was in charge at the DHMA. Thus, PIL translators find that there is non-transparency in relation to the degree of target text-orientation accepted.

8.3.5. Institutional linguistic usage

Some of the pharmacists seem to be influenced by their educational background. Two of them argue that it is easier to translate the Summary of Product Characteristics because the medical register can be maintained. Furthermore, the majority of the pharmacists argue for the use of language which they state is more correct from an expert point of view, i.e. the use of nominalization. For the professional translators, because they have an extensive academic background, they may at times find it difficult to assess the level of knowledge of lay people exemplified by their argument that all people understand *acne* and *incontinence.* This is in line with the research on the curse of expertise (e.g. Hinds, 1999; Lentz & de Jong, 2009), but further research is necessary to draw conclusions about the influence of expert knowledge on the ability to assess lay knowledge.

Based on the results from the two focus groups, it can be concluded that many more contextual factors constrain the translators' work and their expertise. Conclusions about the contextual constraints found in study 3 will be drawn in the following.

8.3.6. Extensive amendments

The extensive amount of small amendments is of detriment to the fluency of the translation, and the PIL translators are not allowed to change other parts of the PIL, which might contain non-lay-friendly elements. The pharmacists also stated that the extensive amendments take time and focus away from linguistic changes that could improve lay-friendliness for PIL receivers.

8.3.7. Lack of language awareness from client

The professional translators find that there is a lack of language awareness from PIL clients, and different clients have different conceptions of quality criteria. Both types of PIL translators showed awareness and uttered frustration that some of the measures taken by EMA which are supposed to ensure quality, such as the template, have not been tested and may thus not ensure quality.

According to Nord, if the client is unwilling to provide the necessary information, the client has to "take what they get", which often is a target text that may fit many different functions, but not necessarily one that fits all the client's needs (Nord, 2006, p. 30). Such an approach also seems to be taken in PIL translation, when the professional translators feel like they are talking to "deaf ears", and such an approach is understandable in the light of the time constraints and financial constraints; however, it might lead to

problematic results for PIL translation. The solution to this problem might thus be to educate translation clients. The pharmacists, who are de facto translators, but also sometimes function as translation clients when translations are sent to translation agencies, do not have a full understanding of what translators need to perform their jobs exemplified by their failure to provide translators with their preferences for specific terms and with information on relevant legislative regulations.

8.3.8. Linguistic review at the Danish Health and Medicines Authority

The pharmacists argued that the reviewers at the DHMA have different quality criteria. They do not agree on quality criteria between them, and it is also argued that their quality criteria change over time. Both groups find that sometimes unnecessary elements are corrected or elements are even changed, which results in the meaning being changed. The pharmacists argue that with the person who used to be in charge, more freedom was given to tailor for the PIL receiver, which meant better translation choices.

Besides the contextual constraints, the focus groups also showed power relations in PIL translation, which can also impact on the lay-friendliness of the texts. These are discussed below.

8.4. Expertise and power

8.4.1. The translator as expert

According to Hönig, in order to act responsibly, translators must be allowed the freedom to decide what is in their clients' best interests in co-operation with their clients (Hönig, 1998a, p. 89). The professional translators in the focus group interview argue that they try to discuss PIL translation issues with the client, and that sometimes this is successful, at other times, the client does not listen, one reason being that they do not understand the reasons why the translators want something changed. The translators also say that they feel that sometimes it is not worth it trying to contact the client unless in very important cases, depending on the client and the experience they have with that client. In the pharmacist group, the discussion with clients about translation choices was not treated, maybe because the pharmacists themselves also play the client role. Instead, they seem to be answering more to the reviewers at the DHMA, but they did not discuss arguing for certain choices with the reviewers – because of the time pressure, some of them argue that they yield instead.

The professional translators see themselves as experts, which supports the results of previous studies (Dam & Zethsen, 2011, p. 987). They generally exercise this expertise towards clients to ensure an optimal translation product. The pharmacists lack translation

competence and training and therefore might be able to argue for translational choices. As seen in Chapter 3, according to Holz-Mänttäri, what distinguishes expert translators from lay translators is the ability of the expert to substantiate the function of the text (Holz-Mänttäri, 1986, p. 352).

Functionalist approaches do consider the situation that the translator is not viewed as an autonomous expert by other parties; Hönig states that a translator is only able to act responsibly if s/he is recognised as a person and as a partner (Hönig in Schäffner, 1998b, pp. 48-49) . Therefore, as a starting point, to act responsively as experts, translators need to be granted the freedom and expertise to do so. If the translator is to be responsible for the functional success of the target text, s/he must have knowledge of the needs of clients and end-users. The professional translators seem comfortable exercising their expertise by educating clients on non-lay-friendly choices; however, they also found that some of the other agents in PIL translation do not view them as responsible experts and therefore do not grant them the necessary power to exercise this expertise. Similarly to Dam & Zethsen's study of professional translators who said that translation clients do not understand the importance of "involving the translator in the entire process" (Dam & Zethsen, 2010, p. 202), the professional translators of this study especially feel that they sometimes do not receive sufficient information from clients such as the templates that need to be taken into consideration in the translation. The professional PIL translators – even though sometimes they are actively involved in the process and listened to – feel that they are not perceived as experts by other parties. A similar result was found by Dam & Zethsen in that the professional translators of their studies were not considered experts by other parties (2010, p. 205) and in that the professional translators of their studies did not find a large influence and power connected to their job (2011, p. 992). Along the same line, Dam & Zethsen found that 57% of the core employees working with translators in Danish companies estimated translator education duration to be 3-4 years, and 2% even thought the duration was 1-2 years (Dam & Zethsen, 2008, pp. 86-87).

Dam & Zethsen found in their study that one of the opponents for the status of translators is that people do not know what it requires to be a state-authorised translator and they are not aware of the skills possessed by such translators. They are unable to distinguish between de facto translators and state-authorised translators (Dam & Zethsen, 2010, p. 201). Interestingly, in this study, it was found that even the pharmacist de facto translators were not aware of the difference.

The focus group showed several potential power relations at play in PIL translation, which might influence lay-friendliness; these will be discussed below.

8.4.2. Power relations in PIL translation

As seen above, this dissertation is written within the functionalist approach and from the focus groups, it becomes clear that most of the PIL translators have a functionalist approach to translation; however, because of the legal and contextual environment, the professional translators cannot always function as the expert agents they are. There seems to be some power relations which are at stake in PIL translation, especially related to the power of expertise.

Research on the various roles and status of agents in the translation process has been called for by e.g. Chesterman who states:

> [o]ther questions that seem pertinent to research on translation practice concern the relations between translators and other agents, rather than their actual actions: What is the status of the various agents? How is this status manifested? How to translators perceive their own status? (Chesterman, 2006, p. 21)

The results of the focus group do not only shed light on this issue in PIL translation, but they also show the importance of this status in relation to lay-friendliness in translated PILs. Based on the focus group study results, it can be argued that there are several power and status struggles in PIL translation.

First of all, there are potential translator-client relation tensions. The professional translators feel constrained in their expertise by clients who lack the linguistic understanding of what translation entails. As the client is a pharmaceutical company, the subject-matter expertise of the client is used to argue against translation expertise of the professional translators as expressed by T-Torben: "And then you can pull as many search results out as you want which show that this is actually used a lot more in this way, but it can be like talking to deaf ears sometimes". This power struggle between communication experts and subject-matter experts is not a new phenomenon. Becker Jensen argues that it can be difficult for a communication employee to gain permission to change subject-matter experts' texts because the linguistic and communicative competences rank lower in the institutional system than e.g. lawyers and economists (Becker Jensen, 2007a, p. 19), and here maybe pharmacists. Hönig argues for a similar view: "[p]ower rests with those who produce 'originals' – be they journalists, scientists or politicians…they are the experts; translators, in their view, are not" (Hönig, 1998b, p. 22).

Another power struggle seems to exist between the pharmacist translators and the reviewers at the DHMA. This is not a struggle related to subject matter as the reviewers

have similar educational backgrounds as the pharmacists. However, here, different degrees of status seem to be relevant as well as the power of dependence. The pharmacists as marketing applicants must comply with the rules and conventions set by the reviewers as they have the authority to grant or refuse authorisation. The extensive (perceived at least) power of the two reviewers was seen in the focus group when the pharmacists said that they used to have more freedom and used to be allowed to localize the language when the person (NN) who used to be in charge was the reviewer. The lack of metalinguistic knowledge found in the pharmacist focus group could lead to some problems with lay-friendliness because of this power relationship: As seen in Chapter 2, after the Danish Medicines and Health Authority has checked the translations using QRD Form 1, the marketing applicant must state whether all comments have been implemented using QRD Form 2, and if they have not, it must be justified and discussed. In this situation, a trained, professional translator would be able to argue for linguistic translation choices whereas the pharmacists lack the tools and training to do so.

Some quotes in the focus group show that the translators sometimes win the battle of expertise; however, the translators state that they are frequently overruled by the expertise of other parties for example that "some doctors have said that it is called like that". This has similarities with Gal & Prigat's study in which they concluded that the production of PILs is complicated by experts who may for example insist on including additional complex textual elements or technical details to improve medical accuracy (Gal & Prigat, 2005, p. 489).

Finally, there seems to be a power struggle between the PIL translators – the professional translators and pharmacists-cum-translators. An utterance in the pharmacist focus group about catching the translators when they make mistakes shows that there might be some rivalry. It is also mentioned that the DHMA can see when a professional translator has translated the PIL, because they have not completed the secret codes, which shows that there might not a lack of disclosure of certain information to the professional translators.

Some of these issues of status and power also create potential problems for the division of responsibility of different tasks. We saw in the focus group that there seems to be some divergences between the pharmacists and the professional translators as to who is responsible for what in PIL translation. A study by Ruuskanen investigated the roles and responsibility of translators and authors in relation to the translation and editing of medical research articles. She found that "[w]hen a translator accepts a commission for the translation of a medical or other technical text, there is often a very large gap between client and translator in the perception of what the commission entails" (Ruuskanen, 1994, p. 291). She

found that 59% of the medical experts expected translators to have expert knowledge of the terminology (register) of their special field and half of them expected their translators to have basic medical knowledge; however they did not expect them to edit the text very much (p. 299). Furthermore, the translators and editors themselves felt they had more responsibility for the text than their clients were willing to grant them (p. 296). Similar uncertainties about the different responsibilities could be at play in PIL translation.

These results concerning the different roles in PIL translation are interesting from a broader Translation Studies perspective, and they fit well with the studies of translator status conducted by Dam & Zethsen (Dam & Zethsen, 2008, 2009a, 2009b, 2010, 2011). The role of the translator is also said to be inherently closely connected to the issue of power as the translator (or interpreter) often functions as a double agent caught between two camps (Gentzler & Tymoczko, 2002, p. xix). As noted by Gentzler & Tymoczko, power and translation is not only linked to translation products and the way translations influence target societies or lead to cultural transformation and change, but power is also "inherent in the translation process itself" (Gentzler & Tymoczko, 2002, p. xxviii), e.g. seen in the relationship between the translator and the author, source text and translation. However, even though there seems to be consensus about this omnipresence of power in translation, power constraints and relations within non-literary translation often seem to be overlooked in TS publications. The following exchange from *Translation and Quality* (Schäffner, 1998b, p. 44) shows a similar viewpoint:

> Faiq: [w]hen it comes to non-literary types of texts I think that there is some implicit trust between the parties involved in the translation process.
>
> Schäffner: Could we then say that the translator has more power in the case of pragmatic texts types?
>
> Faiq: Probably, yes.

These quotes show the conception that translators of pragmatic, non-literacy texts have more power than literary translators. The studies of this dissertation show that in PIL translation, power issues are at play, and that these power issues can be of detriment to lay-friendliness. Hönig argues that such issues need to be corrected by educating translation clients: "If we had more informed laypeople, then I am sure we could negotiate better and we would get better results in assessing translation quality, on either side" (Hönig in Schäffner, 1998b, p. 44).

8.5. Overall conclusions

When returning to the main aim of this dissertation and the question asked in the title: "Patient Information Leaflet translators: Translation experts or expert translators?", the answer is that expert translators seem to have more translation competence in relation to ensuring lay-friendly PIL translation; however, because of the extensive legal guidelines and regulations in PIL translation, the extensive amount of contextual constraints make it difficult for even highly trained, professional translators to ensure lay-friendliness in PILs. Such constraining factors need to be considered and eliminated before optimal lay-friendliness in PILs can be ensured.

The conclusion of this study forms a further basis for the importance of co-operation between professional translators, with translation competence and metalinguisic knowledge and pharmacists who possess the pharmaceutical knowledge and the procedural knowledge in relation to the PIL production process. Other scholars have suggested that medical translation should be co-operation between a medical professional and a professional translator (Askehave & Zethsen, 2000b, p. 36; O'Neill, 1998, p. 76), and this study thus adds to this research on the importance of co-production of medical translations.

8.6. Contributions

8.6.1. Translation Studies

Functionalism revisited – idealistic or realistic for PIL translation?

> Vermeer's level of abstraction seems to locate skopos theory in an ideal world, unsullied by any of the practical mess of everyday moods and deadlines and human fallibility… (Chesterman, 1998, p. 157)

This quote shows that according to Chesterman, there are some issues with skopos theory. This study can be seen as an empirical investigation of the possibility of functionalist approaches within the limited field of PIL translation. In skopos theory, it is argued that professional translators are experts, but there is a lack of research investigating whether professional translators see themselves as experts and whether they are allowed to be experts. Functionalism does not claim to be empirically based, and the idealistic approach is acknowledged; however, it is still relevant to investigate empirically this framing of the translator as a responsible expert.

In relation to PIL translation, Askehave & Zethsen argued that"[i]n these cases, the translators fail to fulfill their obligation to act as linguistic experts who should intervene

and improve the text according to the new skopos necessitated by the fact that the audience are now Danish consumers" (Askehave & Zethsen, 2002, p. 23). This study can be said to have similar conclusions with the PIL translators not fulfilling their responsibility as experts. However, as discussed above, PIL translators are not allowed to be experts by other agents. Also Vermeer's statement from Chapter 3 that a "translator is made co-responsible for the success of a communicative act, because he, the translation expert, is the crucial factor in it…" (Vermeer, 1994, p. 13) seems idealistic in the light of results of this study. However, this does not mean that idealism should not be strived for in the future.

Translation Studies research has mainly focused on researching student translators or professional translators, and only very limited focus has been given to the translation competence of non-professional de facto translators who are professionals in another field and translate without any translation training. This study sheds some empirical light on these de facto translators, both by analysing the translation products from pharmaceutical companies that use pharmacists as translators and by focus group interviewing these translators. Even though it has been argued that identifying the ideal translator type for medical translation, i.e. whether it should be a medical professional or a translator, is said to be the oldest discussion within the medical translation field (Fischbach, qtd. in Márquez Arroyo, 2007, p. 74), very limited empirical research has been carried out. This study can be seen as a stepping stone for more research into these two types of medical translators.

The functionalist scholar, Christiane Nord, in her 2012 status article on functionalism, expresses her surprise about the limited research conducted focusing on functionalist approaches (Nord, 2012, p. 31). This dissertation can be seen as a small contribution to empirically investigating some of the elements of functionalist approaches such as the operationalization of skopos, the assessment of skopos fulfilment, the role of the translator as an expert and the roles of the other players in PILs translation. This dissertation shows that some of the idealistic viewpoints in functionalism are difficult to exercise in the context of PIL translation – not because of lack of translation competence, but because contextual elements and other agents play a constraining role.

Skopos theory can be seen as having a sociological viewpoint, in that it gives prominence to the role of the client, to the negotiations between translator and client concerning appropriate translation strategies, and the reactions of the reader (Chesterman, 2006, p. 16). In recent years, there has been a call for more research on translation as a social practice witnessed by the publications related to the sociology of translation (e.g. Wolf & Fukari, 2007). In line with this approach has been a call to focus on the main agent in translation as a social practice – the translator. According to Chesterman, many areas within

translation as a social practice are underresearched, such as client-translator relations and translator status and mobility (Chesterman, 2006, p. 9). The sociological context of translation focuses on people (especially translators), their observable group behaviour, their institutions etc. (Chesterman, 2006, p. 11). This study can be seen as shedding some preliminary light on the roles of PIL translators and other agents in the translation process.

In 2009, Chesterman coined the term Translator Studies as a name for the sub-field of Translation Studies, which studies the translator (and the interpreter) (Chesterman, 2009). He argues that naturally all research on translation at least implies that there are translators behind the translations, but many studies in TS do not take the translator as "the primary and explicit focus, the starting point, the central concept of the research question" (2009, p. 14). Therefore, Translator Studies research focuses principally and explicitly on translators; for example their activities or attitudes, their interaction with their social and technical environment (p. 20). Also Pym argues for a focus on the translator: "…the problem of translation studies is probably not that it has to read more philosophy, **but that it should pay more dialectic attention to what *translators* do and say**" (Pym, 2007, p. 44; my emphasis). This study adds some empirical insights into this sub-field of Translator Studies by involving the translators themselves in the research, here by use of focus groups.

8.6.2. Methodological contributions

The study also has methodological contributions. First, the operationalization of lay-friendliness based on Plain Language literature and its adaptation to assessment of translated PILs can be a valuable tool for PIL producers and researchers. The lay-friendliness framework elaborated in this dissertation could be used in other studies investigating interlingual medical translations and might be useful for other language pairs as well. It could also be a useful tool for PIL translators and PIL reviewers.

Second, the example of skopos operationalization is a methodological contribution. Skopos theory has been heavily criticised for not providing information about how to operationalize a skopos (Stolze, 1994, pp. 164-165); here, this criticism is explored, and an example of such operationalization is given.

Third, the iterative sequential research design used in this study had many qualities because it allowed for a dynamic, generative research design with findings from one stage influencing decisions about the next stage. Such a research design made it possible to explore qualitatively and interpretatively the reasons and logics given by the participants themselves and comparing them with the results of quantitative analysis to explain and understand the social practices of the agents in translation. Pragmatist worldviews and mixed

methods approaches seem to be used often within TS, but without using the term and the typological and terminological apparatus provided by mixed methods theory. This study showed how this is a feasible and useful approach for a TS study including several elements.

8.6.3. Professional applicability of the research

We saw in the corpus analysis that many medical terms, especially Latin-based terms, are transferred or introduced into Danish PILs. These are found in both corpora, but it was especially the case in the pharmacist corpus. The focus group results show that some of the pharmacists wanted to maintain LB terms in their translations and all focus group participants argued that the LB term *incontinence* is understood by everyone. It is argued by Becker Jensen (2001, p. 150) and Kjærgaard (2010, pp. 34-35) that changing the expert code is not only a question of writing technique, but also linked to attitudes. Therefore, this study might be used to educate PIL translators, or de-educate them as proposed by Bromme, Rambow & Nückles when "medicine experts communicate with laypersons, it is important that they have an idea which concepts might be familiar to a layperson" (Bromme, et al., 2001, p. 318). It might be helpful to discuss potential lay-friendliness problems with PIL translators, especially the use of nominalization with pharmacists.

The results of the focus group study showed that the pharmacists argued that they struggle to find competent PIL translators. Interestingly, in Denmark, sworn state-authorised translators are required for the translation of legal documents with legal status; however, for medical translation, not such requirements are in place, and therefore, professional translators and pharmacists might need to find other ways to get in contact with each other. Finally, clarity about the division of responsibility in the PIL translation process would be valuable for all parties.

8.6.4. Social applicability of the research

The conclusions of this dissertation have been that there are many problems with lay-friendliness in translated Danish PILs. Using translators with optimal translation competence and giving them the freedom to exercise their expertise is important to ensure that patients are provided with optimally lay-friendly information which enables them easily to act upon the information in an appropriate manner.

This research offers further explanations for the problems in PIL translation; explanations which are essential as figuring out why PILs are not optimally lay-friendly is of social relevance: "Consider the serious complications that could result from a patient's inability to understand and act on printed instructions about immediately reporting significant

side effects of a treatment or medication to the healthcare provider" (Sand-Jecklin, 2007, p. 121). The failure to understand PILs thus have major ethical and medical consequences. Along the same line, this dissertation adds to the growing body of literature on patient-centeredness by investigating PILs and their complexity for the purpose of ensuring better informed and satisfied patients, by providing them with material to support decision-making.

8.6.5. Policy perspectives

Based on the results of this study, the measures currently in place to ensure lay-friendliness in PILs, such as the readability guidelines, the PIL templates and user-testing are not sufficient. The European Commission states that a key objective in medicines safety is to "improve the quality and dissemination of information, so citizens can make informed choices" (European Commission, 2007, para 1). The findings are thus valuable from a policy perspective, providing further insights into the translation process of PILs, and allowing first conclusions about the effect on lay-friendliness when PILs are translated into Danish by the two different types of translators with different levels and areas of expertise. The conclusions of this study form a further basis for the importance of co-operation between professional translators and pharmacists. Three of the contacted companies in study 1 have already implemented this procedure. Based on the conclusions of this study, it would be valuable to ensuring lay-friendliness in PILs that both experts are involved in the translation process.

The implications of showing the difference in lay-friendliness between the original PIL and the Danish version giving further weight to the similar results of Askehave & Zethsen (2002) could be a reconsideration of the current EU legislation that only the English original must be user-tested to ensure lay-friendliness.

Because of the legal guidelines and regulations in PIL translation, the extensive amount of contextual constraints make it difficult for even highly trained, professional translators to ensure lay-friendliness in PILs. It would be useful if policy makers took into consideration that some of the measures in place to ensure quality PILs actually have the opposite consequences. One example is the many lexical cohesion problems in study 2, which were explained in study 3 by the extensive amendments in PILs. To avoid such inconsistency of terminology, which is detrimental to lay-friendliness, the possibility of the PIL translators being allowed to take the entire text into consideration should be considered.

Furthermore, both PIL translator types – even the ones with extensive experience – find that there is not sufficient transparency as to how much can be changed; therefore, it would be valuable for both PIL translators to be able to perform an optimal translation and for

the PIL receiver that the degree of freedom is made clear, and that all parties in the PIL translation process work from similar quality criteria.

As mentioned in Chapter 2, when user-testing was implemented as part of the legal requirements, it must have been based on the assumption that the medical professionals were not able to assess the lay-friendliness of the PIL. Based on the conclusions of this dissertation, and from a Translation Studies point of view, it would be valuable from a lay-friendliness perspective if someone with translation competence became part of the reviewer team of PILs at the Danish Health and Medicines Authority.

8.7. Future research perspectives

The concept of lay-friendliness and its operationalization was based on previous empirical research and theoretical considerations; however, this study did not investigate whether actual PIL users find the same elements of detriment to lay-friendliness. Therefore, a future study testing the lay-friendliness framework with lay people would be valuable to give further empirical evidence to the usefulness of the framework.

Furthermore, because of the great importance of the contextual constraints, it would be interesting to investigate the professional translators' and pharmacists' translation competence under ideal circumstances, without the contextual constraints.

Because of the lack of information about the micro level production processes of monolingual and translated PILs in this study, an ethnographic study of PIL production and translation would be interesting to see the specific macro level and micro level decisions being made and the backgrounds of the various people involved in the process. Such as study would follow one or more English PILs being produced based on the Summary of Product Characteristics, being user tested, being revised accordingly, being translated and checked and revised again. Such a study would provide valuable insights into the roles of the agents of PIL translation such as text producers, translator, reviewers, both in-house at pharmaceutical companies and at the Danish Medicines and Health Authority. Such a study would also shed further light on other potential contextual constraints.

9. Lists of tables and figures

9.1. List of tables

Table 1: Overview of the three empirical studies. 9
Table 2: Fundamental characteristics of the research design. 64
Table 3: Advantages and disadvantages of mixed methods research designs, borrowed from Schmeltz (2012, p. 43). 65
Table 4: Characteristics of the research design of this dissertation. 68
Table 5: Characteristics of study 1. 68
Table 6: Characteristics of study 2. 69
Table 7: Characteristics of study 3. 70
Table 8: Overview of the sub-competences presumed to be possessed by pharmacists and professional translators. 82
Table 9: Strengths and weaknesses of experimental vs. naturalistic studies for the study of PILs. 91
Table 10: PIL corpus. 95
Table 11: Criticism of Plain Language. 107
Table 12: Differences between translators and pharmacists in their use of LB terms. 132
Table 13: Use of LB terms that are likely to influence lay-friendliness negatively. 133
Table 14: Use of nominalization. 133
Table 15: The introduction of a Danish medical term as the translation of a lay item in the English source text. 134
Table 16: Use of compounds. 134
Table 17: Use of officialese expressions. 135
Table 18: Problems of accuracy in target texts. 135
Table 19: Passive voice in source text changed into active voice in target text. 140
Table 20: Active voice in source text changed into passive voice in the target text. 141
Table 21: Imperative in source text changed into passive voice in target text. 141
Table 22: Use of un-Danish expressions in both translator corpora. 147
Table 23. Participants in translator focus group. 167
Table 24: Participants in pharmacist focus group. 168
Table 25: Transcription symbols. 172

9.2. List of figures

Figure 1: Legislative measures related to the production of PILs. 15
Figure 2: Marketing application through the Centralised Procedure, with steps relevant for the production and translation of PILs. 18
Figure 3: Time for translation part of PIL production. 19
Figure 4: The production process of a Danish PIL (Askehave & Zethsen, 2011). 33
Figure 5: The communicative situation of translated PILs. 34
Figure 6: Holmes' map (based on Holmes (1988 (reprinted 2000))), borrowed from Chesterman (2009). 39
Figure 7: Diverging conceptions of translation between Translation Studies and the European Medicines Agency. 54

Figure 8: The interconnection of worldviews, strategies of inquiry and research methods (Creswell, 2009, p. 5). 58
Figure 9: Top-down approach in the meta-physical paradigm. 60
Figure 10: The central role of the research interest in the pragmatism. 61
Figure 11: Overall research design. 67
Figure 12: PACTE translation competence model (PACTE, 2003, p. 58). 74
Figure 13: The translators of Danish PILs used in pharmaceutical companies. 78
Figure 14: Overview of lay-friendliness framework. 119
Figure 15: Analysis procedure. 121
Figure 16: Revised analytic framework. 130
Figure 17: Potentially diverging approaches to translation and the translation process. 156
Figure 18: Potentially diverging and identical conceptions of lay-friendliness in (translated) PILs. 157

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11. List of appendices

1. Danish PIL template
2. English PIL template
3. QRD form 1
4. QRD form 2
5. Email to pharmaceutical companies - study 1
6. Final ethics approval
7. Ethics amendment approval
8. Recruitment email - focus group
9. Background question sheet - translator
10. Background question sheet - pharmacist
11. Preparation email for translators
12. Preparation email for pharmacists
13. Consent form
14. Interview guide
15. Handout with examples for focus group participants
16. Key word posters
17. Transcription of focus group - translators
18. Transcription of focus group - pharmacists

Appendix 1: Danish PIL template

Version 7.3.1, 03/2010

INDLÆGSSEDDEL: INFORMATION TIL BRUGEREN

{Lægemidlets (sær)navn styrke lægemiddelform}

{Aktivt/aktive indholdsstof/indholdsstoffer}

<**Læs denne indlægsseddel grundigt inden <De><du> begynder at <tage> <bruge> medicinen.**

- Gem indlægssedlen. <De><Du> kan få brug for at læse den igen.
- Spørg lægen eller på apoteket, hvis der er mere, <De><du> vil vide.
- <Lægen har ordineret {navn} til <Dem><dig> personligt. Lad derfor være med at give det til andre. Det kan være skadeligt for andre, selvom de har de samme symptomer, som <De><du> har.>
- Tal med lægen eller apoteket, hvis en bivirkning bliver værre, eller <De><du> får bivirkninger, som ikke er nævnt her.> >

<**Læs denne indlægsseddel grundigt. Den indeholder vigtige informationer.**

<De><Du> kan få {navn}uden recept. For at opnå den bedste behandling skal <De><du> være omhyggelig med at følge anvisningerne for {navn}

- Gem indlægssedlen. <De><Du> kan få brug for at læse den igen.
- Spørg på apoteket, hvis der er mere, <De><du> vil vide.
- Kontakt lægen, hvis <De><du> får det værre, eller hvis De/du ikke får det bedre <inden {antal} dage.>
- Tal med lægen eller apoteket, hvis en bivirkning bliver værre, eller <De><du> får bivirkninger, som ikke er nævnt her.> >

Oversigt over indlægssedlen:

1. Virkning og anvendelse

2. Det skal <De><du> vide, før <De><du> begynder at <tage> <bruge> {navn}

3. Sådan skal <De><du> <tage> <bruge> {navn}

4. Bivirkninger

5. Opbevaring

6. Yderligere oplysninger

1. VIRKNING OG ANVENDELSE

<Kun til diagnostisk brug.>

2. DET SKAL <DE><DU> VIDE, FØR <DE><DU> BEGYNDER AT <TAGE> <BRUGE> {NAVN}

<Tag> <brug> ikke {navn}

- <hvis <De><du> er overfølsom (allergisk) over for {det/de aktive stof(fer)} eller et af de øvrige indholdsstoffer.>
- <hvis ...>

Vær ekstra forsigtig med at <tage> <bruge> {navn}

- <hvis <De><du>...>
- <når...>
- <Inden behandling med {navn}>

Brug af anden medicin

<Fortæl det altid til lægen eller på apoteket, hvis <De><du> bruger anden medicin eller har brugt det for nylig. Dette gælder også medicin, som ikke er købt på recept.>

Brug af {navn} sammen med mad og drikke

Graviditet og amning

<Spørg <Deres><din> læge eller apoteket til råds, før <De><du> <tager> <bruger> nogen form for medicin.>

Trafik- og arbejdssikkerhed

<Kør ikke bil eller motorcykel og lad være med at cykle<fordi…>.>

<Lad være med at arbejde med værktøj eller maskiner.>

Vigtig information om nogle af de øvrige indholdsstoffer i {navn}

3. SÅDAN SKAL <DE><DU> <TAGE> <BRUGE> {NAVN}

<Tag/brug altid {navn} nøjagtigt efter lægens anvisning. Er <De><du> i tvivl, så spørg lægen eller på apoteket.> <Den sædvanlige dosis er {angivelse}.>

<Brug til børn>

Hvis <De><du> har <taget> <brugt> for <meget> <mange> {navn} {lægemiddelform}

Hvis <De><du> har glemt at <tage> <bruge> {navn}

<De><Du> må ikke tage en dobbeltdosis som erstatning for den glemte <tablet> <dosis> <...>.>

Hvis <De><du> holder op med at <tage> <bruge> {navn}

<Spørg lægen eller på apoteket, hvis der er noget, <De><du> er i tvivl om.>

4. BIVIRKNINGER

{Navn} kan som al anden medicin give bivirkninger, men ikke alle får bivirkninger.

Tal med lægen eller apoteket, hvis en bivirkning er generende eller bliver værre eller <De><du> får bivirkninger, som ikke er nævnt her.

5. OPBEVARING

[Opbevaring: se Appendiks III]

Opbevares utilgængeligt for børn.

Brug ikke {navn} efter den udløbsdato, der står på pakningen. <Udløbsdatoen (Exp) er den sidste dag i den nævnte måned.>

<Brug ikke {navn}, hvis {beskriv synlige tegn på nedbrydning}.>

<Spørg på apoteket, hvordan <De><du> skal aflevere medicinrester. Af hensyn til miljøet må <De><du> ikke smide medicinrester i afløbet, toilettet eller skraldespanden.>

6. YDERLIGERE OPLYSNINGER

{Navn} indeholder:

- Aktivt stof(fer): {navn(e)}
- Øvrige indholdsstoffer: {navne}

Udseende og pakningsstørrelser

Indehaver af markedsføringstilladelsen og fremstiller

{Navn og adresse}

<{tlf}>

<{fax}>

<{email}>

Hvis <De><du> vil have yderligere oplysninger om {navn}, skal <De><du> henvende dig til den lokale repræsentant:

België/Belgique/Belgien

{Nom/Naam/Name}

<{Adresse/Adres/Anschrift }

B-0000 {Localité/Stad/Stadt}>

Tél/Tel: + {N° de téléphone/Telefoonnummer/

Telefonnummer}

<{e-mail}>

Luxembourg/Luxemburg

{Nom}

<{Adresse}

L-0000 {Localité/Stadt}>

Tél/Tel: + {N° de téléphone/Telefonnummer}

<{e-mail}>

България

{Име}

<{Адрес}

{Град} {Пощенски код}>

Тел.: + {Телефонен номер}

<{e-mail}>

Magyarország

{Név}

<{Cím}

H-0000 {Város}>

Tel.: + {Telefonszám}

<{e-mail}>

Česká republika

{Název}

<{Adresa}

Malta

{Isem, #1618}

<{Indirizz}

CZ {město}>

Tel: +{telefonní číslo}

<{e-mail}>

Danmark

{Navn}

<{Adresse}

DK-0000 {by}>

Tlf: + {Telefonnummer}

<{e-mail}>

Deutschland

{Name}

<{Anschrift}

D-00000 {Stadt}>

Tel: + {Telefonnummer}

<{e-mail}>

Eesti

(Nimi)

<(Aadress)

EE - (Postiindeks) (Linn)>

Tel: +(Telefoninumber)

<{e-mail}>

Ελλάδα

{Όνομα}

MT-0000 {Belt/Raħal}>

Tel: + {Numru tat-telefon}

<{e-mail}>

Nederland

{Naam}

<{Adres}

NL-0000 XX {stad, #452}>

Tel: + {Telefoonnummer}

<{e-mail}>

Norge

{Navn}

<{Adresse}

N-0000 {poststed}>

Tlf: + {Telefonnummer}

<{e-mail}>

Österreich

{Name}

<{Anschrift}

A-00000 {Stadt}>

Tel: + {Telefonnummer}

<{e-mail}>

Polska

{Nazwa/ Nazwisko:}

<{Διεύθυνση}

GR-000 00 {πόλη}>

Τηλ: + {Αριθμός τηλεφώνου}

<{e-mail}>

España

{Nombre}

<{Dirección}

E-00000 {Ciudad}>

Tel: + {Teléfono}

<{e-mail}>

France

{Nom}

<{Adresse}

F-00000 {Localité}>

Tél: + {Numéro de téléphone}

<{e-mail}>

Ireland

{Name}

<{Address}

IRL - {Town} {Code for Dublin}>

Tel: + {Telephone number}

<{e-mail}>

Ísland

<{Adres:}

PL – 00 000{Miasto:}>

Tel.: + {Numer telefonu:}

<{e-mail}>

Portugal

{Nome}

<{Morada}

P-0000–000 {Cidade}

Tel: + {Número de telefone}

<{e-mail}>

România

{Nume}

<{Adresă}

{Oraş} {Cod poştal} – RO>

Tel: + {Număr de telefon}

<{e-mail}>

Slovenija

{Ime}

<{Naslov}

SI-0000 {Mesto}>

Tel: + {telefonska številka}

<{e-mail}>

Slovenská republika

{Nafn}

<{Heimilisfang}

IS-000 {Borg/Bær}>

Sími: + {Símanúmer}

<{Netfang}>

Italia

{Nome}

<{Indirizzo}

I-00000 {Località}>

Tel: + {Numero di telefono}>

<{e-mail}>

Κύπρος

{Όνομα}

<{Διεύθυνση}

CY-000 00 {πόλη}>

Τηλ: + {Αριθμός τηλεφώνου}

<{e-mail}>

Latvija

{Nosaukums}

<{Adrese}

{Pilsēta}, LV{Pasta indekss }>

Tel: + {Telefona numurs}

<{e-mail}>

{Meno}

<{Adresa}

SK-000 00 {Mesto}>

Tel: + {Telefónne číslo}

<{e-mail}>

Suomi/Finland

{Nimi/Namn}

<{Osoite/Adress}

FIN-00000 {Postitoimipaikka/Stad}>

Puh/Tel: + {Puhelinnumero/Telefonnummer}

<{e-mail}>

Sverige

{Namn}

<{Adress}

S-000 00 {Stad, #452}>

Tel: + {Telefonnummer}

<{e-mail}>

United Kingdom

{Name}

<{Address}

{Town} {Postal code} – UK>

Tel: + {Telephone number}

<{e-mail}>

Lietuva

{pavadinimas}

<{adresas}

LT {pašto indeksas} {miestas}>

Tel: +370{telefono numeris}

<{e-mail}>

Denne indlægsseddel blev senest godkendt { MM/ÅÅÅÅ **}**

<{Navn} er godkendt med en ”betinget godkendelse”. Det betyder, at der kommer yderligere information om {Navn}.

Det europæiske Lægemiddelagentur vil hvert år vurdere ny information vedrørende {navn} og vil om nødvendigt opdatere denne indlægsseddel.>

<{Navn} er godkendt under ”særlige omstændigheder”. Det betyder, at det ikke har været muligt at opnå fuldstændig dokumentation for {navn} <fordi det drejer sig om en sjælden sygdom> <af videnskabelige årsager> <af etiske grunde>. Det europæiske Lægemiddelagentur vurderer hvert år ny information vedrørende {navn}, og denne indlægsseddel vil om nødvendigt blive opdateret.>

<De><Du> kan finde yderligere information om {navn}på Det europæiske Lægemiddelagenturs hjemmeside http://www.ema.europa.eu/. <Der er også links til websites om sjældne sygdomme, og hvordan de behandles.>

<----------

<Følgende oplysninger er tiltænkt læger og sundhedspersonale:>>

Appendix 2: English PIL template

Version 7.3.1, 03/2010

PACKAGE LEAFLET: INFORMATION FOR THE USER

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

<**Read all of this leaflet carefully before you start <taking> <using> this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor> <or> <pharmacist>.
- <This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.>
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

<**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to <take> <use> X carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve <after {number of} days.>
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.>

In this leaflet:

1. What X is and what it is used for
2. Before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Further information

1. WHAT X IS AND WHAT IT IS USED FOR

<This medicine is for diagnostic use only.>

2. BEFORE YOU <TAKE> <USE> X

Do not <take> <use> X

- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of X.>
- <if...>

Take special care with X

- <if you ...>
- <when ...>
- < Before treatment with X, …>

<Taking> <Using> other medicines

<Please tell your <doctor> <or> <pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking> <Using> X with food and drink

Pregnancy and breast-feeding

<Ask your <doctor> <or> <pharmacist> for advice before taking any medicine.>

Driving and using machines

<Do not drive <because...>.>

<Do not use any tools or machines.>

Important information about some of the ingredients of X

3. HOW TO <TAKE> <USE> X

<Always <take> <use> X exactly as your doctor has told you. You should check with your <doctor> <or> <pharmacist> if you are not sure.> <The usual dose is...>

<Use in children>

If you <take> <use> more X than you should

If you forget to <take> <use> X

<Do not take a double dose to make up for a forgotten <tablet> <dose> <…>.>

If you stop <taking> <using> X

<If you have any further questions on the use of this product, ask your <doctor> <or> <pharmacist>>.

4. POSSIBLE SIDE EFFECTS

Like all medicines, X can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor> <or> <pharmacist>.

5. HOW TO STORE X

[For Storage condition statements see Appendix III.]

Keep out of the reach and sight of children.

Do not use X after the expiry date which is stated on the <label> <carton> <bottle> <…> <after {abbreviation used for expiry date}.> <The expiry date refers to the last day of the month.>

<Do not use X if you notice {description of the visible signs of deterioration}.>

<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

6. FURTHER INFORMATION

What X contains

- The active substance(s) is (are)…
- The other ingredient(s) is (are)...

What X looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien	**Luxembourg/Luxemburg**
{Nom/Naam/Name}	{Nom}
<{Adresse/Adres/Anschrift }	<{Adresse}

B-0000 {Localité/Stad/Stadt}>

Tél/Tel: + {N° de téléphone/Telefoonnummer/

Telefonnummer}

<{e-mail}>

L-0000 {Localité/Stadt}>

Tél/Tel: + {N° de téléphone/Telefonnummer}

<{e-mail}>

България

{Име}

<{Адрес}

{Град} {Пощенски код}>

Тел.: + {Телефонен номер}

<{e-mail}>

Česká republika

{Název}

<{Adresa}

CZ {město}>

Tel: +{telefonní číslo}

<{e-mail}>

Danmark

{Navn}

<{Adresse}

DK-0000 {by}>

Tlf: + {Telefonnummer}

<{e-mail}>

Deutschland

{Name}

<{Anschrift}

Magyarország

{Név}

<{Cím}

H-0000 {Város}>

Tel.: +Telefonszám}

<{e-mail}>

Malta

{Isem, #1618}

<{Indirizz}

MT-0000 {Belt/Raħal}>

Tel: + {Numru tat-telefon}

<{e-mail}>

Nederland

{Naam}

<{Adres}

NL-0000 XX {stad, #452}>

Tel: + {Telefoonnummer}

<{e-mail}>

Norge

{Navn}

<{Adresse}

D-00000 {Stadt}>

Tel: + {Telefonnummer}

<{e-mail}>

Eesti

(Nimi)

<(Aadress)

EE - (Postiindeks) (Linn)>

Tel: +(Telefoninumber)

<{e-mail}>

Ελλάδα

{Όνομα}

<{Διεύθυνση}

GR-000 00 {πόλη}>

Τηλ: + {Αριθμός τηλεφώνου}

<{e-mail}>

España

{Nombre}

<{Dirección}

E-00000 {Ciudad}>

Tel: + {Teléfono}

<{e-mail}>

France

{Nom}

<{Adresse}

F-00000 {Localité}>

Tél: + {Numéro de téléphone}

N-0000 {poststed}>

Tlf: + {Telefonnummer}

<{e-mail}>

Österreich

{Name}

<{Anschrift}

A-00000 {Stadt}>

Tel: + {Telefonnummer}

<{e-mail}>

Polska

{Nazwa/ Nazwisko:}

<{Adres:}

PL – 00 000{Miasto:}>

Tel.: + {Numer telefonu:}

<{e-mail}>

Portugal

{Nome}

<{Morada}

P-0000–000 {Cidade}>

Tel: + {Número de telefone}

<{e-mail}>

România

{Nume}

<{Adresă}

{Oraş} {Cod poştal} – RO>

Tel: + {Număr de telefon}

<{e-mail}>

Ireland

{Name}

<{Address}

IRL - {Town} {Code for Dublin}>

Tel: + {Telephone number}

<{e-mail}>

Ísland

{Nafn}

<{Heimilisfang}

IS-000 {Borg/Bær}>

Sími: + {Símanúmer}

<{Netfang }>

Italia

{Nome}

<{Indirizzo}

I-00000 {Località}>

Tel: + {Numero di telefono}>

<{e-mail}>

Κύπρος

{Όνομα}

<{Διεύθυνση}

CY-000 00 {πόλη}>

Τηλ: + {Αριθμός τηλεφώνου}

<{e-mail}>

<{e-mail}>

Slovenija

{Ime}

<{Naslov}

SI-0000 {Mesto}>

Tel: + {telefonska številka}

<{e-mail}>

Slovenská republika

{Meno}

<{Adresa}

SK-000 00 {Mesto}>

Tel: + {Telefónne číslo}

<{e-mail}>

Suomi/Finland

{Nimi/Namn}

<{Osoite/Adress}

FIN-00000 {Postitoimipaikka/Stad}>

Puh/Tel: + {Puhelinnumero/Telefonnummer}

<{e-mail}>

Sverige

{Namn}

<{Adress}

S-000 00 {Stad, #452}>

Tel: + {Telefonnummer}

<{e-mail}>

Latvija

{Nosaukums}

<{Adrese}

{Pilsēta}, LV{Pasta indekss }>

Tel: + {Telefona numurs}

<{e-mail}>

United Kingdom

{Name}

<{Address}

{Town} {Postal code} – UK>

Tel: + {Telephone number}

<{e-mail}>

Lietuva

{pavadinimas}

<{adresas}

LT {pašto indeksas} {miestas}>

Tel: +370{telefono numeris}

<{e-mail}>

This leaflet was last approved in {MM/YYYY}

<This medicine has been given "conditional approval".

This means that there is more evidence to come about this medicine.

The European Medicines Agency will review new information on the medicine every year and this leaflet will be updated as necessary.>

<This medicine has been authorised under "Exceptional Circumstances".

This means that <because of the rarity of this disease> <for scientific reasons> <for ethical reasons> it has been impossible to get complete information on this medicine.

The European Medicines Agency will review any new information on the medicine every year and this leaflet will be updated as necessary.>

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu <There are also links to other websites about rare diseases and treatments.>

<----------

<The following information is intended for medical or healthcare professionals only:>

Appendix 3: QRD form 1

QRD Form 1:
For Member States' product information check

DAY 229

(Applicant to complete Section 1 and to send to the Agency by Day 215)
(MS to complete Section 2 and to send to applicant and Agency by Day 229)
(NO and IS to send to applicant and Agency upon finalisation of the check)

SECTION 1:

Application Details (to be completed by the applicant):

Product Name	:	
Application Number	:	
Worksharing submission		Yes☐ No☐
Grouping submission		Yes☐ No☐
Applicant Name & Address	:	
Details of contact person for translations (Name, tel, fax & E-mail)	:	
Rapporteur and Co-Rapporteur	:	
Product Team Leader	:	

/ Project Manager	

Extensions ONLY	:	*<Provide here a short description of the differences between the already authorised presentations and the new extension (e.g. indicate sections amended)>*

SECTION 2:

Product information check (to be completed by Member States):

Language :

BG	CS	DA	DE	EL	ES	ET	FI	FR	HU	IS	IT

LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV

Details of MS contact for translations check	:	

Total checking time (hours)	:	

		YES	NO
Assisted by CHMP member and/or assessors	:		
Assisted by other staff members	:		
Assisted by Standing Committee member	:		

		VG	G	A	UN*
Overall quality of translation	:				
• **SmPC**	:				

• **Annex II**				
• **Labelling** :				
• **Package Leaflet** :				
• **Annex IV (if applicable)**				

(VG=Very Good; G= Good, A = Acceptable; UN=Unacceptable)

***** If unacceptable, return translation **<u>within 3 days</u>** to the applicant (copy Agency) and include an explanation in the box below.

The translation was unacceptable because:

Nature of comments:

	M	S	F
Missing words or sentences :			
Scientific incorrect translations (e.g. terminology) :			
Inaccuracies (incorrect translations – incl. spelling, punctuation, grammatical mistakes)			
Editorial, stylistic changes (e.g. rephrasing) :			

(M=Many; S=Several; F=Few)

Any other comments (e.g. formatting problems):

Date of completion of form :	

Appendix 4: QRD form 2

QRD Form 2:
For applicants when submitting revised translations to the European Medicines Agency

DAY 235 / DAY + 25

(Applicant to complete by Day 235 and send to QRD Secretariat)
(Applicant to complete by Day +25 and send to PTL secretary)
(Only one form to be completed for all the languages)
(Only one form to be completed for Worksharing and grouping submissions)

SECTION 1:

(to be completed by the applicant)

Product Name	:	
Application Number	:	
Worksharing submission		Yes☐ No☐
Grouping submission		Yes☐ No☐
Applicant/MAH Name & Address	:	
Details of contact person for translations (name, tel, fax & e-mail)	:	
Worksharing submission ONLY	:	*<Confirm here that changes implemented to this CAP will be implemented in all CAPs included in the worksharing submission>*

All Member States' comments implemented :

BG	CS	DA	DE	EL	ES	ET	FI	FR	HU	IS	IT

LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV

Tick the appropriate box for each language as follows:
✓ - Comments received and implemented
X - Comments received, not all implemented
NC- Confirmation received that there are no comments on the translation for this procedure
n/a – No comments received from MS

If not, a justification should be provided for the appropriate language(s) stating why certain comments are not reflected in the final texts. Please indicate, as presented below, for the language(s) concerned the document (SmPC, Annex II, labelling or package leaflet) and section to which the disputed comment relates together with an alternative proposal or an indication of how the issue has been resolved.

If comments have been discussed and agreed/revised with the Member States, a copy of any relevant correspondence should be attached to this form.

{LANGUAGE}
- SmPC

Section Title & Paragraph	Comment	Alternative proposal or how was the issue resolved?

SECTION 2:
(to be completed by Procedure Secretary):

	New Application	Line extension	Renewal	Annual Re-assessment	Art.61.3 Notifications
Type of procedure					
	Referral	**Type II Variation 30 Days**	**Type II Variation 60-90 Days**	**Type IB Variation**	**USR**
	Generic Application				

Opinion date or Start of procedure[48] **:**

[48] Start of procedure for 30-Days Type II Variations and USRs only; opinion date for all other procedures.
(only one form to be completed per procedure, even if (multiple) comments may be received at different stages)

Deadline for providing linguistic comments :	
Form completed by :	

	BG	CS	DA	DE	EL[49]	ES	ET	FI	FR	HU	IS	IT
Check performed by MS* :												

	LT	LV	MT	NL	NO	PL	PT	RO	SK	SL	SV
Check performed by MS* :											

*MSs who have sent comments or sent an e-mail confirming they have no comments on the translation have to be ticked: ✓ (= Comments received)

- **Delay in MS comments?** If yes, provide country name and number of days delayed

- **Delay in transmitting translations to EC?** **Yes O** **No O**
  If yes, provide further details in "Any other feedback"
- **Any other feedback?**

[49] New applications are checked by Cyprus, all other procedures are checked by Greece.

Appendix 5: Email to pharmaceutical companies - study 1

Kære XX

Jeg kontakter jer i forbindelse med min ph.d.-afhandling, som handler om brugervenlighed i indlægssedler, herunder oversættelse af indlægssedler. Selvom indlægssedler er blevet meget bedre og mere brugervenlige de sidste 10 år, er der stadig mange udfordringer forbundet med deres oversættelse.

For at jeg kan danne mig et fyldestgørende billede af, hvem der oversætter de danske indlægssedler, vil jeg bede jer svare på følgende spørgsmål - det vil være en stor hjælp for mig i min videre forskning:

Hvem oversætter jeres indlægssedler? Vælg venligst en af nedenstående kategorier (I må gerne sætte flere krydser samt skrive en kommentar, hvis det er aktuelt).

- Intern oversættelse
    - En medarbejder med medicinsk baggrund
    - En medarbejder, der er translatør (cand.ling.merc)
    - En medarbejder med anden sproglig baggrund
    - En medarbejder med anden faglig baggrund? I så fald, hvilken?
- Ekstern oversættelse
    - Et translatørbureau i Danmark
    - Et oversætterbureau i udlandet
    - En freelance translatør (cand.ling.merc)
    - En freelance oversætter
    - En anden person? I så fald med hvilken faglig baggrund?

Har I kommentarer til spørgsmålet, så skriv dem venligst her:

Jeg garanterer selvfølgelig virksomhedens anonymitet.

I må meget gerne besvare spørgsmålet via e-mail, men hvis I synes det er nemmere at forklare, hvordan jeres indlægssedler bliver oversat over telefonen, så send en mail, så ringer jeg op, når det passer jer.

Med venlig hilsen

Matilde Nisbeth Jensen, cand. ling. merc.
Ph.d.-studerende
Institut for Sprog og Erhvervskommunikation
Handelshøjskolen i Århus, Århus Universitet
T: +45 8948 6784
M: matnj@asb.dk

Appendix 6: Final ethics approval

Subject: FW: HS Ethics Final Approval (5201200159)

---------- Forwarded message ----------

From: Fhs Ethics <fhs.ethics@mq.edu.au>

Date: 24 May 2012 15:01

Subject: RE: HS Ethics Final Approval (5201200159)

To: Ms Helen Marjorie Slatyer <helen.slatyer@mq.edu.au>

Cc: Miss Matilde Jensen <matilde.jensen@mq.edu.au>

Dear Ms Slatyer,

Re: "Medical translators for lay receivers: The case of Patient Information Leaflets"

Thank you for your recent correspondence. Your response has addressed the issues raised by the Faculty of Human Sciences Human Research Ethics Sub-Committee and you may now commence your research.

This research meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). The National Statement is available at the following web site:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf.

The following personnel are authorised to conduct this research:

Miss Matilde Jensen

Ms Helen Marjorie Slatyer

Please note the following standard requirements of approval:

1. The approval of this project is conditional upon your continuing compliance with the National Statement on Ethical Conduct in Human Research (2007).

2. Approval will be for a period of five (5) years subject to the provision of annual reports.

Progress Report 1 Due: 1st June 2013

Progress Report 2 Due: 1st June 2014

Progress Report 3 Due: 1st June 2015

Progress Report 4 Due: 1st June 2016

Final Report Due: 1st June 2017

NB. If you complete the work earlier than you had planned you must submit a Final Report as soon as the work is completed. If the project has been discontinued or not commenced for any reason, you are also required to submit a Final Report for the project.

Progress reports and Final Reports are available at the following website: http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

3. If the project has run for more than five (5) years you cannot renew approval for the project. You will need to complete and submit a Final Report and submit a new application for the project. (The five year limit on renewal of approvals allows the Sub-Committee to fully re-review research in an environment where legislation, guidelines and requirements are continually changing, for example, new child protection and privacy laws).

4. All amendments to the project must be reviewed and approved by the Sub-Committee before implementation. Please complete and submit a Request for Amendment Form available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

5. Please notify the Sub-Committee immediately in the event of any adverse effects on participants or of any unforeseen events that affect the continued ethical acceptability of the project.

6. At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the University. This information is available at the following websites:

http://www.mq.edu.au/policy

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/policy

If you will be applying for or have applied for internal or external funding for the above project it is your responsibility to provide the Macquarie University's Research Grants Management Assistant with a copy of this email as soon as possible. Internal and External funding agencies will not be informed that you have final approval for your project and funds will not be released until the Research Grants Management Assistant has received a copy of this email.

If you need to provide a hard copy letter of Final Approval to an external organisation as evidence that you have Final Approval, please do not hesitate to contact the Ethics Secretariat at the address below.

Please retain a copy of this email as this is your official notification of final ethics approval.

Yours sincerely,

Dr Peter Roger
Chair
Faculty of Human Sciences Ethics Review Sub-Committee
Human Research Ethics Committee

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Faculty of Human Sciences - Ethics
Research Office
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Helen Slatyer

Lecturer

Department of Linguistics

Macquarie University

http://www.ling.mq.edu.au/

Celebrating AUSIT's Silver Jubilee

Biennial Conference 2012: Sydney

Appendix 7: Ethics amendment approval

Subject: Ethics Amendment 1 - Approved (Ref No. 5201200159)

---------- Forwarded message ----------

From: Fhs Ethics <fhs.ethics@mq.edu.au>

Date: 19 June 2012 15:49

Subject: RE: Ethics Amendment 1 - Approved (Ref No. 5201200159)

To: Ms Helen Marjorie Slatyer <helen.slatyer@mq.edu.au>

Cc: Miss Matilde Jensen <matilde.jensen@mq.edu.au>

Dear Ms Slatyer,

RE: 'Medical translators for lay receivers: The case of Patient Information Leaflets ' (Ref: 5201200159)

Thank you for your recent correspondence regarding the amendment request.

The amendments have been reviewed and we are pleased to advise you that the amendments have been approved.

This approval applies to the following amendments:

1. Revised recruitment email;
2. Incentive for participants.

Please note: if the English version of the recruitment e-mail is used, the researchers may wish to remove the comma between the words "time" and "which" in the paragraph 2 of the e-mail to pharmacists/translators.

Please accept this email as formal notification that the amendments have been approved.

Please do not hesitate to contact us in case of any further queries.

All the best with your research.

Kind regards,

FHS Ethics

****

Faculty of Human Sciences - Ethics

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Appendix 8: Recruitment email - focus group

Emne: Medvirken i forskningsprojekt om oversættere af indlægssedler, fokusgrupper

Kære [navn på kontaktperson ved medicinalvirksomheden eller oversættelsesbureauet]

[Individuel tekst: Tak for jeres hjælp i år 2010, hvor jeg spurgte jer om, hvilken type oversættere I bruger til oversættelse af indlægssedler til dansk. Det var en stor hjælp for mig, og jeg tillader mig nu at kontakte jer igen]

Jeg skriver for at invitere farmaceuter/translatører, som har erfaring med oversættelse af indlægssedler til at deltage i en fokusgruppe, som handler om oversættelse af indlægssedler. Jeg vil derfor sætte stor pris på, hvis du vil sende den nedenstående forespørgsel videre til interesserede farmaceuter/translatører:

Kære translatør/farmaceut

Jeg skriver for at invitere dig i den egenskab af farmaceut/translatør med erfaring i oversættelse af indlægssedler til at medvirke i et studie. Din medvirken omfatter deltagelse i en fokusgruppe sammen med andre farmaceuter/translatører. Fokusgruppen vil blive afholdt i efteråret 2012, og vil vare cirka 2 timer. Emnet for fokusgruppen er jeres syn på oversættelse generelt og jeres syn på nogle uddrag af indlægssedler. Formålet er på ingen måde er at kritisere individuelle oversættere, men at blive klogere på processen. Fokusgrupperne vil blive lydoptaget. [Fokusgruppen vil blive holdt i Emdrup/Århus, og tidspunkt vil blive fastlagt så det passer bedst muligt for alle deltagere].

Studiet udføres af undertegnede, Matilde Nisbeth Jensen, som en del af en ph.d.-afhandling ved Institut for Erhvervskommunikation, Aarhus University & Department of Linguistics, Macquarie University, Australien, e-mail: matnj@asb.dk.

Alle oplysninger eller personlige informationer, som indsamles i forbindelse med fokusgruppen er fortrolige. Alle medvirkende vil være anonyme, og vil ikke kunne identificeres i fremtidige publikationer af resultaterne.

Det er selvfølgelig frivilligt at deltage i dette studie, og alle deltagere bestemmer selv, om de vil deltage og kan trække deres deltagelse tilbage uden at skulle give en forklaring og uden konsekvenser.

Jeg håber, at du vil være med til en faglig interessant og samfundsmæssig vigtig diskussion omkring oversættelse af indlægssedler med andre translatør/[farmaceut]kolleger. Som tak for din deltagelse i undersøgelsen vil du modtage en lille gave.

Mange hilsner

Matilde Nisbeth Jensen

Appendix 9: Background question sheet - translator

Baggrundsspørgsmål:

Deltager:

Uddannelsesbaggrund:

- Har du uddannelse inden for oversættelse?

- Har du uddannelse inden for det medicinske/farmaceutiske område?

- Andet relevant for indlægssedler?

Erfaring med oversættelse:

- Hvor mange års oversættelseserfaring har du?

Erfaring med oversættelse af indlægssedler:

- Hvor mange indlægssedler tror du, du har oversat i alt (et cirkatal er helt fint)?

Appendix 10: Background question sheet - pharmacist

Baggrundsspørgsmål:

Deltager:

Uddannelsesbaggrund:

- Har du uddannelse inden for det medicinske/farmaceutiske område?

- Har du uddannelse inden for oversættelse?

- Andet relevant for oversættelse og/eller indlægssedler?

Antal års erfaring:

- Hvor mange år har du været uddannet?

Erfaring med oversættelse af indlægssedler:

- Hvor mange indlægssedler tror du, du har oversat i alt (et cirkatal er helt fint)?

Appendix 11: Preparation email for translators

Kære oversætter

Så er det på torsdag d. 20. september kl. 14, vi skal mødes til fokusgruppen. Jeg sender derfor lidt oplysninger om fokusgrupper, om mit projekt, samt vejledning til at finde lokalet.

Kort om fokusgrupper:

- Jeg vil rigtig gerne lære noget af jer, der sidder med oversættelse til daglig
- Der er ingen rigtige eller forkerte svar
- Fokusgruppen er ikke et interview, derfor må I meget gerne tale med hinanden, ikke kun til mig
- Jeg vil gerne høre om jeres konkrete erfaringer, meget gerne eksempler og holdninger
- I vil blive optaget, men alt er anonymt

Kort om projektet:

Jeg vil gerne forstå processen og tankerne omkring oversættelse af indlægssedler. Jeg har analyseret en mængde indlægssedler, men vil gerne vide mere om, hvorfor de er oversat, som de er. Jeg vil derfor gerne have en bedre forståelse for motivationen bag de valg, I tager, når I oversætter indlægssedler. Jeg vil også gerne vide, om I synes, at det er svært, let, udfordrende? Om I møder udfordringer eller begrænsninger, både i teksten og i processen omkring.

Samtykkeerklæring:

Jeg har vedhæftet en samtykkeerklæring, som I meget gerne må skimme, inden I kommer. Jeg har en udskrevet udgave klar, som vil vi begge underskrive, inden vi starter. Min ph.d. skal også indleveres på Macquarie University i Australien, og de kræver sådan en erklæring for at beskytte deltagere i forskningsstudier.

Baggrundspørgsmål:

Til sidst har jeg vedhæftet et dokument med et par spørgsmål om jeres uddannelsesmæssige baggrund. Hvis I har mulighed for at udfylde den, inden I kommer, ville det være rigtigt dejligt. Ellers kan I udfylde den, inden vi starter på torsdag.

Rutevejledning:

Instituttet ligger på hjørnet af Nordre Ringgade og Randersvej. Hvis I bruger GPS, kan I skrive Jens Chr. Skous Vej 4, 8000 Århus C. På dette link

(http://bcom.medarbejdere.au.dk/praktiskinfo/parkering/) kan I se parkeringsmuligheder og også bygning **1481**, hvor jeg bor. I skal gå/tage elevator op på 6. etage i den bygning, så til sydenden og finde mødelokale nr. 624. Men hvis I først finder 6. etage, skal jeg nok også finde jer. Mit mobilnummer er 51343235, hvis I farer vild.

Glæder mig til at se jer på torsdag.

Mange hilsner

Appendix 12: Preparation email for pharmacists

Kære farmaceut

Så er det på torsdag d. 27. september kl. 14, vi skal mødes til fokusgruppen. Jeg sender derfor lidt oplysninger om fokusgrupper, om mit projekt, samt vejledning til at finde lokalet.

Kort om fokusgrupper:

- Jeg vil rigtig gerne lære noget af jer, der sidder med oversættelse af indlægssedler
- Der er ingen rigtige eller forkerte svar
- Fokusgruppen er ikke et interview, derfor må I meget gerne tale med hinanden, ikke kun til mig
- Jeg vil gerne høre om jeres konkrete erfaringer, meget gerne eksempler og holdninger
- I vil blive lydoptaget, men alt er anonymt

Kort om projektet:

Jeg vil gerne forstå processen og tankerne omkring oversættelse af indlægssedler. Jeg har analyseret en mængde indlægssedler, men vil gerne vide mere om, hvorfor de er oversat, som de er. Jeg vil derfor gerne have en bedre forståelse for motivationen bag de valg, I tager, når I oversætter indlægssedler. Jeg vil også gerne vide, om I synes, at det er svært, let, udfordrende? Om I møder udfordringer eller begrænsninger, både i teksten og i processen omkring.

Samtykkeerklæring:

Jeg har vedhæftet en samtykkeerklæring, som I meget gerne må skimme, inden I kommer. Jeg har en udskrevet udgave klar, som vil vi begge underskrive, inden vi starter. Min ph.d. skal også indleveres på Macquarie University i Australien, og de kræver sådan en erklæring for at beskytte deltagere i forskningsstudier.

Baggrundspørgsmål:

Til sidst har jeg vedhæftet et dokument med et par spørgsmål om jeres uddannelsesmæssige baggrund. Hvis I har mulighed for at udfylde den, inden I kommer, ville det være rigtigt dejligt. Ellers kan I udfylde den, inden vi starter på torsdag.

Rutevejledning:

Jeg har fået at vide, at det letteste er at køre til Emdrupvej 115C og benytte opgang D1. Så skal I gå til venstre, når I er kommet ind, og op på 3. sal og til lokale D320.

Mit mobilnummer er 51343235, hvis I får brug for at ringe.

Glæder mig til at se jer på torsdag.

Mange hilsner

Appendix 13: Consent form

Informations- og samtykkeerklæring

Projektets navn: Medical translators translating for lay receivers: The case of Patient Information Leaflets

Du er inviteret til at deltage i et studie, som handler om oversættelse af indlægssedler. Formålet med dette studie er at se, hvordan oversættere med forskellig baggrund oversætter indlægssedler. Studiet undersøger også, hvordan forskellige oversættere opfatter oversættelse og hvordan deres oversættelsesproces foregår, når de oversætter indlægssedler. Desuden er studiet interesseret i, hvordan oversættere af indlægssedler sikrer, at patienterne forstår oversættelserne.

Studiet foretages af Matilde Nisbeth Jensen, Institut of Erhvervskommunikation, Aarhus Universitet & Department of Linguistics, Macquarie University, Australien. Matilde Nisbeth Jensens e-mail er: matnj@asb.dk, Studiet udføres som del af en ph.d.-grad under vejledning af Karen Korning Zethsen (kkz@asb.dk), Institut of Erhvervskommunikation, Aarhus Universitet og Helen Slatyer (helen.slatyer@mq.edu.au), Department of Linguistics, Macquarie University, Australien.

Hvis du vælger at deltage vil du blive bedt om at deltage i ét fokusgruppeinterview, som varer cirka 2 timer. Under fokusgruppeinterviewet vil du dele din erfaring og holdning omkring oversættelse af indlægssedler med 5 andre. Fokusgrupperne vil blive lydoptaget.

Alle oplysninger eller personlige informationer indsamlet i dette studie er fortrolige. Ingen individer vil blive identificeret i nogen publikation af resultaterne. Et resumé af resultaterne kan blive sendt på opfordring.

Deltagelse i dette studie er fuldstændigt frivilligt. Du er ikke forpligtet til at deltage, og hvis du vælger at deltage kan du altid trække din deltagelse tilbage uden at skulle give en forklaring og uden konsekvenser.

Jeg, har læst og forstået informationerne ovenfor, og eventuelle spørgsmål jeg måtte have er blevet besvaret tilfredsstillende. Jeg vil gerne deltage i dette studie, og ved, at jeg kan trække min deltagelse tilbage når som helst uden konsekvenser. Jeg er blevet givet en kopi af denne blanket.

Deltagers navn:_____

(Block letters)

Deltagers underskrift:_____Dato:_____

Forskerens navn:_____

(Block letters)

Forskeren underskrift: _____ ___Dato:_____

De etiske aspekter i dette studie er blevet godkendt af Macquarie University Human Research Ethics Committee. Hvis du har nogen klager eller forbehold over nogle af de etiske aspekter angående din deltagelse in denne forskning kan du kontakte kommitteen gennem the lederen af Research Ethics (telephone +61 2 9850 7854; e-mail ethics@mq.edu.au). Alle klager vil blive fortroligt behandlet og undersøges og du vil blive informeret om resultatet.

(FORSKERS//DELTAGERS KOPI)

Appendix 14: Interview guide

Introduktion til fokusgrupper – oversættere

- **Kaffe, the, vand og kage**
- **Læg papir og kuglepinde på bordet**
- **Uddel navneskilte**
- **Uddel samtykkeerklæringer**
- **Uddel baggrundsspørgsmål**

Intro:

Tak fordi I ville komme og fordi I var så fleksible med tidspunkter. Det gjorde det meget nemmere for mig. Kaffe og kage. Vi har cirka 2 timer sammen. Kort intro – selvom I har fået lidt tilsendt.

I er blevet inviteret fordi I alle har erfaring med indlægssedler og fordi I samtidig har en eller anden form for sproglig baggrund.

Om projektet:

Vil gerne forstå processen og tankerne omkring oversættelse af indlægssedler. Gerne snakke om både oversættelse og indlægssedler, både processen omkring (ekstratekstuelt) og valg I tager i selve teksten (intratekstuelt)

Jeg har analyseret en mængde indlægssedler, og fundet forskellige oversættelsesmæssige valg men vil gerne vide mere om, hvorfor de er oversat, som de er. Jeg vil derfor gerne have en bedre forståelse for motivationen bag de valg, I tager, når I oversætter indlægssedler. Jeg vil også gerne vide, om I synes, at det er svært, let, udfordrende? Om I møder udfordringer eller begrænsninger, både i teksten og i processen omkring. Hvad målet med oversættelse generelt er? Hvordan I oversætter til en bestemt målgruppe.

Regler for FG:

- Vil gerne lære noget fra jer, jer der sidder med det til daglig. Ingen rigtige eller forkerte svar, heller ikke enighed er målet
- Ikke som et interview, tal med hinanden, ikke mig
- Vil gerne høre om konkrete erfaringer, meget gerne eksempler.
- Alle skal snakke, alle bidrag er lige velkommen
- Belyse emnet fra mange synspunkter, ikke at opnå enighed
- Normal FG: hjælper hinanden
- Blive optaget, anonymt
- Praktisk: optages – pas på med kaffekopper

- Navne – pga. transskriptionen
- Hjælper – Line, teknisk

Præsentationsrunde:

Jeg vil gerne, hvis vi kan tage en runde, hvor I introducerer jer selv. Lidt om hvor I kommer fra og hvad jeres erfaring med oversættelse af indlægssedler er.

Inden vi starter runden – har I nogen spørgsmål?

Question guide

Emner der skal belyses:

- **Oversættelse af indlægssedler, udfordringer, begrænsninger**
- **Oversættelse af indlægssedler, processen (formål, vejledning, instruktioner, regler, værktøjer)**
- **Målgruppen**
- **Oversættelse generelt, som begreb, processen**
- **Specifikke eksempler**

Oversættelse af indlægssedler

Starte med en runde, hvor I fortæller om jeres erfaring med indlægssedler, sjovt, let, svært. Konkrete erfaringer, eksempler

Oversættelse af indlægssedler, processen

- Hvordan starter I på en ny oversættelse?
- Får I konkrete vejledninger? Brief?
- Har I bestemte trin I gennemgår?
- Er det nogen firmaguides I kan bruge?
- Oversættelsesværktøjer?
- Hvordan tjekker I medicinske termer?

Lægvenlighed

Hvad er jeres hovedformål når I oversætter indlægssedler? (Nøjagtighed, præcision, brugervenlighed)

Direktiv 2001/83/EC: "Indlægssedlen skal være letlæselig og være affattet i udtryk, der er klare og forståelige og dermed giver brugerne mulighed for at handle på behørig vis, om nødvendigt med hjælp fra sundhedspersoner". Er det vigtigt i jeres proces?

Hvordan forsikrer I, at oversættelsen kan forstås af modtagerne?

Hvordan bestemmer I, hvilke ord/vendinger I bruger? (er det f.eks. vigtigt at bibeholde latinske betegnelser?)

Opfattelse af oversættelse/oversætterens tasks:

Hvad mener I er den vigtigste mål for oversættelse generelt?

Hvad er oversætterens hovedopgave?

Hvis en kildetekst ikke er af god kvalitet, er det okay for oversætteren at lave oversættelsen bedre?

Specifikke eksempler:

Medicinsk terminologi:

For hvert eksempel: Hvilke muligheder ville du overveje til oversættelse af de understregede ting? Hvad mener I er vigtigt at overveje?

1. Osteoporosis is a thinning and weakening of the bones, which is common in women after the menopause
2. An oral solution of XX is available for children 3 years of age
3. Side effect include inflammation of the vagina, acne, incontinence, irritation or itching at the site of injection

Sweating – svedudbrud

exposed bone – blodlagt knogle

Sammensatte ord:

1. The maximal blood pressure lowering effect should be reached 4-6
2. If you are receiving somatropin for growth hormone deficiency following a previous tumour (cancer)

For hvert eksempel: diskuter oversættelsen.
Hvilken oversættelse ville du vælge? Hvorfor?

Nominalisering:

1. Kildetekst: It is used to treat vitamin E deficiencies
   - Mulighed 1: Det bruges til behandling af mangel på E-vitamin
   - Mulighed 2: Det bruges til at behandle mangel på E-vitamin
2. Kildetekst: A medicine used to suppress the immune system
   - Mulighed 1: Et lægemiddel, der bruges til undertrykkelse af immunsystemet
   - Mulighed 2: Et lægemiddel, der bruges til at undertrykke immunsystemet

Personlige pronominer

Måltekst 1: "Hvis du får epoetin alfa, bør du have **hæmoglobinniveauet** målt regelmæssigt, indtil et stabilt niveau opnås, og derefter periodevist."

Måltekst 2: "Hvis du får epoetin alfa, bør du have **dit hæmoglobinniveau** målt regelmæssigt, indtil et stabilt niveau opnås, og derefter periodevist."

Kildetekst: Where your body does not produce enough insulin

Måltekst 1: at kroppen ikke danner tilstrækkeligt insulin

Måltekst 2: at din krop ikke danner nok insulin

Kancellistil:

Kildetekst: If you are currently treated with another anti-copper agent

Måltekst: hvis de for nærværende er i behandling med andre anti-kobber præparater

Blandet

localised swelling – lokale væskeansamlinger

local allergic reactions – lokale allergiske reaktioner

Kildetekst: drug rash with systemic symptoms (drug rash with eosinophilia and systemic symptoms)

Måltekst: lægemiddelforårsaget udslæt (med eosinofili og systemiske symptomer)

Orange juice –> orange juice

Vitamin D –> Vitamin D

Lactose –> lactose (laktose)

lipoatrophy -> lipoatrophy (lipoatrofi)

phosphate –> phosphat (fosfat)

Danske måltekstesempler:

- yngre en 6 år
- hjetesygdomme
- vedrøende
- blodsukker niveauet.
- vitamin D mangel
- vand og salt ophobning

Afsluttende spørgsmål:

Oversætter som plain language/intralingual?

Hvem bør oversætte indlægssedler?

Afsluttende kommentarer?

Gave

Appendix 15: Handout with examples for focus group participants

Specifikke eksempler:

1.
For hvert eksempel: Hvilke muligheder ville du overveje til oversættelse af de understregede ting? Hvilke faktorer ville spille ind på dit valg?

4. Osteoporosis is a thinning and weakening of the bones, which is common in women after the menopause
5. An oral solution of XX is available for children 3 years of age
6. Side effects include inflammation of the vagina, acne, incontinence, irritation or itching at the site of injection

---

2.
For hvert eksempel: Hvilke muligheder ville du overveje til oversættelse af de understregede ting? Hvilke faktorer ville spille ind på dit valg?

3. The maximal blood pressure lowering effect should be reached 4-6 weeks
4. If you are receiving somatropin for growth hormone deficiency following a previous tumour (cancer)

3.

For hvert eksempel: diskuter oversættelsen.

Hvilken oversættelse ville du vælge? Hvorfor?

1. Kildetekst: Where your body does not produce enough insulin
   - Måltekst 1: hvor kroppen ikke danner tilstrækkeligt insulin
   - Måltekst 2: hvor din krop ikke danner nok insulin

4.

For hvert eksempel: diskuter oversættelsen.

Hvilken oversættelse ville du vælge? Hvorfor?

3. Kildetekst: It is used to treat vitamin E deficiencies
   - Måltekst 1: Det bruges til behandling af mangel på E-vitamin
   - Måltekst 2: Det bruges til at behandle mangel på E-vitamin

1. Kildetekst: A medicine used to suppress the immune system
   - Måltekst 1: Et lægemiddel, der bruges til undertrykkelse af immunsystemet
   - Måltekst 2: Et lægemiddel, der bruges til at undertrykke immunsystemet

---

5.

For hvert eksempel: diskuter oversættelsen.

Hvilken oversættelse ville du vælge? Hvorfor?

1. Kildetekst: If you receive epoetin alfa you should have your haemoglobin levels

   - Måltekst 1: Hvis du får epoetin alfa, bør du have **hæmoglobinniveauet** målt regelmæssigt, indtil et stabilt niveau opnås, og derefter periodevist.
   - Måltekst 2: Hvis du får epoetin alfa, bør du have **dit hæmoglobinniveau** målt regelmæssigt, indtil et stabilt niveau opnås, og derefter periodevist.

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6. Diskuter oversættelsen.

Sweating – svedudbrud

exposed bone – blodlagt knogle

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7. Diskuter oversættelsen

1. Kildetekst: If you are currently treated with another anti-copper agent
    - Måltekst: hvis de for nærværende er i behandling med andre anti-kobber præparater

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8.

Blandede eksempler

For hvert eksempel: Hvilke muligheder ville du overveje til oversættelse af de understregede ting?

localised swelling

local allergic reactions

1. Kildetekst: drug rash with systemic symptoms (drug rash with eosinophilia and systemic symptoms)
    - Måltekst: lægemiddelforårsaget udslæt (med eosinofili og systemiske symptomer)

Diskuter valget af oversættelse:

Orange juice –> orange juice

Vitamin D –> Vitamin D

Lactose –> lactose

Lipoatrophy –> lipoatrophy

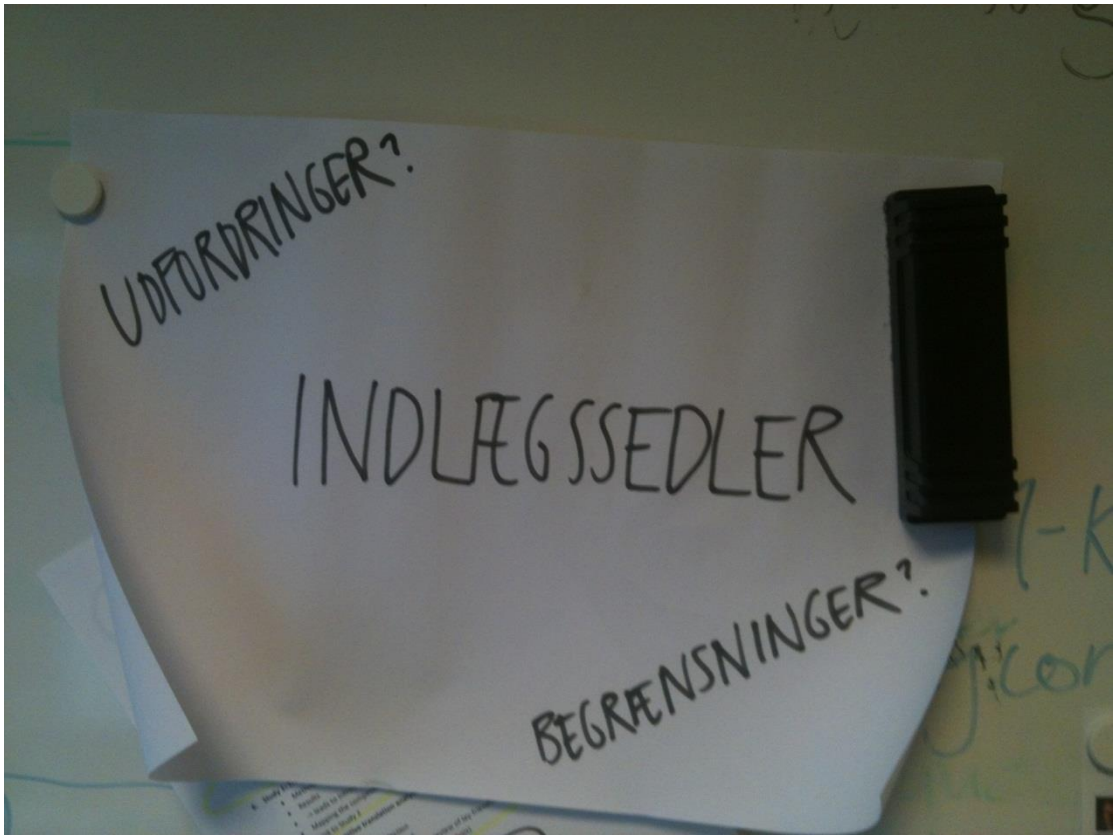
Phosphate –> phosphat

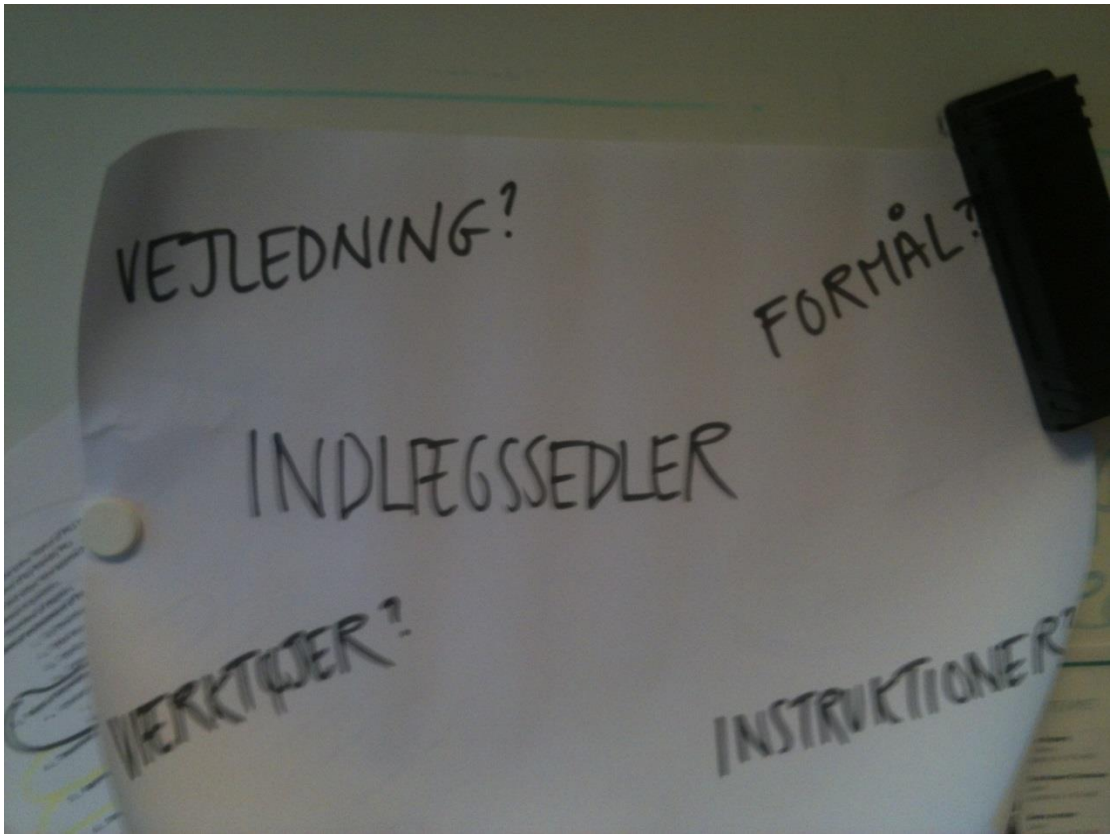
Danske måltekstesempler: Diskuter

- yngre en 6 år
- hjetesygdomme
- vedrøende
- blodsukker niveauet.

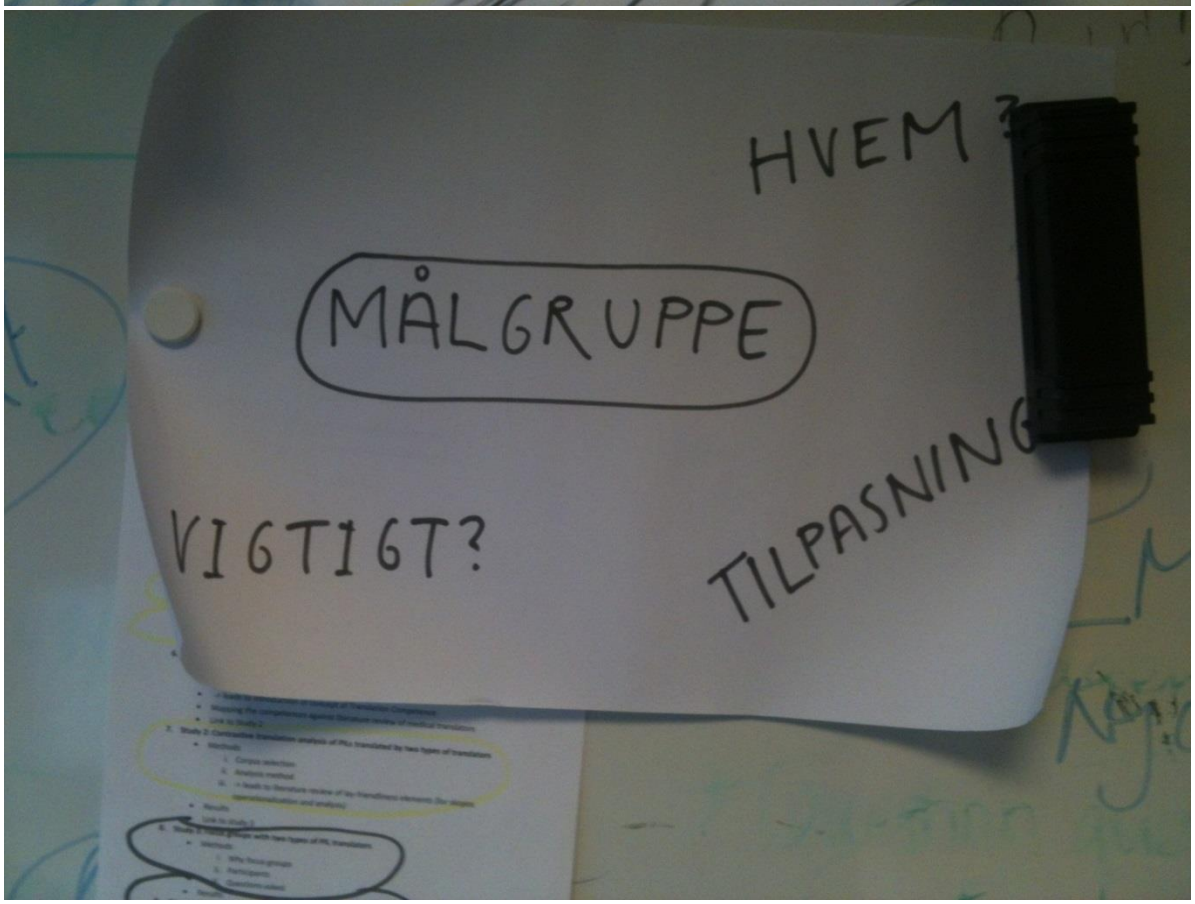
- vitamin D mangel
- vand og salt ophobning

Appendix 16: Key word posters





OVERSATTERENS
ROLLE


HVEM?
MÅLGRUPPE
VIGTIGT?
TILPASNING

Appendix 17: Transcription of focus group – translators

Please contact the author at matnj@asb.dk to obtain this appendix.

Appendix 18: Transcription of focus group - pharmacists

Please contact the author at matnj@asb.dk to obtain this appendix.