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Science popularization in English and translated Dutch patient information leaflets: specialized versus lay terminology and explicitation

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Abstract

Information in patient information leaflets (PILs) must be comprehensible for lay readers. For that purpose popularization strategies can be applied. These include explicitation of scientific terms as well as replacing scientific terms with lay terms. Increased comprehension may entail increased patient compliance, as a result of decreased uncertainty. We analyzed scientific versus lay medical terminology and other explicitation strategies as a measure for uncertainty avoidance (Hofstede, 2001) in a corpus of 12 English PILs and their Dutch translations. Although Dutch-speaking societies have a higher uncertainty avoidance index than English-speaking societies such as the UK, the Dutch PILs contain a similar number of instances of explicitation as the English PILs. But, uncertainty avoidance is reflected in an overall higher amount of lay terminology in the Dutch PILs, notably in section 4 (*Possible side effects*). From this it appears that terminology in the Dutch PILs of our corpus is oriented more towards a lay audience than that in the English PILs. However, the apparent higher scientific orientation of the English PILs may be related partially to the Latin-based origin of medical scientific terminology and the higher Latin-based character of general English terminology compared to Dutch, rather than a higher scientific orientation in the English PILs as such.

Keywords

Explicitation, lay terminology, specialized terminology, medical terminology, health information

1. Introduction

A patient information leaflet (PIL), sometimes also referred to as package leaflet (PL), is the "written information included in a medicine package" (Jensen & Zethsen, 2012, p. 31) and informs patients on how to use medicines safely. Accessible and easy-to-read PILs are a prerequisite in order to ensure safe and appropriate use of medicines (Piorno, 2012; Van Dijk *et al.*, 2014). The information in PILs can only be communicated effectively if the patient notices, reads, understands, believes and remembers this information (Van Dijk *et al.*, 2014, p. 14). Despite numerous efforts to improve PIL content, PILs are perceived as difficult and hard to read (Raynor, 2007; Pander Maat & Lentz, 2010; Van Dijk *et al.*, 2014; Nisbeth Brøgger, 2017). With regard to difficulty, the target group should be taken into account. In this respect, the PIL can be described as a patient-friendly version of the so-called Summary of Product Characteristics (SmPC) (Pines, 2015; Wermuth, 2016; Wermuth & Verplaetse, forthcoming). The SmPC is written by and for experts and therefore contains a very specific and technical language (Delaere *et al.*, 2009).

Drawing up patient-friendly PILs requires a shift from the specialist information in the SmPC to information for consumers (lay readers) in the PIL (Askehave & Zethsen, 2000, p. 65). Providing comprehensible PIL information for lay people is not an easy task, as the information to be transferred is often very complex and knowledge levels between experts and lay people generally do not match (Jensen, 2013), particularly with regard to terminology. In order to convey specialized medical information to a lay target group so-called popularization[1] strategies can be used. These popularization strategies often involve explicitation, which is used as means for explaining scientific (medical) terms/lay terms.

In this study the amount of scientific (medical) terminology, lay terminology and explicitation in a corpus of English PILs and their corresponding Dutch translations is assessed. As every PIL contains various sections, the number of instances of scientific/lay terminology and explicitation and also their lay-friendliness most likely differs per section. By considering the PIL sections separately, it can be established whether there are any differences in the most frequently used popularization strategies per section, e.g. more lay terminology for side effects as it is important to ensure that patients fully understand these in order to judge their severity.

The degree of explicitation also relates to the concept of uncertainty avoidance (Verplaetse & Wermuth, 2014; Gotti, 2015). It is expected that the higher the uncertainty avoidance, the higher the degree of explicitation (Gotti, 2015, p. 11). As Hofstede (2001) and Hofstede *et al.* (2010) found that the United Kingdom has a lower level of uncertainty avoidance than Dutch-speaking societies (Belgium and the Netherlands), it is assessed whether this expectation can be confirmed by means of the corpus of English and Dutch PILs for this study.

With regard to the specific terminology used in PILs Askehave & Zethsen (2011) found that in English-speaking countries the Latin names of, for instance, body parts or illnesses have often

[1] The term 'popularization' is used in this article to refer to strategies and processes by means of which specialized and/or scientific terms are adapted to make them better comprehensible for lay target groups. Some authors refer to these processes and strategies with the term 'determinologisation'. This is notably the case in the context of medical information for lay target groups in which our study is also situated (cf. Jimenez-Crespo, 2017, pp. 4, 5, 6, 10, 18), who also refers to Montalt and Shuttleworth (2012, p. 16) in this respect. Cf. also Andrés (2013). However, we will not make use of this term in the current article in view of the reference of this term, in a more strictly terminological sense, to processes which take place when a term "transcends the boundaries of expert language and starts to be used by the general public" referred to as 'de-terminologization' by Meyer and Mackintosh (2000, p. 111).

been introduced into common language without there being an Anglo-Saxon alternative. Thus, in English these terms are considered lay terminology despite their Latin origins, and in some cases indirect Greek origins (cf. section 2 below on Greek Latinized terms), but in other languages Latin-based terminology might be incomprehensible or very formal and should therefore be replaced by lay terminology (Zethsen, 2004; Askehave & Zethsen, 2011; Jensen & Zethsen, 2012; Jiménez-Crespo, 2017). For this reason also, we expect a decreased level of Latin-based terminology in the translated Dutch PILs compared to the English source texts.

2. PIL terminology and popularization strategies

Edung (2013) describes a term or a terminological unit as "a particular specialized concept within the given subject field" (p. 36), which is in line with earlier definitions referring to terms as words or expressions designating concepts specific to particular subject fields or domains (Dubuc, 1997; Wright, 1997). The number of terms used in a text is related to the technicality of that text: the more technical a text, the higher the number of terms used (Wermuth, 2016) and vice versa. The concept of a term can be extended by also taking phraseology (expressions) into account (Cabré Castellví, 2003, p. 168), as phraseological units consist of terms or terminological units and of other words co-occurring with this term or terminological unit (Edung, 2013, p. 36), e.g. *bowel movements, breakup of red blood cells, ...*

Initially Greek was the language of medical terminology. Greek terms were subsequently introduced into Latin during the Roman period, and Latin terms were added to medical terminology. Latin became the medical lingua franca in the Renaissance, containing hybrid Greek and Latin terms. Since the 20th century national European languages, such as French and English gained importance as medical languages in the Western world, and since the 1950s English has effectively become the medical *lingua franca* (Wermuth & Verplaetse, forthcoming)[2]. When translating Latin-based expert terminology from English, this may pose significant problems to the lay reader in another (non-Romance) language, which did not undergo a similar Romance language influx as English did in the twelfth century. In order to overcome this type of problems and to decrease the technicality of a text, popularization strategies can be used in the interlingual translation process. By means of these strategies specialized (scientific) terminology can be converted into lay terminology: they entail “shifts which replace technical (in this case medical) terms with non-technical terms” (or lay terms) (Hill-Madsen, 2017, p. 92). Medical terminology, in particular scientific, technical terms, are often copied from the Summary of Product Characteristics (Delaere *et al*., 2009). As PILs are meant to be read and understood by people from different backgrounds, and not only by medical staff, scientific terms will often require explicitation in order to be understood. Because scientific expert terminology is one of the main causes of the lack of comprehension when people read a PIL (Delaere *et al.*, 2009) popularization strategies can be very useful.

In contrast to scientific terms lay terms are terms which people with different backgrounds should be able to understand and act upon (Askehave & Zethsen, 2011, p. 14).

Popularization strategies may operate on the level of the term, by replacing scientific terms with lay terms. In addition, explicitation may be used as a popularization strategy. Explicitation can be described as extra lexical items in the target text in comparison with the source text, which have an explanatory function (Hill-Madsen, 2017, p. 98). Lexical items are determiners of comprehensibility (Garner, Ning & Francis, 2012, p. 298), which implies that these items

[2] For a more detailed account of the history of medical terminology see Wermuth & Verplaetse (forthcoming).

play an important role in the reader's correct understanding of a text. In translation, "a translator applying explicitation makes elements which were implicit in the ST [source text] explicit in the TT [target text], for instance by explaining something more thoroughly" (Jensen, 2009, pp. 34-35). This can be achieved by using explanatory phrases or by spelling out implicatures, marking the difference between lay terminology and explicitation, as explicitation is generally considered to be more extensive than the use of proper lay terminology.

Explicitation can follow two patterns: (i) term + explicitation, e.g. *orthostatic hypotension (a drop in blood pressure*) or (ii) explicitation + term, e.g. *blood clots in the veins of your leg (deep vein thrombosis)* (Wermuth, 2016). Explicitation may "contain prepositions, conjunctions or relative pronouns and verbal constructions and may even constitute entire sentences" (Wermuth & Verplaetse, forthcoming).

Table 1 shows the different popularization strategies.

Popularization strategy		Explanation
a)	scientific term + lay term	
b)	lay term + scientific term	
c)	scientific term only	no lay term or explicitation added
d)	lay term only	no scientific term or explicitation added
e)	scientific term + explicitation	
f)	lay term + explicitation	

Table 1. Popularization strategies in PILs (Verplaetse & Wermuth, 2013; Wermuth & Verplaetse, forthcoming)

Instances of explicitation were only included in combination with lay or scientific terminology. The classification 'scientific term only' is, of course, not a popularization strategy, but is was included in Table 1 for the sake of completeness.

3. Lay-friendly PILs

PILs require clear and understandable language so that patients can easily grasp the information it contains. For PILs issued in the European Union, this requirement is stipulated in directive 2004/27/EC, amending directive 2001/83/EC, stating the following with regard to PILs or 'package leaflets': "the package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals" (Directive 2004/27/EC, 2004, Article 63(2), p. 49).

In other words, PILs must be *lay-friendly* (Jensen & Zethsen, 2012; Jensen, 2013). The concept of *lay-friendliness* refers to the understandability of texts for lay people: people who are unfamiliar with, in this case, specialized medical terms.

Throughout the years several initiatives have been taken to enhance the lay-friendliness of PILs, among which are user testing, the Readability Guideline and PIL templates in the European Union. In addition, there are also local initiatives, such as the *lijst met patiëntvriendelijke termen voor bijsluiters* (list with patient-friendly terms for patient information leaflets) issued by the Dutch *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB).

3.1 User testing

The European Union (EU) implemented user testing (consultations with target patient groups) in 2005 in accordance with article 59(3) from directive 2004/27/EC, viz. “the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use” (p. 49).

3.2 Readability Guideline

The Readability Guideline was first issued by the European Union in 1998 and last revised in January 2009. The main aim 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, Enterprise and Industry Directorate-General, 2009, p. 6).

3.3 PIL templates

Along with the introduction of the Readability Guideline, PIL templates were issued in all EU languages on the European Medicines Agency (EMA) website. These templates include the information which must be included on the labelling and package leaflet, as well as format, lay-out (cf. headings) and specific formulations, of medicines in accordance with Directive 2001/83/EC, e.g. identification of the medicine, conditions of use, circumstances in which the medicine should not be used, ... The use of the templates ensures that information appears as intended by the Directive and that it will be consistent across different medicines and Member States (European Commission, Enterprise and Industry Directorate-General, 2009, p. 11). The PIL templates contain six different default sections (www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000134.jsp):

1. What is your medicine and what is it used for
2. What you need to know before you take or use your medicine
3. How to take or use your medicine
4. Possible side effects
5. How to store your medicine
6. Contents of the pack and other information

3.4 Patient-friendly translations list

In the Netherlands the Dutch medicine regulation body, the *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB) took an initiative related to PIL terminology specifically, as it drew up a list of acceptable patient-friendly translations of scientific (medical) terms often used in PILs, the *lijst met patiëntvriendelijke termen voor bijsluiters* (list with patient-friendly terms for patient information leaflets).

The list is available in Dutch only on the CBG-MEB website (https://english.cbg-meb.nl/) and was last updated in 2015 (www.cbg-meb.nl/documenten/richtlijnen/2017/01/01/lijst-met-patientvriendelijke-termen). The list is meant as a guideline for PIL writers, rather than binding in nature. The writer can adapt the formulations offered at will.

4. Explicitation and uncertainty avoidance

Explicitation expresses uncertainty avoidance (Verplaetse & Wermuth, 2014). Hofstede (2001) defines uncertainty avoidance as follows: “the extent to which the members of a culture feel threatened by uncertain or unknown situations” (2001, p. 161). This is reflected in the Uncertainty Avoidance Index (UAI). The UAI per country was calculated by questioning employees of the corporation International Business Machines (IBM). It was based on their mean scores for job stress, rule orientation (to what extent the respondent agrees with the statement that "company rules should not be broken") and the percentage score of employees who intend to pursue a long-term career with the company (Hofstede *et al.*, 2010, p. 191). The UAI ranges from around 0, describing weak uncertainty avoidance, to around 100 for the strongest uncertainty avoidance, with a few exceptions as some countries with uncertainty avoidance indices of more than 100 were still added later (Hofstede *et al.*, 2010, p. 195).

The Dutch-speaking part of Belgium has a score of 97 on the UAI index. The French-speaking part has a similar score, viz. 93 (Hofstede *et al.*, 2010, p. 192).[3] These are two of the highest scores among the 76 countries in which Hofstede *et al.* (2010) measured the UAI index, with 112 as the highest score in the UAI for Greece.

In the Netherlands, avoiding uncertainty is also preferred, with a mid-range uncertainty avoidance score of over 50, viz. 53 (Hofstede *et al.*, 2010, p. 193). The Netherlands has a much lower uncertainty avoidance index than Belgium. This means that Belgium can be characterized as much more uncertainty-avoiding than the Netherlands. With a score of 35 on uncertainty avoidance the United Kingdom is a low uncertainty avoiding country (Hofstede *et al.*, 2010, p. 194). When comparing the uncertainty avoidance indices of Belgium and the Netherlands (Dutch-speaking societies) to the UK it can be concluded that the need to avoid uncertainty is higher in both Belgium and the Netherlands. This led to the hypothesis of a higher level of explicitation in Dutch PILs than in the original English PILs. Still, national differences must be taken into account, even within the English and Dutch language groups here, especially with a considerable deviation in UAI scores between the Dutch-speaking part of Belgium (97) and the Netherlands (53). Furthermore, it cannot be firmly established whether the PIL translations are produced by Netherlandic Dutch (cf. UAI score 53) or Belgian Dutch (cf. UAI score 97) translators, as all the pharmaceutical companies mentioned in the PILs have subsidiaries in both Belgium and the Netherlands, apart from the PILs for Xagrid (subsidiary in Belgium only) and Trisenox (subsidiary in the Netherlands only).

5. Research questions

The research questions of this study can be summarized as follows:

1) Can differences in the English and the Dutch PIL sections be detected regarding lay terminology, scientific terminology and explicitation to ensure lay-friendliness?

2) Do more Latin-based terms which are common language lay terms occur in the English PILs than in the Dutch PILs?

3) Is there more explicitation in Dutch patient information leaflets as Belgium and the Netherlands have a higher Uncertainty Avoidance Index than the United Kingdom?

[3] Currently no data are available for the German-speaking part of Belgium.

6. Methodology

6.1 Corpus compilation

We compiled a parallel corpus of randomly chosen PILs: it consists of English source texts and their corresponding Dutch translations. The corpus contains 24 PILs in total (12 English source texts and 12 Dutch translations). The PILs all originate from the EMA website. They contain information about medicines for cancer treatment (Caelyx, Temodal, Thalidomide Celgene, Trisenox, Velcade), diseases which might develop into cancer (viz. essential thrombocythaemia) (Xagrid), and infections (Victrelis, Rebetol, Prezista, Noxafil, Ecalta, Cancidas). [4]

All PILs on the EMA website are granted market authorization through the so-called centralised procedure in order to be marketed in the EU (www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp). As the English PIL is the first to be submitted in the marketing authorization process, the English PIL is always the first one to be produced (Jensen & Zethsen, 2012, p. 31). This implies that the PILs in the study were all originally written in English, and the Dutch PILs are translations.

6.2 Classification criteria

The terms and instances of explicitation included for this study meet the criteria set forth in the following sections.

6.2.1 Scientific terms

PILs are mostly intended for non-expert readers, as they are a patient-friendly rendering of the SmPC, which contains a more technical and specialized vocabulary. Therefore, scientific terms in PILs will often require explicitation to be understood. For example, *antiarrhythmics (drugs used to correct irregular heartbeats)*.

A resource to determine whether Dutch terms are to be considered scientific terms or not is the list with acceptable patient-friendly translations of Dutch scientific (medical) terms often used in patient information leaflets, the *lijst met patiëntvriendelijke termen voor bijsluiters* (list with patient-friendly terms for patient information leaflets) issued by the Dutch *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB).

Some scientific English terms can be described using synonyms that are easier to understand for lay people (lay terms). For example, *blood clot* as a lay term synonym for *embolism*, so that *embolism* is classified as a scientific term.

A number of corpus PILs contains the section “information intended for medical or healthcare professionals only” *(informatie alleen bestemd voor beroepsbeoefenaren in de gezondheidszorg)* (cf. section 6.3). As this information is not meant for people without a medical background, it will mostly contain scientific terminology.

To native Dutch speakers, Latin-based terms will often be regarded as scientific terms. If such a term is directly translated into Dutch from English, this might result in difficulties in understanding the text, as the register level increases (cf. Jiménez-Crespo, 2017, p. 5). Therefore, Latin-based terms should be replaced by lay terminology as they might be

[4] The PILs were produced by a wide range of pharmaceutical companies, viz. *MSD* (5 PILs), *Janssen-Cilag* (3 PILs), *Pfizer* (1), *Teva Pharma* (1 PIL), *Celgene Europe* (1 PIL) and *Shire* (1 PIL).

incomprehensible and very formal (Askehave & Zethsen, 2011, p. 16), which contrasts with native English speakers' register perception, for whom Latin-based terms are sometimes considered lay terms. This is the case when in English only a Latin-based term is available. For example, *constipation*. This is a Latin-based term for which the English language has no real equivalent, so native English speakers consider *constipation* a lay term. However, the Dutch word *constipatie* is regarded as a (Latin-based) scientific term, as a Dutch lay term is also available, viz. *verstopping*. The combination of the Latin-based Dutch term *constipatie* followed by its non-Latin based lay term *verstopping* demonstrates how popularization strategies can lower the register and can be used to adapt textual genres to a lay readership (cf. Jiménez-Crespo, 2017, p. 18).

The classification criteria of the current study for scientific terminology can be summarized as follows:

- Latin-based terms in English and in Dutch function as scientific terminology if a non-Latin based (Germanic) lay term equivalent is available;

- non-Latin-based terms in English and in Dutch for which no lay term equivalent is available;

- scientific entries in the *lijst met patiëntvriendelijke termen voor bijsluiters* (list with patient-friendly terms for patient information leaflets), issued by the Dutch *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB).

6.2.2 Lay terms

Terms which people with different backgrounds should be able to understand and act upon are considered lay terms (Askehave & Zethsen, 2011, p. 14). The PIL should be understandable for lay people who are unfamiliar with specialised scientific (medical) terms. Dahm (2012) also states that "[…] even native speakers might have various degrees of word knowledge or 'understanding' for different words, and understanding should therefore generally be seen as fluctuating rather than fixed" (p. 87): what is considered a lay term for some people might be considered a scientific term by others. Moreover, a lay term must not always be accompanied by a scientific term. According to the 2015 guidelines from the *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB), PIL writers can add a scientific (medical) term as they see fit. For example, *hives* (lay term). If the writer deems it necessary, the PIL writer can add *urticaria* (scientific term) to this term between brackets, but this is no obligation.

The classification criteria for lay terminology for the purposes of our study can be summarized as follows:

- English and Dutch non-Latin based terms for which a scientific (Latin-based) equivalent exists, e.g. *platelets* (scientific equivalent: *thrombocytes*), *shingles* (scientific equivalent: *herpes zoster*), *dikke darm* (scientific Dutch equivalent: *colon*), *blauwe plekken* (scientific Dutch equivalent: *hematomen*) (haematoma).

- English Latin-based terms for which no other (lay) equivalent is available, e.g. *constipation*, *retina*.

6.2.3 Explicitation

The aim of explicitation is to explain the scientific terms and even in some cases lay terms, by clarifying them or adding (more) explicit information. English or Dutch phrases containing prepositions, conjunctions or relative pronouns are not considered terms, but explicitation. Scientific or lay terms requiring extra information in order to be understood are classified as popularization strategies *scientific term + explicitation*, *explicitation + scientific term*, *lay term + explicitation or explicitation + lay term.*

The 2015 guidelines of the *College ter Beoordeling van Geneesmiddelen (CBG)* (Medicines Evaluation Board) (MEB) state that the popularization order *lay term + scientific term* (between brackets) is recommended in case the use of scientific (medical) terms is useful or necessary. The popularization strategy with the order *scientific term + lay term* is recommended by the *CBG* only if a sentence becomes difficult to read when the order *lay term + scientific term* is applied. This may be due to the length of the explicitation or in case the context requires the use of scientific (medical) terms.

The British Medicines and Healthcare Products Regulatory Agency (MHRA), together with the Working Group on Patient Information, developed a glossary for lay readers for reasons of consistency and the production of clear and understandable leaflets. This list is found in a report of the Committee on Safety of Medicines Working Group on Patient Information entitled "Always read the leaflet: Getting the best information with every medicine" (2005). The terms provided in this report were also used as a point of reference for explicitation in this study, together with an updated version of the list ("Glossary of medical terms in lay language") (http://besttext.pl/upload/htmle/file/Glossary_of_Medical_Terms_pil_spc.pdf).

A general rule of thumb applied in the corpus to distinguish an English/Dutch lay term from English/Dutch explicitation is that explicitation mostly consists of at least three words, often also including words belonging to different word classes. For instance, *blood clots in the arteries leading to your lungs* or (Dutch) *ernstige allergische reactie die kan beginnen als uitslag op één plek, maar zich uitbreidt met aanzienlijk huidverlies over het hele lichaam* (*serious allergic reaction that may begin as a rash in one area but spreads with extensive loss of skin over the whole body*). However, for reasons of uniformity, the corpus uses the classification *lay term + explicitation* in the case of a (one-word) lay term and a (one-word) synonym of that lay term used together. In other words, when two lay terms with the same meaning are used together the classification will be *lay term + explicitation*. An example in Dutch is *verhoging (koorts)* ([*temperature*] *increase (fever)*). Explicitation in English or Dutch may also consist of an entire sentence or a sentence part, often functioning as a description of the lay/scientific term it refers to, for instance *constipation (difficulty passing stools)*. *Constipation* is classified as an English (Latin-based) lay term, as in English no other (scientific) term is available. *Difficulty passing stools* is the description of what constipation is and is therefore classified as explicitation.

The classification criteria for explicitation can be summarized as follows:

- explicitation may "contain prepositions, conjunctions or relative pronouns and verbal constructions and may even constitute entire sentences" (Wermuth & Verplaetse, forthcoming).

These criteria apply in the following contexts:

- Dutch scientific Latin-based terms which require extra information to be understood;

- English or Dutch scientific terms which have no lay term equivalent and therefore require extra information to be understood (popularization strategy *scientific term + explicitation* or *explicitation + scientific term*;

- English or Dutch lay terms requiring extra information (popularization strategy *lay term + explicitation* or *explicitation + lay term*).

6.3 Corpus content

In the English PILs 39,245 words were analyzed (sections 1-6 of the PIL and the subsequent section 'information intended for medical or healthcare professionals only'[5] in the PILs containing this section). The Dutch PILs contained 41,010 words. The entire corpus consisted of 80,255 words.

For each instance of scientific terminology, lay terminology and explicitation in the corpus, the following information was provided:

- the name of the medicine of the PIL;

- the section (1-6) in which the instance of lay/scientific terminology and/or explicitation occurred; terms occurring in the section with information intended for medical or healthcare professionals only were indicated with an asterisk in the corpus;

- the popularization strategy of each instance in the English PIL;

- the popularization strategy of each instance in the Dutch translated PIL.

Latin-based terms or terms containing a Latin-based element are abbreviated as *LB* in Table 2.

Table 2 shows a sample of the corpus.

Medicine name + section	Kind of medicine	English	Dutch	Classification	
				English	Dutch
Caelyx (1)	antitumour	multiple myeloma, a cancer of the blood	multipel myeloom, een vorm van bloedkanker	scientific term + explicitation	scientific term + explicitation
Caelyx (4)	antitumour	seizures (convulsions)	stuiptrekkingen (convulsies)	Lay term + scientific term (LB)	Lay term + scientific term (LB)
Caelyx (4)	antitumour	anaemia (reduction in red blood cells)	anemie (vermindering van rode bloedcellen)	scientific term (LB) + explicitation	scientific term (LB) + explicitation

Table 2. Corpus sample

6.4 Quantitative data assessment

The corpus data were assessed quantitatively. First all instances of lay terminology, scientific terminology and explicitation were classified according to the popularization strategies in Table 1 (*scientific term + lay term*, *lay term + scientific term*, *scientific term only*, *lay term only*, *scientific term + explicitation*, *lay term + explicitation*).

[5] This was a very limited section with only 14 terms in total being included in the analysis.

A few additional categories could be added to the popularization strategies in Table 1 based on the relevant corpus content found. These additional categories were *explicitation only* and *explicitation + lay term*. An example of *explicitation only* is the Dutch phrase *onderdrukking van het afweersysteem* (*suppression of the immune system*) as a translation for the English scientific term *immunosuppression*.

In the Dutch corpus PILs also one instance of *lay term + scientific term + explicitation* occurred, viz. *bloedarmoede (anemie) (als u te weinig gezonde rode bloedcellen heeft, die de zuurstof in uw lichaam vervoeren)* as a translation of the English *anaemia (when you lack enough healthy red blood cells, which transport oxygen around your body)*.

The different classifications in the corpus were counted. The numbers retrieved were used to make comparisons between the English and the Dutch PILs in order to answer the following questions:

- whether there are any differences in the amount of scientific/lay terminology and explicitation between the PIL sections in the English and the Dutch PILs;

- whether it holds true that in the English PILs of the corpus there are more Latin-based terms which function as lay terminology than in the Dutch PILs;

- whether the Dutch PILs contain more explicitation than the English PILs (cf. higher uncertainty avoidance in Dutch-speaking societies [Belgium and the Netherlands] than English-speaking societies [United Kingdom]).

7. Results

7.1 General

In the 24 corpus PILs (12 English PILs and their 12 Dutch translations) 369 instances of scientific terminology, lay terminology and/or explicitation were found over the six different sections of all the PILs in the corpus.

Table 3 provides an overview of the different classifications in the English and the Dutch PILs.

Classification	Number of occurrences	
	English PILs	Dutch PILs
scientific term only	141	93
lay term only	42	62
explicitation only	3	14
scientific term + lay term	8	13
lay term + scientific term	16	36
scientific term + explicitation	68	56
explicitation + scientific term	64	59
lay term + explicitation	15	25
explicitation + lay term	12	10
lay term + scientific term + explicitation	0	1
Total	369	369

Table 3. Lay/scientific terminology and explicitation in the corpus PILs

Most instances of scientific terminology, lay terminology and explicitation (206) were found in PIL section 4 (*Possible side effects/Mogelijke bijwerkingen*).

7.2 Popularization strategies in the English versus the Dutch PIL sections

Table 4 provides an overview of the popularization strategies containing scientific terminology, lay terminology and explicitation in the English and Dutch PILs of the corpus respectively.

	English PILs	Dutch PILs
scientific terminology	297	258
lay terminology	93	147
explicitation	162	165

Table 4. Distribution of scientific terminology, lay terminology and explicitation in the corpus PILs

We found that the number of popularization strategies containing scientific terminology was higher in the English PILs than in the Dutch PILs. The popularization strategies in the Dutch PILs clearly contain much more lay terminology, but no real difference could be established with regard to explicitation.

Table 5 provides a more detailed overview of the most frequent popularization strategies per PIL section with regard to scientific terminology.

PIL section	Most frequent popularization strategy containing scientific terminology	
	English PILs	Dutch PILs
1	scientific term only (15)	scientific term only (14)
2	scientific term only (51)	scientific term only (39)
3	scientific term only (4) explicitation + scientific term (4)	explicitation + scientific term (4)
4	scientific term only (55)	lay term only (51)
5	scientific term only (3)	scientific term only (3)
6	scientific term only (13)	scientific term only (15)

Table 5. Most frequent scientifically oriented popularization strategies per PIL section

When assessing the differences in the relative proportions of lay terminology, scientific terminology and explicitation in the English and the Dutch PIL sections (cf. research question 1), we see that for both the English and the Dutch PILs *scientific term* is the most frequent strategy in nearly all PIL sections. The only sections in which this is not the case, are PIL sections 3 and 4 in the Dutch PILs: looking specifically at scientific and lay terminology in section 4 scientific terminology is the most frequent category in the English PILs with 55 instances, whereas lay terminology is the most frequent category in the Dutch PILs with 51 instances.

In section 3 *scientific term only* and *explicitation + scientific term* both occur 4 times (the maximum number) in the English PILs. In the Dutch PILs, the most frequent strategy in PIL section 3 is *explicitation + scientific term.* However, it must be noted that in this PIL section overall only 16 classifications were found.

If we look at lay terminology in particular, the following popularization strategies listed in Table 6 can be distinguished per PIL section.

PIL section	Most frequent popularization strategy containing lay terminology	
	English PILs	Dutch PILs
1	lay term only (2) explicitation + lay term (2) lay term + explicitation (2)	lay term + scientific term (2) explicitation + lay term (2) lay term + explicitation (2)
2	lay term only (7)	lay term only (9)
3	lay term only (3)	lay term only (2) lay term + explicitation (2)
4	lay term only (28)	lay term only (51)
5	-	-
6	lay term only (2)	-

Table 6. Most frequent lay terminology oriented popularization strategies per PIL section

In almost all PIL sections, *lay term only* is the most frequent popularization strategy with regard to lay terminology.

When comparing the English and the Dutch PILs no major differences can be detected between the most frequently used strategies.

With regard to popularization strategies containing explicitation the strategy *explicitation + scientific term* is used most frequently in all PIL sections, with the only exception being section 2 (*What you need to know before you take or use your medicine/Wanneer mag u dit middel niet gebruiken of innemen of wanneer moet u er extra voorzichtig mee zijn*), where *scientific term + explicitation* occurs more often than *explicitation + scientific term*, both in the English (23 versus 11 times) and in the Dutch PILs (18 versus 15 times) (cf. Table 7).

PIL section	Most frequent popularization strategy containing explicitation	
	English PILs	Dutch PILs
1	explicitation + scientific term (4)	explicitation + scientific term (4)
2	scientific term + explicitation (23)	scientific term + explicitation (18)
3	explicitation + scientific term (4)	explicitation + scientific term (4)
4	explicitation + scientific term (44)	explicitation + scientific term (35)
5	explicitation + scientific term (1)	explicitation + scientific term (1)
6	-	-

Table 7. Most frequent explicitation oriented popularization strategies per PIL section

In terms of most frequent popularization strategies per PIL section, no major differences could be detected looking at the English and the Dutch PILs separately (cf. research question 1).

However, when comparing the English and the Dutch PILs a clear difference can be noted in PIL section 4, where the popularization strategy *scientific term only* occurs most frequently in the English PILs, as opposed to *lay terminology only* in the Dutch PILs.

7.3 Use of Latin-based terminology in English vs Dutch PILs

In the English PILS 297 terms (lay or scientific terms) are Latin-based or contain a Latin-based element, e.g. *cornea* (Latin-based lay term), and *orally* (Latin-based scientific term) versus *by mouth* (explicitation for lay readers). 1 example of Latin-based lay explicitation can be found, e.g. *tiredness* (*fatigue*). In the English PILs 42 instances of Latin-based elements are classified as lay terminology on the basis of the criterion that these are Latin-based terms for which no other (lay) equivalent is available. Examples of such Latin-based lay terms are *sinuses* and *antifungals*.
In the Dutch PILs 214 terms (lay or scientific terms) are Latin-based or contain a Latin-based element. One instance of explicitation, viz. *infectie met hepatitis C* (*infection with hepatitis C*), also contains Latin-based elements, more specifically *infection* and *hepatitis*.
In the Dutch PILs only 2 Latin-based elements classify as lay terminology as opposed to 42 in the English PILs (cf. supra), viz. *indigestie* (*indigestion*) as a lay term for *dyspepsie* (*dyspepsia)* and *eczema*. All other corpus examples of lay/scientific terminology and explicitation do not contain any Latin-based elements. These results confirm the second research question that the English PILs of the corpus contain more Latin-based terms which are considered lay terminology (42) than the Dutch PILs (2). In English often no equivalent for Latin-based terms is available; these terms then function as lay terminology.

7.4 Explicitation and uncertainty avoidance

Our third research question relates to explicitation and uncertainty avoidance and is formulated as follows in section 5: is there more explicitation in Dutch patient information leaflets as Belgium and the Netherlands have a higher Uncertainty Avoidance Index than the United Kingdom?

In order to answer this research question we first looked at the classifications containing *explicitation* in the PIL, viz. *explicitation only*, *explicitation + scientific term*, *scientific term + explicitation*, *lay term + explicitation*, *explicitation + lay term* and *lay term + scientific term + explicitation*. We found 162 instances containing explicitation in the English PILs, as opposed to 165 in the Dutch PILs. This means that the relative proportions of explicitation in the English PILs and their Dutch translations are very similar. Therefore, the research question cannot be confirmed for the overall language groups containing different nationalities.

But as indicated in section 4 national differences within the English and Dutch language groups might account for the similar levels of uncertainty avoidance we found for the English PILs issued by the EMA and their Dutch translations. A considerable deviation in UAI scores pertains between the Dutch-speaking part of Belgium (97) and the Netherlands (53) on the one hand. The UAI score for the UK (35) is considerably lower than the UAI for the Netherlands (53). The Dutch language translators' origin (the Netherlands or Belgium) cannot be traced. But in a scenario of UK-English source text (cf. UAI 35) and Netherlandic Dutch target text, the UAI scores for the corresponding countries are less dissimilar (35 for the UK and 53 for the Netherlands) than in a comparison with the Belgian Dutch UAI (97).The smaller difference between these UAI scores for the UK and for the Netherlands reflects the number of instances of explicitation in the English source text PILs (162) and the Dutch language target text PILs of the corpus (165) somewhat more closely, so that the research question might partially be confirmed on the presumption that Netherlandic Dutch translators translated the original English PILs issued by the EMA.

8. Discussion of the results

The comprehensibility of PILs may be hampered by various factors, e.g. the use of (Latin-based) scientific medical terminology, as the PILs are based on the SmPC (van Vaerenbergh *et al.*, 2010; Pines, 2015; Wermuth, 2016; Wermuth & Verplaetse, forthcoming). The higher degree of receptivity to Latin-based terminology of languages with a (partial) Latin/Romance influx such as English compared to languages such as Dutch (cf. Zethsen, 2004; p. 132) is confirmed in our study, as the English PILs contain more Latin-based (lay) elements.

The nearly equal degree of explicitness of original English PILs and their Dutch translations shown in this study may, apart from the (Dutch/Flemish) origin of the translator (cf. section 7.4), also relate to specific translation procedures, viz. the EMA prefers translations which are close to the original (Askehave & Zethsen, 2002, p. 27). In other words, the translations must be oriented towards the English source text, which is the authorized version in the EU procedure (Nisbeth Brøgger, 2017, pp. 403-404). Therefore, the explicitation already present in the original English PILs may simply have been transferred to the Dutch translations.

The origin of the PIL writers, who are often medical experts such as pharmacists instead of linguists (Askehave & Zethsen, 2000; Askehave & Zethsen, 2002; Zethsen, 2004), may also play a role in the use of Latin-based terminology. If medical experts carry out the translation of the PIL, they use more Latin-based terms than translators do. More often than translators medical experts also just transfer Latin-based terms and lay terms/explicitation without making any changes (Jensen & Zethsen, 2012, p. 43). If such a direct transfer of Latin-based terms takes place and an explicitation or lay term is provided, in some cases the Latin-based nature may become subordinate, e.g. *seizures (convulsions*) and the Dutch translation *stuiptrekkingen (convulsies).* In this way, the Latin-based term will still be understandable for the lay reader because of the popularization strategy provided, even for the Dutch PIL-reader, for whom Latin-based *convulsies* is not immediately comprehensible from general language use, contrary to the English use of *convulsions.*

9. Conclusions

Even though translators have various popularization strategies at their disposal in a specialized genre such as a PIL, we found considerable uniformity in the popularization strategies used within the different PIL sections, but a clear difference between languages (in this case English versus Dutch) when the possible side effects of the medicine are explained in the PIL (PIL section 4). Whereas the (original) English PILs appear more scientifically-oriented, the Dutch (translated) PILs are directed more towards a lay readership.

The English target group is much more familiar with Latin-based terms in PILs as these terms have found their way into general language use. This may partially explain the apparent higher scientific orientation in the English PILs compared to the Dutch PILs. In contrast, for Dutch lay PIL readers Latin-based terminology is more often part of the scientific vocabulary spectrum. Therefore, these readers require additional lay terminology or explicitation in order to understand the Latin-based PIL information provided, which contributes to an increase in uncertainty avoidance.

With regard to explicitation as an expression of uncertainty avoidance, the results of the corpus analysis show no clear difference between the degree of explicitation in the English PILs and their Dutch translations, even though English-speaking societies in general are less uncertainty-avoiding than Dutch-speaking societies according to Hofstede (2001) and Hofstede *et al.* (2010). But national differences within the English and Dutch language groups

considered by Hofstede respectively show a more nuanced distribution of uncertainty avoidance in the language communities related to the PILs analyzed for the current study. This is reflected in the number of explicitations in the English and Dutch PILs of our corpus to some extent. However, with regard to terminology Dutch PILs are oriented more towards a lay target group, with overall a greater proportion of lay terminology in comparison to their English source texts. This indirectly implies a higher degree of uncertainty avoidance from a terminological point of view. We may conclude then that a higher degree of uncertainty avoidance in the Dutch PILs of the corpus is expressed by means of lay terminology rather than by means of explicitations.

10. Limitations and further research

The classification criteria in this contribution were specifically designed for this study. The use of other criteria might yield different results.

For this article the researcher analysed the use of lay terminology, scientific terminology and explicitation in original English PILs and their Dutch translations. The classifications found were analysed separately and then compared against each other over the different PIL sections. A mutual comparison of differences in the classifications per term (English versus Dutch) will be the object of further research.

This article only focusses on basic quantitative analysis. In an extended analysis phase statistical techniques such as the chi-square test of independence and the t-test comparing two proportions could be applied.

In this study only a parallel corpus was examined. In the future, comparable research could be carried out using PILs which are originally written in different languages, for instance, English versus Dutch, provided that the original language of these PILs can be firmly established.

Both the English language and the Dutch language contain national dialects (e.g. British versus American English or Belgian Dutch versus Netherlandic Dutch). In some cases, this may cause difficulties in determining the origin of the PILs. Further research could be conducted to specify these national dialects in order to compare national dialects in terms of scientific terminology, lay terminology and explicitation. Similarly, the comparison of PILs in other source and target languages can be conducted to examine whether there are any salient differences.

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