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ANALYSIS OF THE EFFECT OF TRANSLATION (ENGLISH-SPANISH) ON THE READABILITY OF PATIENT INFORMATION LEAFLETS

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Abstract

This paper focuses on the potential effects of translation from English into Spanish on the readability of patient information leaflets. It is based on the quantitative and qualitative analysis of the elements involved in the degree of readability of a corpus of 150 patient information leaflets specifically selected for this purpose. The results obtained and the conclusions reached after the analysis may be used to determine whether the translation process has any impact on the degree of readability of translated texts against original ones and, if so, to which degree it affects it.

Resumen

El presente artículo es una aproximación al estudio de los posibles efectos de la traducción inglés-español en la legibilidad de los prospectos de medicamentos. Se basa en la realización de un análisis cuantitativo y cualitativo de los elementos que intervienen en el grado de legibilidad de un corpus de 150 prospectos seleccionados de acuerdo con unos criterios ajustados a ese fin. Los resultados y conclusiones extraídos tras el análisis servirán para determinar si el proceso de traducción puede influir en el grado de legibilidad en los textos traducidos frente a los originales y, de ser así, en qué medida lo hace.

Keywords: Patient information leaflet. Translation. Readability. Genre. Corpus.

Palabras clave: Prospecto de medicamento. Traducción. Legibilidad. Género. Corpus.

1. Introduction

This article is based on a previous paper (cf. Martínez Motos, 2012) aimed at revising the different models of assessments of the quality of patient information leaflets in English and Spanish, and proposing a new model for the analysis of the effect of translation in the production of readable and usable patient information leaflets.

The implementation of such model included the following stages and methodologies: first, the analysis of a series of qualitative and quantitative aspects of a corpus selected in accordance with the research aim. Second, the extraction of information relating to users by means of a questionnaire. Third, the addition of extratextual data by means of a case study oriented at the description of the professional environment in which texts similar to those analysed in the first stage are translated. And, finally, the triangulation of results in order to reach conclusions presumably different from the ones obtained in previous work that dealt with the study of patient information leaflets from other perspectives.

This paper is aimed at presenting some of the results obtained from the quantitative analysis of a corpus, that is, the implementation of the aforementioned first stage. More specifically, the analysis focuses on the level of readability observed in original PILs in Spanish in comparison with those translated to this same language from English. In other words, it is aimed at determining whether the process of translation may have any effect on the level of readability of translated texts as opposed to original ones.

In the following paragraphs the concept of *readability* will be revised and PILs will be approached from a triple perspective as an object of study, i.e., as an object of legal harmonization, as a genre, and as an object of translation; followed by a description of the most relevant studies carried out on PILs from a generic, linguistic and translation perspective. Then, the criteria used for the selection of the corpus subsequently analysed are presented, as well as a description of the methodology used for said analysis. Later, the quantitative results are introduced, followed by their qualitative description. Finally, the conclusions reached are presented.

2. Key concepts and elements of the research aim

This article takes previous work from authors such as Askehave & Zethsen (2000, 2002), Clerehan, Hirsh & Buchbinder (2009), Gal & Prigat (2005), Hoste *et al*. (2010) and Pander Maat & Lentz (2010) as a starting point. They all agree that, in spite of all the intentions and efforts made both by the pharmaceutical industry and competent authorities, PILs are still not easily read by the layman and, as a result, they do not meet the linguistic and communicative needs of their potential users. The search for a potential answer to this question leads us to consider the following general hypothesis: patient information leaflets present readability problems for the lay receiver and the main reason for this would be the inappropriate use of language. If we add the fact that some PILs are the result of a double process of writing and, subsequently, translation, the following question arises: is the translation process (English-Spanish) a relevant factor in the production of more readable patient information leaflets? Are original PILs more readable than translated ones and vice versa?

Before focusing on providing a possible answer to these questions, the concept of *readability* must be tackled. Dubai (2004: 3) defines it as "what makes some texts easier to read than others" and adds that "it is often confused with legibility, which concerns typeface and layout". Göpferich (2009: 48) also emphasises this distinction and describes a different term, *legibility*, to refer to the "layout and design characteristics (macro-typography), the fonts used and other paraverbal features (micro-typography), as well as nonverbal elements". In Spanish, unlike Suárez Muñoz & Suárez Ramírez (2013), who use two different terms, *legibilidad* and *lecturabilidad*, Barrio Cantalejo *et al*. (2008b: 136) employ the same term, *legibilidad* ('readability') to refer to both typographical and linguistic aspects, but add the corresponding adjective, *legibilidad tipográfica* and *legibilidad lingüística*, and then establish a further distinction within the latter, i.e., *grammatical readability* (related to the structure and grammatical construction of the text) and *lexical readability* (linked to words and their meaning). In the present paper we will use the term 'readability' in reference to what Barrio Cantalejo *et al.* (2008b) called 'linguistic readability' in general.

3. Descriptive approach to PILs from a triple perspective

The number of articles dealing with different aspects of patient information leaflets has rapidly grown over the past two decades. Among other arguments aimed at justifying this increasing interest in the study and analysis of PILs, Jensen (2012: 237) points out the fact that "patients today demand transparency

and enough information in order to make informed choices about a proposed treatment option, or about taking a specific medication, etc." In other words, patients, potential users of PILs (among other health information materials), now play a more active role in their health management "as a result of a patient empowerment process within the healthcare system facilitated by means of a wide range of empowerment tools" (Askehave & Zethsen, 2010: 105). Among those tools stand out the political steps taken so that "people can participate in an informed way in the management of their own health" (Hall 2006: 271). That is, these are measures aimed specifically at guaranteeing the access to relevant and adequate information about treatments, medication and surgical procedures to patients. Regarding the implementation of such political and administrative measures, Connor *et al*. (2008: 117) state that "the degree to which a patient comprehends written messages related to prescription medications may be an important factor influencing patients' adherence to directives about medication use".

Thus, an increase in the level of awareness about the readability and usability problems of health information materials in general and PILs in particular is observed, although it seems that "in spite of all the intentions, complex and ambiguous texts still abound inexpert writing for the general public" (Askehave & Zethsen, 2002: 15), that is, many texts are still not easily read by the layman, among which PILs are included. To date, this statement has not been categorically and definitely refuted, thus leading to the establishment of new perspectives in the approach and analysis of the potential factors that play a role in it. In order for this to be achieved, the defining aspects of PILs must be approached and reviewed from three different perspectives: a) as objects of legal harmonization; b) as a type of genre; and c) as objects of translation.

3.1. PILs as objects of legal harmonization

In the European Union, member states are subject to both European and domestic legislation regarding the production, distribution and use of medicinal products. A single, standardised document is provided with prescription and non-prescription drugs. As far as PILs are concerned, European authorities have legislated by means of directives (Directive 2001/83/EC and Directive 2004/27/EC), a legislative act that sets out a goal that all EU countries must achieve and that allows the national authorities of each individual country to devise their own laws on how to reach these goals. In addition, a Working Group on Quality Review of Documents (QRD) to provide assistance to the European Medicines Agency's scientific committees and to companies on linguistic aspects of the product information for medicines was created. Thus,

a document called *Compilation of QRD decisions on stylistic matters in product information* was published in 2014.

In order to ensure that all the binding information was included in the right place and by means of a type of language adapted to patients' needs, European member states and the European Medicines Agency also agreed on a tool that would enable the review of the quality of the documents and the harmonization of templates called *Quality Review of Documents (QRD) templates*. These templates have been made according to the legislation in force and the linguistic parameters established on the *Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use* issued in 2009 by the Pharmaceutical Committee of the European Commission.

As a Member State, Spain adopted the provisions included in the above mentioned directives and launched a series of initiatives aimed at guaranteeing their implementation, such as the issuing of a document titled *Plan Estratégico de Política Farmacéutica* in 2004 and the appointment of the Spanish Agency of Medicines and Medical Devices (AEMPS) as responsible for the setting of new criteria aimed at guaranteeing the improvement of PIL's readability. According to this, low readability is mainly derived from the fact that very often the information contained is excessive, incomprehensible or inadequate. As a result, an association in charge of the advancement and spreading of pharmaceutical law in Spain called *Asociación Española de Derecho Farmacéutico*, ASEDEF, issued a document in 2007 titled *La redacción del prospecto: recomendaciones para mejorar su comprensión*. There, factors such as the use of scientific terms, abbreviations, lack of pictures to clarify information, lack of information in certain sections and the lack of updating of some information were pointed out.

Moreover, the obligation to provide PILs with medicines, as well as the requirements to which producers are subject regarding their format and content are, nowadays, the result of those changes introduced in the European legislation, to the point that the competent authority shall refuse the marketing authorization if the labelling or the package leaflets do not comply with the provisions. To sum up, PILs have to adhere to the communication patterns stipulated in a legal document which, ultimately, play a role in their level of readability and comprehension.

3.2 PILs as a genre

Patient information leaflets are considered a genre, defined as a "forma convencionalizada de texto que posee una función específica en la cultura en la que se inscribe y refleja un propósito del emisor previsible por parte del receptor" (cf. García Izquierdo, 2002: 3). The research group GENTT established

a classification of medical genres in which the first level was the category of macrogenre; the second level was the genre itself; and the third, if any, the subgenre. Accordingly, PILs, as a genre, would be included under the macrogenre *clinical texts* and would not have a subgenre under it (cf. García Izquierdo 2009: 129-133).

Askehave & Zethsen (2003) analysed the communicative situation in which PILs are produced and used, as well as the elements involved, and classified them as a prototypical example of what they called *public communication* "that occurs when a company or an organization communicates with the general public" (cf. Askehave & Zethsen 2003: 23) and includes genres that satisfy the following criteria: (a) are aimed at a large audience, often potentially the entire population of a country; (b) the audience is extremely heterogeneous; (c) the sender-receiver relationship is asymmetrical, that is, the sender is usually an expert and the receiver is a layperson; (d) the sender is unknown to the reader; (e) interaction between sender and receiver is practically nonexistent; (f) the channel through which the communication is transmitted is often the genre itself; (g) genres often, but not always, come into being as a result of legislation; (h) the purpose of public communication is functional, that is, the receiver is not only informed about something but is often supposed to use the document to perform some kind of action (cf. Askehave & Zethsen 2003: 24-25).

More specifically, Gamero Pérez (2001: 82) allocates PILs a double function, expositive and exhortative, given the fact that they are addressed to a doctor and to a patient at the same time. Likewise, García Izquierdo (2008: 2) envisages them as a predominantly instructive genre with expositive elements addressed to patients and used as a connecting bridge between them and the pharmaceutical industry. Montalt i Resurrecció & González Davies (2007: 57) classified medical genres according to two parameters: the global rhetorical purpose of the sender (instructive) and the global social function of the text (to follow a treatment).

In this paper, the idea of PILs having a double function is shared; however, the aforementioned distinction between two types of receivers (cf. Gamero Pérez 2001) would be in conflict with the asymmetrical sender-receiver relationship that characterises PILs as a prototypical example of public communication. This is added to the fact that PILs are aimed at general consumers as main receivers whereas health professionals are the receivers of a different, more specialized type of genre called *summary of product characteristics* (Mercado López 2003a: 83).

To sum up, PILs as a genre are the channel through which the pharmacist (sender) conveys a message with the aim of informing and instructing patients/consumers (receiver) about the safe use of pharmaceutical products and how to gain the most benefit from them, as well as how to take them correctly and effectively in order to protect patients/consumers against medication errors.

3.3 PILs as an object of intergeneric and intralinguisitc translation

In the European Union, there are two possible routes for authorising medicines: the centralised authorisation route and the national authorisation route (that includes the mutual-recognition procedure and the decentralised procedure). It all depends on the countries where the company intends to market the PIL and whether it was previously authorised at national level. Under the centralised authorisation procedure, pharmaceutical companies submit a single application to EMA and marketing authorisation is granted in all Member States at once. Among other things, the pharmaceutical company must provide a PIL, which in the centralised procedure is originally written in English and has to be translated into all EU languages.

We will now focus on two studies (Montalt i Resurrecció & García Izquierdo 2013; Askehave & Zethsen 2000) that add two more concepts to the description of PILs and other health information materials, i.e., intergeneric and intralinguistic translation. More specifically, Askehave & Zethsen (2002) point to two determining factors and reasons why, despite the legislation covering package leaflets at the European level, these still fail to meet users' communicative needs. Those factors are linked to translation: a) *intergeneric* translation, which takes place when the information of the summary of product information is extracted and transferred to the patient information leaflet; here the concept of *translation* is understood in a sense which is different to the traditional one, as the translation from a genre into a different one; b) *interlinguistic* translation, in the traditional sense of translation between languages, when the PIL in English is translated into other languages.

Therefore, the intergeneric translation that takes place in the production of PILs is a determining factor for the readability and usefulness of PILs, given the fact that it entails the selection of the information relevant for its lay receiver and its transfer to a different genre by means of the appropriate type of language. Another factor is added in the case of those PILs that must, subsequently, be subject to a process of interliguistic translation.

4. Previous studies on patient information leaflets as a genre

Studies carried out on PILs in the last two decades are based on both quantitative and qualitative methodologies. Quantitative methodologies focus on the use of readability formulas that estimate the level of comprehensibility and readability of health-related texts aimed at a lay audience (cf. Hedman 2008, Hardwood & Harrison 2004, Buchbinder *et al*. 2001, Ley & Florio 1996) and of patient information leaflets (cf. Ballesteros Peña & Fernández Aedo 2013, Barrio Cantalejo *et al*. 2008a/b, Mottram & Reed 1997). The application of these mathematical formulas gives a score corresponding to a statistical foreseeability of the degree of literacy needed by an average reader to be able to read and understand health related documents. There is a variety of formulas (cf. Dale-Chall, Flesch-Kincaid, SMOG and FOG index, Flesch-Szigriszt index, INFLESZ scale) that can be easily applied, although their validity and usefulness as the sole analysis tool have been challenged by some authors. Nevertheless, there are hybrid studies that combine both the application of a readability formula and other methods, such as interviews and focus groups (cf. March Cerdá, 2010). Studies aimed at statistically obtaining and quantifying data about the presence or not of specific terminological elements have also been published (cf. Delaere *et al*. 2009, Hoste *et al*. 2008, 2010).

As far qualitative methodologies are concerned, two different approaches can be distinguished regarding health-related texts in general and PILs in particular. On the one hand, the so-called *reception studies,* also known as *consumer-tests* or *user-tests*, are empirical studies aimed at obtaining data relating to the perception and/or satisfaction of users with PILs by means of the application of a series of research strategies such as interviews (cf. Connor *et al*. 2010, Barber et al. 2009, Wolf *et al*. 2007), focus groups (cf. Dickinson *et al*. 2013; Raynor *et al*. 2004, Koo, Krass & Aslani 2002), questionnaires (cf. Pander Maat & Lentz 2010, Clerehan *et al*. 2009, Berry *et al*. 2004, Berry, Michas & Bersellini 2003, Dickinson, Raynor & Duman 2001); or even a combination of the three (cf. Jensen 2013, Hirsh *et al*. 2009). These studies focus on the results, given the fact that the analysed data enable the description of the effect produced by a text on the reader (degree of comprehension, satisfaction and perception regarding its usability for the intended purpose).

On the other hand, textual studies are also used as a distinguished example of qualitative methodology. They involve the qualitative study and assessment of the textual, linguistic, stylistic or design elements of PILs, which can be done employing different approaches: a) translatology (cf. Askehave & Zethsen 2000a, 2002, 2003, 2006, 2008; Cacchiani 2006); b) systemic functional linguistics (cf. Clerehan, Hirsh & Buchbinder 2009, Clerehan & Buchbinder

2006, Clerehan, Buchbinder & Moodie 2005, Hirsh *et al*. 2009); c) discourse analysis (cf. Fage-Butler 2011a, 2011b; Askehave & Zethsen 2010; Connor *et al*. 2008; Dixon-Woods 2001).

4.1 Studies on PILs as a genre in Spain

In Spain, studies can be classified in two groups in accordance with the researchers involved and the objective pursued: a) those carried out by researchers from the field of translation, mostly focused on the contrastive analysis of an English-Spanish parallel corpus from a systemic functional linguistics approach (cf. Martí Ferriol 2016; García Izquierdo 2008; Mercado López 2003a, 2003b, 2004; Ruiz Garrido *et al*. 2006; Ruiz Garrido, Fortanet Gómez & Palmer Silveira 2008; Vázquez & del Árbol 2013, 2014); b) those performed by healthcare specialists, aimed at analysing and establishing the level of readability of a corpus in Spanish by means of the application of readability formulas (cf. Ballesteros Peña & Fernández Aedo 2013, March Cerdá *et al*. 2010, Barrio Cantalejo *et al*. 2008 a/b).

Three studies are especially relevant to this paper. Firstly, Barrio Cantalejo *et al.* (2008) measured the readability of 55 PILs by applying the Flesch Reading Ease Score (which indicates on a scale from 0 to 100 the level of difficulty that the comprehension of a text entails). Secondly, March Cerdá *et al*. (2009) combined the application of the same readability formula to the analysis of 100 PILs with two more methods of qualitative research, a semi-structured interview and a focus group). Lastly, Ballesteros Peña & Fernández Aedo (2013) measured the readability of a corpus made of PILs corresponding to the 30 most widely consumed medicines in Spain by means of a software called INFLESZ 1.0, which can be used to measure the readability of texts in Spanish according to the Flesch-Szigriszt Index (IFSZ).

5. Selection criteria of the corpus

In the above mentioned studies carried out in Spain, the selection of texts for the corpus of analysis was done in accordance with the following criteria: a) most common illnesses in a specific age range and; b) translations or originals in English and Spanish (cf. Ruiz Garrido, Palmer Silveira & Fortanet Gómez 2008; García Izquierdo 2007; Mercado López 2003b, 2004); c) most sold medicines (cf. Vázquez & del Árbol 2013, 2014; Ballesteros Peña & Fernández Aedo 2013; Barrio Cantalejo *et al.* 2008a/b; March Cerdá *et al*. 2010).

In the present study, the corpus was made of two parallel, monolingual (in Spanish), textual and closed subcorpora. Basically, two criteria were applied in

the selection of the texts: a) the source and; b) the language. In other words, there was a subcorpus of texts translated from English into Spanish made up of PILs authorised through the centralised procedure by the European Medicines Agency (EMEA) and a subcorpus of texts originally written in Spanish made up of PILs authorised through the national procedure by the Spanish Agency of Medicines and Medical Devices (AEMPS). The reasons for choosing these sources were: a) direct access to the complete document through the Internet via their reliable *web* page; b) the possibility of choosing and downloading from a large number of documents; c) availability of PILs in Spanish (translated in the case of EMA and originals in the case of AEMPS); d) availability of texts subject to a similar authorization procedure and thus subject to a series of legal requirements.

Furthermore, hospital medicines were excluded, as patients do not usually have access to their PIL before their administration, which is subject to the exclusive criteria of healthcare professionals. The same happens with vaccines, administered according to a calendar previously established by healthcare authorities and whose PIL is not normally available to the patient unless they are not included in the official vaccination calendar and need to be acquired in a pharmacy. Although these PILs are available by other means (such as the aforementioned *web* pages), not everybody has access to these online documents. Access to them depends highly either on the availability of Internet access and/or the ability of patients to use it or on healthcare professionals' will to provide it to inpatients.

The main disadvantage of these selection criteria lies in the lack of control of two variables: the production process of the documents and the people responsible for this production. However, there is no need to control these variables in order to attain the objectives of this paper, given the fact that these aims focus on the detection and identification of specific elements that play a role in the readability of PILs, instead of finding the reasons that determine, partially or completely, the presence of these elements. Once the sources had been chosen, the application of additional criteria for their selection was necessary in order to compile a corpus coherent with the function of the specific aim. Thus, only authorized PILs were selected, excluding those subject to additional follow-up and those related to hospital medicines and vaccines. Similarly, to ensure that all the PILs from the corpus contained the same sections, only those referring to compressed tablets were chosen.

Added to the previous criteria, a representative, limited number of texts was established, given the space-time limitations of the study. In accordance with the previous aspects, as well as with the size of corpora used in previous

studies, it was estimated that the random selection of 150 texts (from the pre-selected ones), 75 original (AEMPS corpus) and 75 translated (EMA corpus), was appropriate to the research goal.

6. Analysis methodology

As previously stated, this article focuses on readability in relation to the informative capacity (to transmit information in a clear and understandable way for the lay receiver) of PILs and their translation; thus the communication-based approach of the analysis. More specifically, the study is aimed at determining if the translation process may influence the degree of readability of translated texts as opposed to originals. In order to do so, the above-described corpus was analyzed (translated texts and originals separately) by means of the application of a readability formula called the INFLESZ scale. The quantitative data obtained would be subsequently analyzed qualitatively in order to establish the difference or similarities in the degree of readability of translations and originals in Spanish.

This formula, as well as others including Flesch Reading Ease Formula, SMOG index, Flesch-Kincaid Grade Level, Gunning FOG test or Fry Graph readability formula, base their analyses on the assumption that texts with a higher number of words and shorter sentences are easier to read and are used to establish the mathematical correlation between the size of words and sentences and how easily they can be read. Specifically, the RES Flesch scale rates texts on a 100-point scale divided in 7 sections. The average difficulty of a text was found to be between 60 and 70; the higher the score, the easier it is to understand the document. In 1959, Fernández-Huerta, a Spanish pedagogue adapted the scale to texts written in Spanish, associating each section to an academic level, and renaming it as *fórmula de lecturabilidad* (readability formula).

READABILITY	LEVEL	DEGREE
90-100	VERY EASY	FIT FOR 4th GRADE
80-90	EASY	FITFOR 5th GRADE
70-80	QUITE EASY	FIT FOR 6th GRADE
60-70	NORMAL	FITFOR 7thAND 8th GRADE
50-60	SOMEWHAT DIFFICULT	PREUNIVERSITARY
30-50	DIFFICULT	SELECTIVE COURSES
0-30	VERY DIFFICULT	UNIVERSITARY (SPECIALIZED)

Figure 1: Difficulty of texts in Spanish according to Fernández-Huerta's index

In his doctoral thesis, Szigriszt Pazos (1992) validated and adapted the Flesch Reading Ease Formula to texts in Spanish, and called it Flesch-Szigriszt Index (IFSZ). With this in mind, he modified the constants of the Flesch score, and named it 'Clarity Level Scale'. According to it, the score for texts in Spanish with an average level of readability was 50-65; the lower the score, the more difficult it is to understand the document.

Later on, Barrio Cantalejo *et al*. (2008b) claimed that said formula lacked consistency, as the text sample was neither representative nor random and thus the conclusions were not sufficiently consistent. They reviewed the Szigriszt scale comparing it with the Flesch scale and proposed an index according to Spanish reading habits called the INFLESZ index. It established five levels of difficulty for texts written in Spanish, as shown in the following figure:

POINTS	LEVEL	TYPE OF PUBLICATION
< 40	VERY DIFFICULT	Universitary, scientific
40-55	SOMEWHAT DIFFICULT	Baccalaureate, scientific information, specialized press
55-65	NORMAL	Secondary education, general press, sport press
65-80	QUITE EASY	Primary education, yellow press, successful novels
> 80	VERY EASY	Primary education, comics

Figure 2: Difficulty of texts in Spanish according to the INFLESZ scale

The INFLESZ index can be calculated automatically by means of a freeware version of a program called INFLESZ 1.0. It was chosen as an analysis tool in this study due to several factors, i.e., an electronic corpus could be analyzed and it was originally conceived as a reliable tool for the analysis of the readability of written texts in Spanish aimed at patients and later validated with PILs. The parameters measurable with INFLESZ 1.0 are the following: words, syllables, sentences, average syllables/word, average words/sentence, Flesch-Szigriszt Index [the formula is: 206,835 – (62,3 x S/P) – P/F, where P is the number of words of the active text, S the number of syllables and F the number of sentences]; the Inflesz Scale Grade (adapted from the Flesch-Szigriszt Index), Word correlation (resulting from the inclusion of Flesch formula in the Microsoft word utilities), Fernández-Huerta Index [206,84-(60 x (S / P)) – (1,02 x (P / F), where S is the number of syllables, P is the number of words and F the number of sentences]. The most relevant quantitative

results obtained with the application of INFLESZ to our corpus are presented and discussed in the following sections.

7. Results

7.1 Quantitative results from the application of INFLESZ 1.0

Sentence length is one of the parameters used to measure readability. Both the European Commission (2009) (with regard to PILs) and Askehave & Zethsen (2006) (with regard to expert-lay communication in general), recommend avoiding the use of long and complicated sentences (not only due to their length, but also to the lexis and structures used). In order to enable the visualization of the data obtained relating to this parameter, results were divided into 7 groups with a difference of 50 sentences, in other words, the first group comprised texts containing less than 150 sentences and the last consisted of texts with more than 400 sentences, as shown in the following graph:

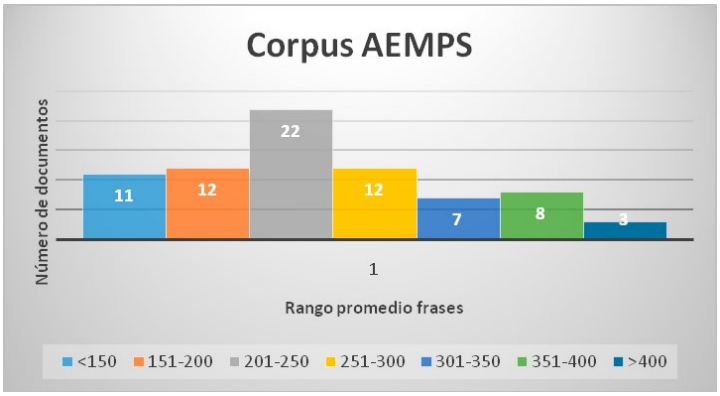

Figure 3: average number of sentences (AEMPS)

In the AEMPS corpus texts were divided up quite fairly within these 7 sections. The group of texts containing an average of 201-250 sentences in particular stands out from the group with 22 documents (29.33%), as does the group of texts containing less than 150 words in average, with only 2 texts. There are two more sections with 12 documents each corresponding to the texts with an average of 151-200 and 251-300 sentences respectively and another section including 11 documents with 150 sentences or less on average; at the other end of the scale, there is a group of 8 documents with an average of 351-400 sentences and another group made of 7 documents with an average of 301-350 sentences. Only 3 texts (4%) contain more than 400 sentences.

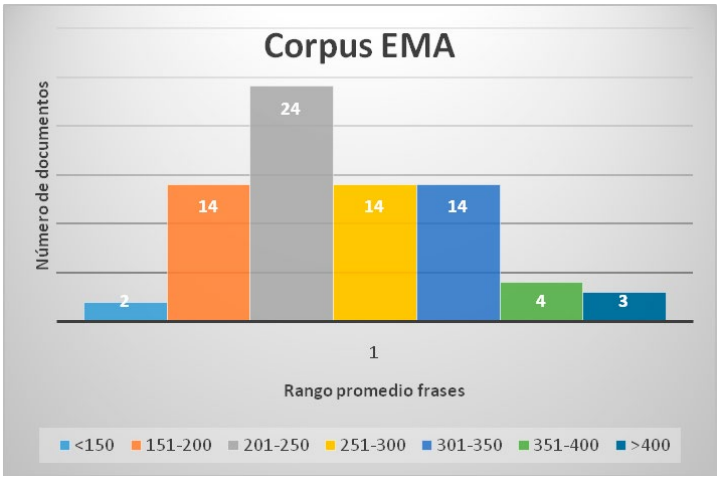

Figure 4

In the EMA corpus, 24 documents (32%) are made up of 201-250 sentences on average, followed by three groups with 14 documents each, made up of 151-200, 251-300 and 301-350 sentences respectively. Then there is a group of 4 documents with an average of 351-400 sentences and another of 3 texts with more than 400 sentences on average. Lastly, only 2 texts contain an average lower than 150 sentences.

The average of words per sentence is also a determining factor in the measurement of texts' readability. In fact, among other things (simple words and short sentences), the European Commission (2009) recommends the use of short paragraphs and the use of no more than 6 bullet points to organize the information. Traditionally, original texts in Spanish (especially lay-lay and expert-lay) are made of long sentences and paragraphs, full of subordinate clauses and appositions, compared to English texts, normally made up of more simple and short syntactic structures. To a lesser extent, the tendency to use long, syntactically complicated sentences is common in Spanish even in scientific and technological texts, whose textual conventions establish (above all expert-expert texts) the use of shorter sentences in order to ensure the precision and objectivity that of the type of information that is conveyed.

The analysis of the PILs that make up our corpus provides data regarding the words/sentence average. This data is divided into different sections, each within a span of 10 words. The following figure shows the AEMPS corpus results:

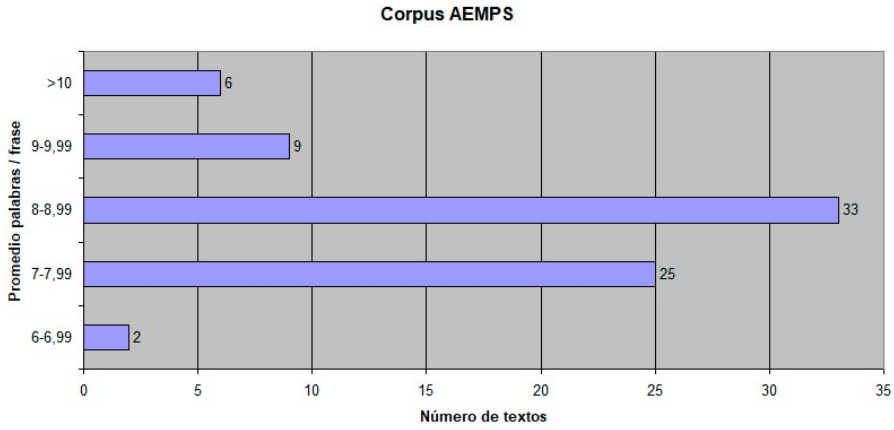

Figure 5: Average words/sentence (AEMPS)

Most of the PILs from the AEMPS corpus contain an average of 7-9 words per sentence; more specifically 33 (44%) had 8-8.99 and 25 (33.33%) had 7-7.99. It is followed, far behind, by a group of 9 (12%) texts with an average of 9-9.99 words per sentence and another of 6 documents with over 10 words. Only 2 texts are made up of 6-6.99 words/sentence in average.

As far as the EMA corpus is concerned, the biggest group was made up of 41 documents (54.6%) with an average of 8-8.99 words/sentence, followed far behind by a group composed of 17 texts (22.6%) with an average of 7-7.99. Then, there is a smaller group with 11 documents (8.25%) whose sentences are made of 7-7.99 words on average. Finally, a group of 5 documents with more than 10 words per sentence on average and, on the other end of the scale, 1 text with an average of 6-6.99 words, as shown in the following figure:

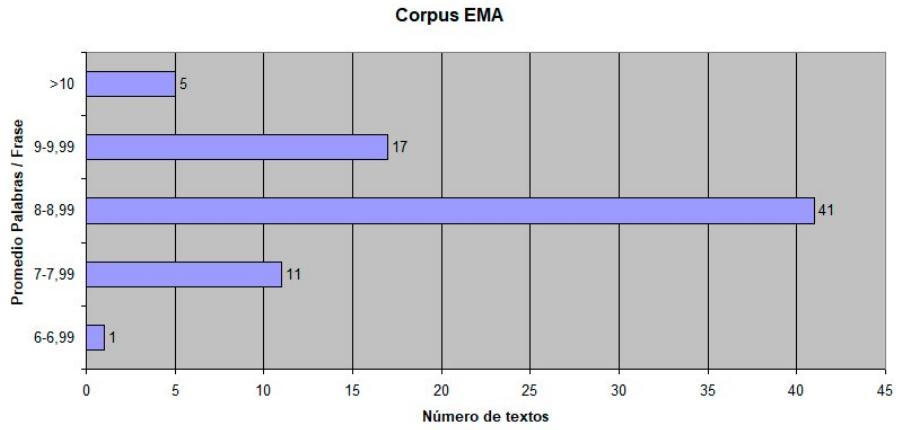

Figure 6: Average words/sentence (EMA)

Going back to the Inflesz scale readability level arising out of the combination of the Flesch-Szigriszt Index (a formula that combines the number of words, syllables and sentences in a text) and the Inflesz scale, which establishes five levels of readability for texts in Spanish. The results of the analysis of our corpus using this tool shows two differentiated groups in both subcorpora, each corresponding to two levels of readability, i.e., 'somewhat difficult' (40-55 points in the Flesch-Szigriszt Index) and 'normal' (equivalent to 55-65 points).

Nevertheless, the results of each subcorpus are opposed, given the fact that in the EMA corpus, 70.6% of PILs have 55-65 points in the Flesch-Inflesz Index, which corresponds to a 'normal' level of readability, and the rest has 40-55 points, which corresponds to a 'somewhat difficult' level of readability, as shown in the figure:

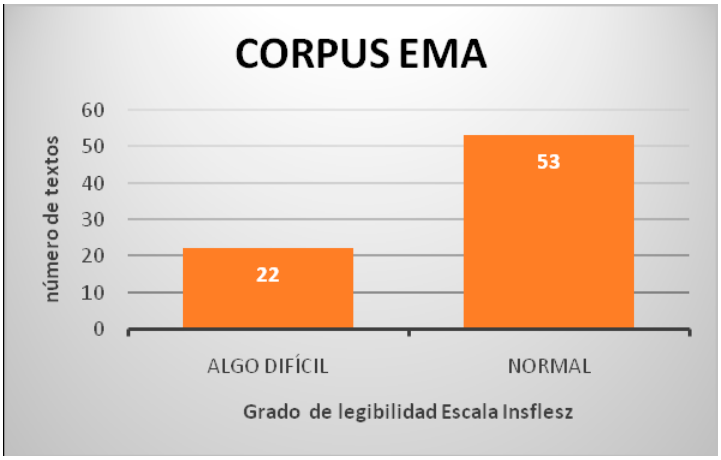

Figure 7: INFLESZ Scale (EMA)

On the contrary, 48 (64%) PILs from the AEMPS corpus get 40-55 points, that is, they are 'somewhat difficult' to read on the Inflesz scale, against 27 (36%) that present a 'normal' level of difficulty according to the same scale:

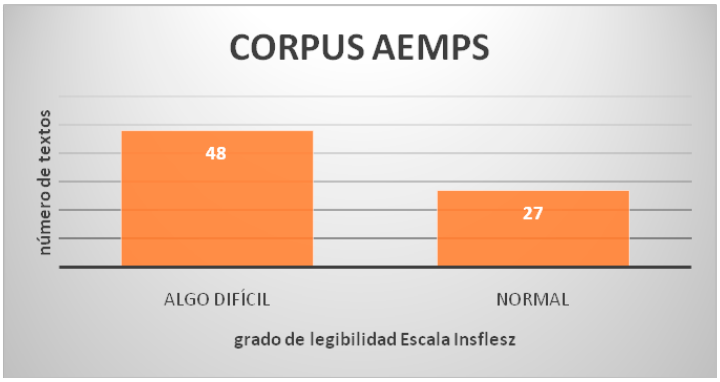

Figure 8: INFLESZ Scale (AEMPS)

The results obtained according to the Fernández-Huerta Index show very similar results in the case of EMA corpus, as 21 documents are located in the 'somewhat difficult' section (against 22 according to Inflesz Scale) and 54 in the 'normal' section (compared to 53 according to Inflesz Scale), as shown in the following figure:

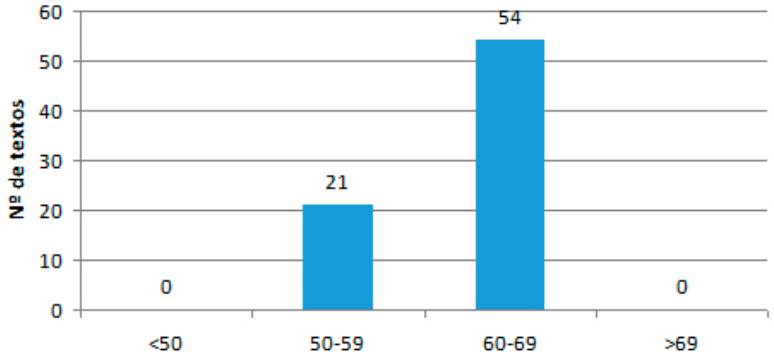

Figure 9: Fernández Huerta Index (EMA)

In the AEMPS corpus, 45 documents show a 'somewhat difficult' level of readability against 27 with 'normal' readability. Moreover, 2 are considered to be 'difficult' and 1 'quite easy' according to the Fernández-Huerta Index.

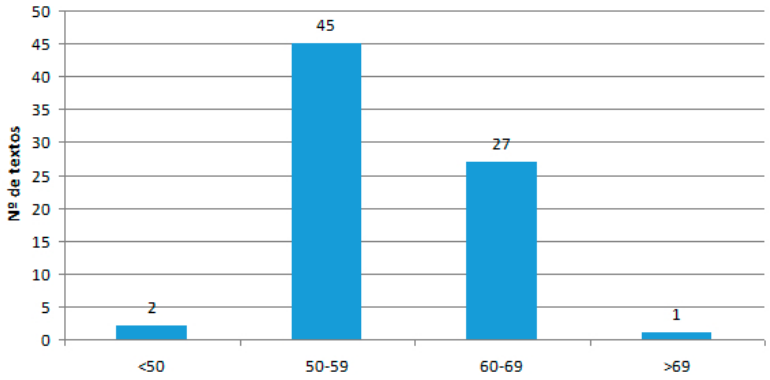

Figure 10: Fernández Huerta Index (AEMPS)

After the presentation of the most remarkable quantitative data regarding the analysis of readability in the corpus, their implications from a qualitative perspective shall now be evaluated and discussed.

7.2. Qualitative analysis of quantitative data

In relation with the average number of sentences that comprise the documents included in each subcorpus, originals (AEMPS) and translations (EMA), a

predominance of texts composed by an average number of 201-250 (almost a third of the total amount in both cases) can be observed. However, the total number of documents that contain an average of more than 250 sentences is higher in the EMA corpus, with 35 documents (46.66%), compared to 30 (40%) in the AEMPS corpus. Nevertheless, the difference regarding texts that comprise an average of less than 250 is more significant, given the fact that only 2 EMA patient information leaflets (2.66%) are included in this group against 11 AEMPS patient information leaflets (14.66%). In general, most of the documents of the EMA corpus are located in the middle sections (66 documents, 88%, with an average number of 150 to 350 words). But texts in the AEMPS corpus are much more unequally distributed among the 7 sections and show no significant difference between them. This leads to the conclusion that translations are more homogeneous as far as the structure and the length of the sentences used is concerned, compared to the originals, which show a higher level of heterogeneity and variety in this respect.

In contrast, the average number of words per sentence is higher in translated texts from the EMA corpus, as only 12 documents (16%) have equal or less than 7.99 words/sentence on average while the rest have a higher amount; compared to this, 27 original PILs (36%) were made up of sentences containing 7.99 words or less. As regards those with a higher amount of words, 33 texts (44%) have an average of 8-8.99 words per sentence in the AEMPS corpus, while in EMA corpus this number increased to 41 documents (54.6%). Finally, the analysis clearly shows the fact that the number of texts with an average of 9 words per sentence is higher in the EMA corpus (17 texts, 22.66%, with 9-9.99 words and 5 texts, 6.66%, with more than 10) than in the AEMPS corpus (9 texts, 12%, with 9-9.99 words and 6 texts, 8%, with more than 10).

Therefore, it is noticeable that texts translated from English into Spanish have, in general, a higher word/sentence average than the originals, given the fact that texts in Spanish (derived from the idiosyncratic nature of the language and its syntax) are usually made of longer and syntactically more complicated sentences than original texts in English. So, as a result of the transposition of original structures, translated texts from English into Spanish should naturally be made up of not very long sentences without apparently any complication from a syntactic point of view. This leads us to wonder if this is due to the fact that translators tend to insert clarification elements (such as appositions or explanations) and are more aware of the potential needs of the end receiver, who does not have enough knowledge on the subject area. A more specific answer would though require further analysis in search of data that would allow us to validate or contradict this hypothesis.

Lastly, in relation to readability according to the Inflesz Scale, opposite results between both subcorpora were shown, as 64% original PILs obtained a degree of readability 'somewhat difficult', while the remaining texts showed a 'normal' level of readability; however, 70.6% translated PILs found to be within a 'normal' level of readability, against the remaining 29.4% 'somewhat difficult' texts. Surprisingly, original texts are much less readable than translated texts according to the Inflesz Scale. It could be argued that it is due to the parameters involved in the measurement of Flesch-Szigriszt and Fernández-Huertas indexes, i.e., number of syllables, number of words and number of sentences. However, going back to the results discussed above with regard to the number of sentences and the average of words per sentence, it can be concluded that it could be justified by the absolute numbers, instead of average numbers, and that said 'difficulty' lies in the number of syllables of words more than in the length of the sentences of which the text is composed. This result, together with the results above concerning the average words/sentence, raises the issue of a potential effect of other extratextual parameters and elements that could eventually be analysed in order to obtain further data thereon.

8. Conclusions

To conclude, the qualitative results of this study seem to show that original PILs in Spanish give rise to more readability problems than translated ones. This could be due to the conventions of the Spanish language in general and of Pharmaceutical Science in particular, which are both captured through the use that expert writers make of them. Experts' conceptual and metalinguistic knowledge ensures precision and correction in the information that they convey, despite their linguistic and communicative competence seeming to be more limited. Nevertheless, the latter constitutes a hypothesis that would need to be demonstrated in later studies including other parameters of analysis.

Moreover, the results appear to reflect the impact of the implementation and application of legislative measures and recommendations adopted in the last decade by European and Spanish authorities. The use of templates and the recommendation to use bullet points to avoid long and complicated sentences may have had some influence on the reduction of sentence length and of the number of sentences used in original PILs in Spanish.

Despite the above, readability indexes such as Flesch-Szigriszt (that also includes other parameters, like the number of words, syllables and sentences); still reveal 'negative' results regarding original PILs. In this case, 'somewhat difficult' texts seem to predominate, while the analysis of the translated corpus

shows more 'positive' results, with the predominance of texts located at a 'normal' level of readability.

Therefore, in response to the question of whether the translation process English-Spanish was, in general, a determining factor in the production of easily readable PILs, it should be said that, generally speaking, translation does not seem to have a negative impact on the readability of PILs; however, it does seem to have a limited impact, not due to the translation process itself (as translators seem to have the required linguistic knowledge), but to the legal framework and the wide range of recommendations and translation patterns to which it is paradoxically subject in order to guarantee such readability.

The results of this study naturally lead us to the setting up of new scenarios that would require to be approached in future studies from a perspective that incorporates additional, extratextual parameters. More specifically, it would be a case study geared towards the description of the professional framework in which both the production of original PILs in Spanish and the translation of those originally written in English takes place. It would provide key information about the restrictions and working conditions to which technical writers and translators are subjected to in the fulfilment of their daily professional duties (added to the above mentioned legal restrictions). In addition, it would be interesting to design some kind of consumer testing study, by means of a focal group, an interview or a questionnaire as this would provide additional data and a new perspective in combination with other methodologies.

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