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FINAL THESIS (TFG)

Medical English: Reflections, Translation and Analysis of Scientific-Technical Language in Medicinal Products, a Phraseological Comparison of British and Spanish Patient Information Leaflets from a Linguistic Standpoint.

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Contents

Abstract

The main aim of this dissertation is exploring, defining and comparing patient information leaflets, in the hope of shedding light onto the realm of medical communication from the perspective of linguistics and traductology or translation studies, with a keen focus on phraseological structures as well as the very anatomy of the patient information leaflet, its macro- and microstructure.

In this project I study the concept of Patient Information Leaflets (PILs) as a textual genre and how this genre encompasses medical texts, a distinctive field claiming its own category as the medical genre. One of the core motivations of this thesis is the interest for medical language as a pivotal point to tackle the analysis of different versions (Spanish and English) of package information, presented as a comparative study to offer the interpretations when collating the both renderings of a PIL.

1. Introduction

In order to commence this final thesis, and nearing the end of my degree in English Studies, I will try to apply all the knowledge transmitted to me in 4 years of lectures and seminars, as to fill the primary aim of this project. There is a wide range of areas or fields that this work will touch upon, including linguistics, translation theory, and medical terminology, with a keen interest in observation and comparison.

With regard to the core topic of this dissertation, Patient Information Leaflets(PILs), sometimes addressed without much distinction as package information or package leaflet, it will be studied from a translational analysis perspective, since it is the minor or specialty related with the degree that I personally chose. My minor on translation has always been the cornerstone of the degree throughout this four-year journey, so it is without much deliberation that I have selected this to be the focal point of the thesis.

The discipline of medicine in relation to PILs and their specific vocabulary, as well as the European Union (EU) and the UK's legal stance on either version of the documents, will be taken into account. Moreover, I will also comment on some of the issues and inadequacies that have arisen in terms of the comprehensibility and acceptability of the

information present on these products towards the potential readers and patients they are destined to, that is, I will comment possible difficult or misleading terms or instructions that are to be found in PILs, of which some may lead to misunderstanding. Proper communication in these cases acquires much more importance than in other cases, as the purpose is one of professional supervision, healthcare. and, in general, a case of public health.

2. Methodology

Regarding this thesis, I have selected one patient information leaflet, in both its Spanish and English versions, so as to proceed to carry out a comparative analysis. The — generic medical— product chosen was Tamoxifen 20 mg.

This anti-oestrogen blocks the effects of a hormone called oestrogen in your body. Tamoxifen is used in the treatment and prevention of breast cancer (in the case of women with increased likelihood of developing breast cancer) and also to stimulate ovulation (the production of an egg). The usual dosage prescribed are tablets of 20 mg, even though greater tablets or liquid forms of this medicine may be used — in these cases, usually divided in half and taken twice in a day—. Its route of administration is oral, that is, one should take this medication by mouth (with or without having eaten before), once or twice a day (morning/evening) depending, as I have just said, on the size of dose. I will use the Spanish and the UK version of the PIL to exemplify and present an analysis as the basic document on which the main practical part of the thesis is based on. With regard to the origins of this leaflet, the Spanish version was acquired from the AEMPS (Agencia Española de Medicamentos y Productos Sanitarios), while the English version comes from the website of the Electronic Medicines Compendium (EMC) which provides information about medicines licensed for use in the UK.

The fair disparity in terms of the translation between the two is one of the reasons why I chose them, so as to have a larger repertoire from which to extract and analyse the potential expressions, terms and phrases used in the wording of the document. On another note, and with respect to the structure of the project, it will feature theoretical backdrop and points that will be later on proposed relying on actual legitimate online resources such as articles, thesis and academic publications. The empirical, comparative and observational work in this endeavour will tackle the apprehension of phrases of the

original and the adaptation into Spanish of the medicinal information, all done from a translation studies perspective, as it is the discipline that revolves around a great number of these kinds of textual investigation. Finally, there will be a section which will gather the conclusions and outcomes assembled from the main similarities and differences as well as the concept that will be established around package information/ leaflet information as a textual genre.

3. Theoretical Background

3.1 Legal framework

As to start this theoretical foundation, I will begin by laying out the main regulations concerning the tasks of designing, producing and issuing revisions, directives and additions of the pharmaceutical legislation in force nowadays in the EU, that is, how the patient information leaflets are handled in terms of the legal framework.

To make it clear, I am making a reference here to the EU regulations, since both leaflets have been written in languages from two of the member states of the European Union — and thus official languages—, namely, the UK and Spain. If there were any doubt about whether the UK is still under EU´s laws, policies and restrictions because of the Brexit procedure, the European Union official site states: 'For the time being, the United Kingdom remains a full member of the EU and rights and obligations continue to fully apply in and to the UK.' (European Union). The actual organism that supervises everything is the EMA (The European Medicines Agency). I would like to quote its purpose for the sake of clarity:

> Said organism´s finality is looking after animal and human health monitoring and assessing the medicines as well as granting marketing authorizations, established in 1995 (European Union)

We must keep in mind that there are also regulations that operate within the national level, as it is the case of the AEMPS in Spain, mentioned above. This agency is attached to the Ministry of Health, Social Services and Equality. This institution is in charge of regulating the layout and contents present in the actual patient information leaflets.

The directive 92/27/EEC, passed by the European Council in 1992, originally regulated the contents and placing of the information addressed to the patients, which, according to said legislation, should be clear and precise. Regarding the placement of the

instructive information of the product, it commanded it were present on the leaflet or in the outer packaging if it was possible. Moreover, it also elaborated on what kinds of hints the leaflet should provide in order to make good use of the product, such as: qualitative and quantitative composition, active principles, proper administration and further indications.

Later, this policy was abolished by a community code on medicinal products for human consumption, the directive 2001/83/EEC. Its main objective was to reinforce and underline the fact that medicines should abide by the authorisation rules stated by the EU, following its strict proceedings in order to successfully ensure that all drugs attain the quality standards. Also, it puts special emphasis in expressing the previous dispositions as far as distribution, labelling, production, marketing, etc. Controls of this type usually prevent deceitful publicity from manipulating the product's real usage to deceive or trick the public into thinking that properties are much more noticeable. Besides, these policies compel the manufacturing companies to be clear about the risks and tested data about the drugs' practicality.

Going back to the selected PILs, due to one of them being a British one, I must go through the main regulators for licensed medicines in the UK. In relation with the online document containing the PIL for Tamoxifen that I will be analysing, I must make reference to the electronic archive from which it was retrieved, the EMC. This former website links you to the MHRA (Medicines and Healthcare products Regulatory Agency), a regulatory British government agency. This institution informs about safe drug use, as well as approving the licenses for the prescribed products, or regulating medical devices and blood components for transfusions as an executive agency.

3.2 The concept of the *PIL* as a textual genre

As a starting point, since the invention of writing, there has been a tendency to classify, to group writings into compilations or genres concerning the same content or task, even function. The objective of this categorization, of this way of structuring written works is no other than to be able to orderly store them and have them at hand, all piled together, so as to have access to all papers, books and publications pertaining to one specific topic. This would also mean getting rid of the time-consuming task of

selecting and discarding irrelevant ones. Originally, the concept of "type of text" or textual genres, is often contained within an umbrella term, speech genres, which is usually studied in conjunction with text types, as Angélica Alexopoulou states about the general beginnings of the word "genre":

> Los orígenes del concepto de género se remontan a la Retórica clásica que ha sido recuperada entre otros por el teórico ruso Mijail Bajtín, quien desde la década de los '50 del siglo XX formuló la teoría de los géneros discursivos. Bajtín (1979) puso de relieve que el género es un conjunto de enunciados relativamente estable ligado a una esfera social determinada. (Angélica Alexopoulou, 2011: 101)

PILs, in general, have a similar design or structure, share the same features and, as part of a genre, follow a set of conventions. With regard to the layout, the same structures are repeated in all of them: a careful introduction presenting the product, what it is used for, things to keep in mind before consumption, how to —and how not to— take it or administer it. This would be part of the macrostructure, and as Sebastian Mercado contends:

> "Por último, en cuanto a los géneros, la estructura compartida constituye lo que ahora en adelante llamaremos macroestructura. Este formato u organización superior constituye una de las primeras convenciones de un género. Por otro lado, la estructura secundaria, es decir, las secciones dentro de la macroestructura, está formada por movimientos, igual que los fragmentos de una sinfonía. Los movimientos cumplen una función o intención comunicativa concreta dentro de la macroestructura y son los componentes diferenciados de cada sección" (Alcaraz 2000:135). (Mercado, 2003)

This is so intuitive, a set of characteristics so familiar to us, that even our head can group this information put together based only on a rough schematic view of it, hence, they are recognised and understood by a community of academics, professionals and social groups and in the case of PILs, hopefully by non-specialised readers (mainly, the consumers, the users)

Thus, there is a necessity to form a genre for this kind of textual documents, even more so when we are talking about medical language and professional writings based on science — medical discourse. On the other hand, there is another point worth mentioning which would revolve around the finality of these texts and whether they have any differentiation in terms of the language they use. PILs are texts with an informative purpose, they are instructional, and that would comprise their communicative function or their intention regarding the reader, among other functions like narrative, argumentative or descriptive ones. Also, their register is formal and quite closed, often too reliant on specialised terms which may difficult one of their main

functions, instructing users. This is another issue I will touch upon on upcoming sections on this thesis.

3.3 Parts of the PIL

Patient information leaflets are provided by the manufacturer following a standard template consisting of the same types of information for every medication. Firstly, they feature the commercial name of the product; concerning the nomenclature and the designated names of the product or the active ingredients, there may be some variation depending on the country. As Vincent Montalt and María González Davies contend:

> It is also important for medical translators to bear in mind that some countries prefer using national nomenclatures instead of the international one recommended by the World Health Organization, International Non-proprietary Names, INN. Therefore, the generic name used may vary from one country to another when naming active ingredients of the medicine in the name of the product section of the PIL (Montalt & González-Davies 2007: 72)

Right after the commercial name that has been given to the product, we are presented the pharmaceutical form and its strength, and this is the form in which the drug has been produced for human consumption, whether it is one format or another, such as tablets, syrup, aerosol, capsules... (Montalt & González-Davies, 2007: 70) This is followed by a warning, a request for the reader to read the document calmly and to take into account some basic information that will be of use. Next, a summary is presented, —an enumeration of the main points that the leaflet will be organised in—, usually starting with a description filling in the patient on what the medicine at hand is and what the purpose of taking it is.

After the introduction to the product, it goes on to share some important considerations to be noticed before administering the drug. Then, an explanatory point states how to take the drug, followed by a list of some side effects the patient should be aware of. The last two points make reference at how the drug should be stored or preserved correctly, and, as a final point, it provides additional information basically specifications and data the manufacturer is legally bounded to add. To begin with the first point and its description of this drug it explains what kind of substance it is and the hormone-related conditions it is used to treat, whether it is anovulatory infertility, or reducing the risk of

developing breast cancer in women with proclivity to that condition by suppressing the effects of oestrogen in the body. Regarding the question of infertility, Crosignani and his colleagues discuss the effects of tamoxifen, saying that "...the most cost effective profertility treatment is the administration of an anti-oestrogen such as clomiphene or tamoxifen." (Crosignani et al, 1999: 108)

As for the second point, it specifies some requisites the patient must meet to use the drug safely, e.g. not being allergic to tamoxifen or the ingredients in it, nor being treated with anastrozol or being treated for infertility issues, etc. The "warnings and precautions" section within this second point against ill-uses of this medicine includes further risk factors that can endanger the health of the patient under this treatment such as being overweight, having a family history of blood clots, being treated with chemotherapy—since it is also stated that this drug has a coagulatory effect on the blood— and the like. The use of tamoxifen is also discouraged in post-surgery and immobility scenarios. As for the next sections, it forbids the use of this drug in children, as well as citing a list of substances that can be disruptive with respect to Tamoxifen. For the last section in this point, it asserts that users must make sure they are not pregnant when starting a treatment with Tamoxifen, also prohibiting its use in breast-feeding stages. Finally, it dissuades patients from operating machinery or driving if Tamoxifen has made them feel light-headed.

Regarding the third point, we are given some advice as to how to administer it in an adequate manner, as it informs about the procedure: how to take the tablets, dosages, etc. We are also offered advice about its proper administration on elderly people, as well as indications to follow when patients go over or under the recommended amounts, advising the consumer to not stop taking the drug beforehand if he or she has not consulted his or her doctor yet. The fourth point in the list makes reference to the possible side effects patients are liable to experience and warning them to contact their doctor as soon as possible if said side effects are manifested. The array of side effects is grouped into the following categories; very common, common, uncommon, rare and very rare. The same categories are used to pool a different range of disorders, in this case, ones that can occur after long-term use of Tamoxifen. The fifth point, versing about the proper storing conditions of the product, is brief and tells the user to consider the expiration date, to avoid storing the product above temperatures of 25 degrees

Celsius, from storing it in its own packaging to be protected from moisture and light and finally some eco-friendly ways of correctly disposing of the drug.

On a last note, we are presented with the very ingredients of the drug and the proportions of Tamoxifen citrate in 20mg tablets, a description of the appearance of the tablet in addition to the sorts of plastic containers the drug is available in, displaying various package sizes. Here we can find the composition of the medicinal product, including the qualitative and quantitative composition of the active substance and the full qualitative composition of the excipients. (Vincent Montalt María González Davies 2007: 70). With reference to the package leaflet that concerns this thesis, the composition of the active substance is showcased in point number 6 (Contents of the pack and other information) but there is no mentioning of the quantitative proportions of the excipients included: "mannitol", "maize starch", "croscarmellose sodium" and "magnesium stearate". Lastly, for legal reasons, the Marketing Authorisation Holder and the Manufacturers data are provided, alongside with the last date in which the document was revised.

4. Medical language and doctor-patient relationship

To begin with, I believe this section is strongly linked with the primordial goal of languages in other words, communication. A leaflet is, in its own way, a form of non-direct communication: there is no face-to-face encounter between doctor and patient, for it is the goal of the leaflet to serve as a document that describes the specific features of the drug in enough detail as to make the consumer aware of its usage, risks or way of consumption. Nevertheless, were extra communications needed, the doctor/ pharmacist is available for the consumer. That proves in my opinion that quality communication and information can also take a written form as in patient information leaflets, flyers, patient guidelines, documents that provide lots of factual information of crucial importance to the receiver; dosages, symptoms to watch out for, risk factors, and so on. Everything in the leaflet, however, must be accessible lexically speaking to maximize the comprehensibility of the utterances, guaranteeing brevity and conciseness and hence a better understanding of it. The chemical composition and clinical aspects of the drug

— that is, more "academical" information— must nevertheless be present in every leaflet.

The main problem that arises regarding PILs is that a fair deal of the consumers can be ignoring the leaflet that will instruct them through the course of action they must follow. Skipping the reading part of the leaflet is a practise that consumers should not engage on.

> After de doctor has prescribed the medicine, the patient alone is responsible for taking it as directed; that is, in a safe and effective way. Safety and efficacy depend not only on the indications and contraindications of the medicine but also on taking it exactly as prescribed. Taking more or less medicine than prescribed or taking it under certain circumstances may be a cause for concern. Hence the importance of accuracy and clarity when translating PILs, especially the section devoted to posology and method of administration (Montalt & González-Davies 2007: 69)

Breaking down an upcoming treatment someone will be undergoing means orienting them the right way so as they can be fully conscientious about the repercussions this treatment may have. Making sure they figure out the way they must conduct themselves throughout the time span a disease can last. Doctors and physicians are also in charge of a task that is usually widely disregarded, closing up the gap of incomprehension that can spark up between Doctor and patient, between different spheres or social groups or collectives. The main tool a doctor has available is the way they construct their speech, a discourse that can sometimes be thrown at patients a little too abruptly. The end goal of this section is to shed some light as to how to achieve a closer mediation between the parties, attaining a more efficient interaction that looks up to the hearer's empowerment and well-being. It is primordial in my estimation to not just look at communication as an instrument downgraded to merely a secondary role. This perspective strikes with even more significance when we look at the fact that, being a doctor or a healthcare professional means that one will be dealing with people from the most diverse social classes or age groups, with a multiplicity of internal tendencies that dictate how the interaction will unfold. Hence, it is a tough task for the doctor to accommodate his or her speech to the patients.

People also have their own inadequacies, necessities, expectations, and they process information at a faster or slower pace given the basic knowledge they may have of such advanced medical terminology. As I have pointed out, this is in no way an easy task to carry out. Speech shapes the reality that the recipient imagines and creates, a mental map that will guide him or her in the coming journey. Perhaps it is wiser to tackle this

topic from the ground up, reconsidering one of the main qualities of language, where this compelling power of words stems from. While it is true that statements, as simplistic as they may be, can be boiled down to a simple informative purpose, a dichotomy can certainly arise whenever we talk about utterances. In addition to the essentially informative literal sense, a connotation or a figurative but also performative action may be induced from the sentence or clause. (Palacios, 2004: 137).

Instances of speech, or phrases, automatically put forward the intended meaning of the sender and the subsequent meaning or sense that the recipient may individually perceive. Depending on the way we use language, we can customize what we are uttering, utilizing a combination of various paralinguistic features which modulate our wordings, which hopefully, render an adequate narrative that suits the hearer. Leaflets are just that: In a written form, a leaflet contains and gives information to the user in different levels of language or registers: it provides the user with instructions (normally given away by the doctor as well) on how to use the product. These instructions are to be understood by everyone, regardless their academic background. They also include, as well, many other terms which may be difficult to understand by the majority of users, but which are nevertheless necessary, for example, to inform the user about possible allergies. Leaflets also list side effects in an easy way. To cut it short: leaflets are both a warning and an instructions paper for the user to read, with or without medical assistance or immediate advice.

Besides, another foundation of proper communication within the medical language scope may, to some people, be empathy, a variable which is being factored in through various studies, to see what types of it are there, and how healthcare providers can acquire it. It's obvious that PILs are just a piece of printed paper, without any interactive capabilities, ideally, we could implement technology in the future to make the pamphlet more user-friendly, trying to replicate the humane treatment that some doctors could provide. As a last remark, it should be noted and again stressed that there is a need to adhere to the patient's requirements so as to create ideal conditions for him/her to enhance comprehensibility, although the person being treated must maintain a proportionate degree of listening, as he/she is also a variable within the communicative process. As Vicent Montalt and Isabel García-Izquierdo contend:

> Cuando se produce en las condiciones idóneas, dicha comprensión tiene efectos beneficiosos: mayor adherencia al tratamiento, evitación de ansiedad innecesaria,

> mayor capacidad de toma de decisiones compartidas, mayor sensación de control y participación en el proceso terapéutico, así como mejor calidad del diagnóstico y mayor recuperación del paciente (Brugel et al., 2015) (Vicent Montalt & Isabel Garcia-Izquierdo, 2016: 82).

5. Enhancement of the readability of the package leaflet

Medical texts, as a general rule, are characterised by a series of qualities. This set of qualities, such as accuracy, comprehensiveness, clarity, and rigour, are a very recognizable set of features about medical literature and patient-oriented texts, where we find many subgenres too, such as web pages, package inserts, and brochures/leaflets among many others. Sometimes, these qualities are not met or rather there is a lack thereof, mainly due to poor or deficient proofreading and editing negligence. It is also possible that the common wording, that is, register, used by professionals is usually so dense —terminologically speaking— that said sort of speech poses a real challenge to be understood by the general public. All in all, this defies the very milestone that professional patient information leaflets have set, which is ultimately fulfilling that communicative function towards the patient. That goal is only achieved by producing a document that is concise, truthful and relevant, taking into account how much detail the document will get into. Also, an easy to read description process, not too overwhelming on the reader, would be ideal.

Mistakes in this kind of texts destined both to the patient as well as other specialists, may have various lexical, semantic, orthographical and even grammatical flaws.

Although the main idea I am focusing on is the imprecision of some PILs — since some of them might not be as perfect as I have previously stated—, the problem goes both ways, since patients are not usually acquainted with the vocabulary and expressions employed in the PILs. Many fields of expertise within the realm of medicine branch out, which makes the patients' task even tougher. Every doctor has had to deal with the idiosyncratic interpretation of the signs the patient thinks he or she has. The little medical knowledge many might citizens have further complicates the picture, leaving behind all kinds of made up diseases, conditions... Nonetheless, patient unawareness is fostered until certain extent due to significant errors in the form and content of edited texts destined to reach consumers, texts produced by seemingly

qualified entities, like patient associations, private enterprises, or even public health organizations.

If we stop to analyse this instance selected to illustrate the point by María Blanca Mayor Serrano:

> "El mecanismo funciona pues como una esponja viva en el estado de reposo los cuerpos cavernosos (esponja eréctil), y sus vasos sanguíneos están contraídos y vacíos de sangre y con una estimulación sexual cuando todos los mecanismos citados en el párrafo anterior funcionan se produce una relajación y se llenan de sangre provocando una erección."(Serrano, 2009: 30).

The phrasing is wordy; it meanders around and is not smooth, certainly it does not go, in my opinion, to the point.

In order to make a remark on other aspect I find crucial not to fail on, is the orthographic quality. The correct punctuation makes for a light reading on the consumer, in this case the patient, which will be able to follow through the indications much easily. Finally, an alternative to some medical terms that could be misunderstood is their adaptation to more vulgar or frequently used terms, as Maria Blanca Mayor Serrano states on another publication on recommendations for the production of patient information leaflets:

Expresiones, términos que se recomienda sustituir	*Expresiones, términos recomendados*
Especialidad Farmacéutica, Fármaco	Medicamento
Reacciones Adversas	Efectos adversos
Hipersensibilidad	Alergia
Dispepsia	Digestión pesada, ardor y acidez
Se excreta por la leche materna	Pasa a la leche materna
Abdominal	Del abdomen
Cardíaco	Del corazón

Fecal	De las heces
Intestinal	Del intestino
Renal	Del riñón

Tabla 1. (Mª Blanca Mayor Serrano, 2009:103).

6. Comparative analysis and translation with a focus on language differences

Here I include a comparison between instances of phrases in both versions:

ENGLISH	SPANISH
Do not take tamoxifen	No tome tamoxifeno si…
Package leaflet: information for the patient	Prospecto: Información para el usuario
Do not store	No requiere condiciones especiales de conservación
Do not throw away	Los medicamentos no se deben tirar por los desagües ni a la basura.
Do not take Tamoxifen	No tome tamoxifeno cinfa
If you are allergic to Tamoxifen or any of the other ingredients of this drug	Si es alérgica (hipersensible) al tamoxifeno o a cualquiera de los demás componentes de tamoxifeno cinfa
If you are taking any treatment for treating your infertility	No deberá estar embarazada, ni intentar estarlo
f you are allergic to tamoxifen	Si es alérgica
If you are pregnant	Si usted está embarazada

If you have any further questions, ask your doctor	Consulte/informe a su médico
If you take more Tamoxifen Tablets than you should, talk to a doctor or pharmacist straight away.	Trague los comprimidos
Anovulatory infertility	—[1]
Hormonal replacement	—

Finally, as the last point of this thesis, I will be making a comparative analysis between the Spanish and the British version of the package leaflet on my drug of choice, tamoxifen.

Mainly, I will be covering, that is, comparing, the form and the content of the Spanish and English versions, to establish some previous framework. The main topic that drugs try to instruct about, obviously, is the correct administering of it, posology , as well as some obligatory information they must feature as it is mandated by the law, like forewarnings about the possible side effects that are prone to happen, warnings and precautions, the identification of the drug provided along with its denomination and the pharmaceutical form, when not to take the drug, interactions with other drugs, and at last the Marketing Authorisation Holder as well as the last time the document was revised. All of this presupposing that the drug has been acquired after the respective prescription of a professional, this is specified in the introductory paragraph.

We must bear in mind that this document is a fully written document with no images for illustration since the message, while recommended to be read carefully, is quite brief, concise and to the point, but still makes great emphasis in elaborating on the content with maximal clarity. The overall structures between the two versions follow the same model, dictated by the regulations, as previously mentioned, since these documents do have legal restrictions to follow as regards their macrostructure. There is presence of titles in bold as well as subtitles, implementing enumerations for added clarity.

[1] Note that, due to the Spanish version being shorter, some of these terms do not appear directly or even indirectly

As the main title in the British version we have “Package leaflet: information for the patient” which certainly varies a little bit from the more complete term “Patient information leaflet” as it is a shortened term. In the Spanish version we get “Prospecto: Información para el usuario” Just right at the start we are presented with a series of key points that state the contents the document will be touching upon, a total of 6 points, same as in the Spanish version. Those would be, in the first place, a basic, utterly informative definition as to get the reader acquainted with the substance and explain what it actually is and what its applications are.

Strikingly, we can see a big difference in the extension of this very point: while in the English version we get a 24-line-long fully detailed explanatory account of the product, the Spanish version only provides 2 lines of information, boiling down its content to the following: “tamoxifeno cinfa pertenece al grupo de medicamentos denominados anti-estrógenos. tamoxifeno cinfa está indicado en determinadas patologías de la mama”. Quite a condensed section. I will also be focusing on a deeper level of analysis, the microstructure of the text, to reflect on its configuration, its grammatical structure, moods, lexical characteristics, use of tenses, pronouns, connectors, register, modality, and the like.

Clearly, dealing with this type of texts there is no sign of informal language, no contracted forms... With reference to an instance of clearly formal and specialised language we have the aforementioned introductory paragraph about the product in itself, such as “anovulatory infertility” or “hormonal replacement” typical of scientific definitions. As its already been pointed out, this has been omitted in the Spanish version.

It is important to notice how the grammatical mood in which the document speaks to the reader, the imperative mode, in terms of the tense and aspect of the leaflet, comes into place whenever being direct and blunt to express that using this drug is not recommended in certain scenarios or with pre-existing risk factors, notice the tone utilised, the classic formulae employed by these sorts of documents: “Do not take Tamoxifen:” “Do not store”, “Do not throw away” or as seen in the Spanish version: “Consulte/informe a su médico”, “trague los comprimidos”. There are two types of imperatives in Spanish used in medical texts: The bare infinitive; almacenar, tragar, etc. And the second person of the subjunctive, which is exemplified in the last quotation. Continuing from this, it starts enumerating the factors, and we perceive a distinction

between the versions, In the British version, it shifts to the conditional mode, which changes the tone to condition or possibility.

The same phraseological structure is used in this case in the British version “If you are allergic to Tamoxifen or any of the other ingredients of this drug” or “If you are taking any treatment for treating your infertility”. The Spanish version does use an analogous structure: “Si usted está embarazada” “Si es alérgica”. Since we do have a courtesy form in Spanish — “Usted/es”— it is more adequate to use it in this contexts where one does not know the user.

As the section of the leaflet resumes giving warnings regarding the set of factors patients should watch out on to avert any possible risks, like having a family medical history/record of blood cloths, we can find the use of modal verbs such as “You should speak to your doctor...”, and, a couple of paragraphs below we find some hedging, e.g. “Tamoxifen treatment may be used to”, “You may start treatment with Tamoxifen on any day”, “may affect up to 1 in 10 people”. As we can see, the use of modals in English drug is very common, whereas in Spanish they are likely to be replaced by infinitive or imperative forms.

Some of these preventive warnings on how to properly take the drug are stated as subtitles in bold. It is interesting to compare how some are translated into the Spanish version. Let´s take for example “Elderly” and “Use in children and adolescents”, as well as “Children” These points from the English version are featured within the third section, “How to take Tamoxifen”. Surprisingly, none of these points are present in the Spanish version, and there is a great disparity in terms of the information contained in both leaflets. Concerning the way they are arranged, as I have already mentioned in previous lines, the Spanish version lacks a lot of important information — it is simply omitted— while the English version is much more comprehensive and features more elements within each particular section — by this I mean a greater number of risk factors to be on the lookout for.

All things considered, the English version is eight pages long, leaving behind the Spanish version with just five pages. With regards to the connectors, we don´t see a frequent use of them, even though there are some: the only prominent markers of this class are causal connectors such as “due to” “because” and contrasting ones like “although”. The determiners we find are mostly definite articles, both in English and in

Spanish. With respect to the deictic, cataphoric or anaphoric references in this type of writing, the common tendency is that there are very few examples that are used scarcely whenever a reference to the drug or the leaflet is implied.

For example, “If this is unsuccessful” (referring to the standard dose recommended) or “tómela” in the Spanish version, (referring to a certain dose again) “Si toma más” “Si olvida tomar” “no deje de tomar”. In general, the subject is abundantly omitted in the Spanish version, as it is something the language allows and is not flawed to utilise so as not to make the reading tedious mentioning the reader again and again. Conversely, this procedure is not allowed in the English version. Thus, it is easy to conclude that inferences or room for error when understanding this leaflet want to be avoided, to guarantee that the person undergoing the treatment is fully aware of it.

Cohesion is not a big issue when looking at this sort of guidelines and warnings that are so direct. The sentences do not show a lot of subordinated clauses, since the information is conveyed through mostly single, separated sentences, one statement finishes, and another starts. The information presented is so oversimplified and so easily accessible due to the high degree of schematization.

The contents are laid out in a manner that is not unified and certainly repetitive, but all this serves the primary purpose of providing a set of instructions without any diversions, a document enhanced from the point of view of comprehensiveness. For the sake of an example, there is a group of terms that are fixed — they are reiterated throughout the wording— and taking into account that the formality levels and the field of knowledge from which this leaflet comes from, medical/healthcare writing, we can highlight: “Doctor” “Side effects” “Dosage” ”Medicine”.

Finally, I would like to draw the attention to what I consider to be the central source of complexity in a package leaflet, that is, the technical language having to do with a variety of semantic fields, the lexis.

> Todos los textos incluyen muchos términos propios del campo de la medicina, de la farmacología, y de la enfermedad o enfermedades para la/s que se ha prescrito el medicamento o para la/s que no se recomienda. Asimismo, destacaremos tres campos semánticos: el primero relacionado con términos médicos (enfermedades, síntomas, efectos adversos, etc.), el segundo con los medicamentos en sí y el tercero con los posibles usuarios de estos medicamentos. De todos modos, cabe aclarar que no se trata de compartimentos estancos, puesto que todos se relacionan, se complementan e incluso en algunas ocasiones se dan solapamientos. (Miró 2016: 22)

This classification can also be applied in the PIL at hand. Some examples of medical terms — in this case, some relating with genecology— are “cytotoxic agents”, “deep vein thrombosis”, “pulmonary embolus”, “anovulatory infertility”, “endometrium”, “optic nerve”. “vaginal discharge”, “visual disturbance”, “menstrual cycles”, “liver enzyme levels”, “cirrhosis”, “uterine fibroids”, etc.

As for the second semantic field, in relation with the package leaflet’s vocabulary we get instances such as “ pharmacist”, “active agents”, “blister packs”, “anti-oestrogens”, or “doctor”.

Lastly, the focus is set in the possible consumers of the drug o subjects or individuals to which the use of such drug is prohibited, prompting terms like “adult”, “overweight”, “elderly”, “children” or “adolescents”.

7. Conclusions

As a last and final point, I will be summarising the basic notions and ideas that I have extracted from the making of this thesis, where I have compared these two versions of the same medicinal product, as well as including some personal reflections on the field that I have delved into. Aside from listing and describing the parts that comprise a package leaflet or patient information leaflet, which do not present much variation in terms of the basic structure (macrostructure); whether we take the British version or the Spanish one due to laws mandating a similar outline for pharmaceuticals to follow, I have also dealt with the main issue underlying the general topic, medical English, and how it ties into the concept of PILs as a literary genre.

After the analysis conducted I conclude that generally speaking, British PILs present a freer disposition of the document, with subtle differences in regard to the form. With respect to the contents and the actual language utilized, both versions lead us to the conclusion that this genre in itself boasts a specialized terminology and showcases a very concise and clear phrasing, along with a well organised and structured outline, schematizing the information for the user to have an easy reading of said document. It also makes sure to prioritize that the contents and the set of instructions rendered in the pamphlet are fully understood and can be easily appliable.

One of the challenges of PILs that I have mentioned in this thesis is the need for them to be adapted depending on the target culture, norms and legislation in force. Moreover, we should be looking at an individual level, considering a spectrum of subjects with different backgrounds that will have to be sure on how to properly follow through the PIL. In terms of the quality, the British version offers a more elaborate and extended leaflet overall, which makes the Spanish version look like a simplified adaptation. Due to PILs bearing this amount of responsibility, we can assert that setting our efforts towards improving the readability of this sort of documents should not be a matter to be taken lightly, since it has proven itself to be a social, moral and civil necessity to be assumed for the greater good. This last statement goes in accordance with both the obligation for the pharmaceutical industry to include suitable information leaflets and the subsequent translation work to be done by specialized translators with knowledge in the field if they are needed, given that the leaflets to some products are originally written in the source language.

Lastly, after the completion of this thesis, the very first academic project of this caliber I have ever embarked on, I can start to catch a glimpse of how vast the medical literature is and the basic framework of ideas and knowledge linguistics provides when analysing any type of written document. Regarding the connections I can make between this project and previous subjects in this degree that share a common scheme, serving as a preparatory introduction, I would have to highlight the subject of technical translation. Getting acquainted with texts that feature specialised terminology has not only helped me expand my understanding of topics pertaining to the STEM fields but has also allowed me to approach this endeavour more efficiently, ultimately bringing me closer to the enriching works of scholars.

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