

DIRECTIVES AND THE SWORN TRANSLATOR: THE TERMINOLOGICAL CHALLENGE OF THE MDD 93/42/EEC

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Abstract: the presentation addresses the field of translating EU texts (directives), specifically the Medical Device Directive. The translation of EU instruments lies within the scope of responsibilities of the translators working for the European Commission and the European Parliament. Yet, sworn translators working in their native countries face the need to translate medical documentation both for natural persons (that is necessary for administrative purposes) and for corporate bodies (that operate on the common European market and require e.g., declarations of conformity, instructions for use or EC design examinations certificates to commercialise their products and thus run their business). Naturally, sworn translators while performing tasks commissioned refer to and consult the accepted translated versions of EU instruments to remain in line with the versions that have been transposed into their national legislations. In this paper, the original (English) and the translated (Polish) versions of the Medical Device Directive (93/42/EEC) shall be compared and analysed to find whether the Polish version fully reflects assumed terminological consistency.

Key words: EU texts, directives, medical translation, medical terminology

TLUMACZ PRZYSIĘGLY A DYREKTYWY: TERMINOLOGICZNE WYZWANIA ZWIĄZANE Z TLUMACZENIEM DYREKTYWY DOTYCZĄCEJ WYROBÓW MEDYCZNYCH

Abstrakt: Artykuł dotyczy przekładu tekstów związanych z Unią Europejską (dyrektyw), w szczególności dyrektywy dotyczącej wyrobów medycznych. Tłumaczenie tekstów unijnych znajduje się w gestii tłumaczy pracujących w Komisji Europejskiej i Parlamencie Europejskim. Tłumacze przysięgli świadczący swoje usługi we własnym kraju muszą się zmierzyć z tłumaczeniem tekstów i dokumentacji medycznej zarówno dla osób fizycznych (co bywa konieczne dla celów administracyjnych) oraz dla osób prawnych i firm działających na wspólnym rynku europejskim, które do prowadzenia swojej działalności potrzebują np. deklaracji zgodności, instrukcji użytkowania czy certyfikatów badania projektu WE w celu wprowadzenia produktów do obrotu). Tłumacze przysięgli w trakcie realizowania zleceń odwołują się do zaakceptowanych wersji dokumentów UE, aby zachować zgodność terminologiczną z wersjami przetransponowanymi do polskiego prawa. W artykule zostanie przeprowadzona analiza porównawcza oryginalnej (angielskiej) i przetłumaczonej (polskiej) wersji dyrektywy dotyczącej wyrobów medycznych (MDD, 93/42/EWG), która ma na celu zbadanie zgodności terminologicznej oryginału i przekładu.

Słowa kluczowe: teksty unijne, dyrektywy, tłumaczenie tekstów medycznych, terminologia medyczna

Introduction

The language of legal instruments, itself being a multi-faceted and an intriguing phenomenon, is, undoubtedly, a challenge for all translators, and sworn translators in particular, due to the rights and duties they possess. The European Union through its *acquis communautaire* effectively and clearly designates legal rights and duties of individuals, of social groups, of societies and of entire states. Thus legal instruments have an immense potential to influence human life.

Translating EU texts is a truly challenging task, given high standards that are to be fulfilled in this area. Translators are not a party to the drafting process, yet their knowledge of the issues and terminology occurring in the texts they are to translate should be thorough. The aim of this paper is to briefly discuss the specificity of EU texts, with a special focus laid on one of medicine-related directives that embraces the most comprehensive range of medical devices, i.e., the Medical Device Directive, which shall be followed by the comparison of two versions of the Directive (the English original and its Polish translation) in order to analyse the impact of terminological knowledge deficiencies on the final translation product and resultant far reaching consequences.

EU texts

It has to be borne in mind that the fact whether a given text, or a legal instrument, belongs to the category of legal texts does not rely on its linguistic features, regardless of their importance, but the major classification of legal texts sets the line between texts without the force of the law and normative ones, i.e. authoritative texts that are legally binding their addressees. Therefore an established and generated set of a variety of the sources of law in a given legal system determines the real legal nature of the text. The function of legal texts seems to be the most useful classification 'tool', and the debate pertaining to the fact whether legal texts display an informative function has been developing for years. Šarčević (2000, 11) enumerates three categories of legal texts: 1) primarily prescriptive, 2) primarily descriptive but also prescriptive, 3) purely descriptive (2000, 11). Primarily prescriptive texts embrace laws and regulations, codes, contracts, treaties and conventions (thus directives are also included within this category), and the normative nature is the common feature of those texts. The second category covers judicial decisions and instruments related to judicial or administrative proceedings (appeals, actions, petitions, pleadings); these texts are mainly descriptive. Prescriptive elements tend to have some legal force yet they are not sources of the law and they do not establish legal norms. Finally, purely descriptive texts refer to the doctrine in the form of legal opinions of law experts, scholars, law textbooks, and articles focusing on law-related issues.

Directives, together with regulations and decisions, belong to secondary EU law that comprises legal acts and instruments as well as international agreements concluded by the European Union. Directives are published in the Official Journal of the European Communities and are generated either by the EU Council or the EU Commission. In contrast to regulations, they do not have equivalents in terms of the domestic legislation. They are also binding for a given member state within a specific field and specific

results that are to be achieved. The methods of attaining these results are left to each Member State's discretion.

EU normative texts (embracing the entire legal output and legal regulations of the European Union, i.e., *acquis communautaire*) are part of the working reality of sworn translators. Not only are translators obliged to observe them as citizens of a given member state of the European Union, but also to use them as a source of reference when needed. Obviously, sworn translators do not translate EU texts (it is the responsibility of the Directorate General for Translation), yet relevant terminology applied in those texts may be helpful in accomplishing tasks commissioned.

Provisions of the EU law are currently published in all language versions (official languages) of the EU pursuant to Articles 21 and 290 of the Treaty Establishing the European Community (Jopek-Bosiacka 2006). The languages of member states can be classified into three groups, and these are:

1. authentic languages of treaties that are identically legally valid and form the basis for binding interpretation of treaties
2. official languages are all the official languages of the European Union member states
3. working languages that are used on a daily (working) basis, i.e. English, French and German

The English language used within the EU (and in EU documents) is considered somewhat different from standard English, which may be caused by a variety of factors. First of all, the EU legislation is not always produced and drafted by native speakers of English. Secondly, the supranational nature of normative legislation of the European Union enforces the application of directives and regulations that do not occur in legal systems of member states. Therefore we are witnessing some form of a reformulation of traditional, almost classic, concepts inherent for communicative contexts such as the sender and receiver of a message or a text type, as they become blurred or ambiguous. The emerging product is conceptually similar to what Trosborg called 'hybrid text' (Trosborg 1997, 146) as they are "documents produced in a supranational multicultural discourse community where there is no linguistically neutral ground". This might be the reason why these texts are in a way 'a-cultural' in the sense of not having resulted from particular cultures and languages, but being 'born' on the intercultural plane and derived from the contact between cultures and languages. Koskinen (2000:59) aptly observes that the specificity of EU translations is "the blurred divisions of languages and cultures. It has been taken for granted in translation studies that a change of language always also entails a change of culture, but within the EU context many translations are in fact intracultural".

Thirdly, what is also typical of EU legal documents is certain standardisation of texts; the identity of content (meaning) was mentioned above, yet the very structure and organisation of the texts must be matching as well: articles, paragraphs, sentences, clauses, etc. are organised identically and the text is easier to follow in terms of finding references to other EU official language versions. Trosborg (1997, 152) mentions the full

stop rule which stipulates that the number of full stops both in the source text and its translations must be equal. In terms of terminology, the role of potential connotations of meaning is less essential: the referent is most important (thus the referential function prevails), and a specialist term is viewed in its conceptual context.

The language of those documents is a specialist language, and has properties characteristic of specialist texts. Šarčević (2000) even considers this language a sub-language that is subject to certain specific rules (of syntactic, pragmatic and semantic nature). Additionally, yet another feature is typical of the language of those texts, namely, specialist vocabulary, whose aim is the accurate description of the reality affected by the normative function legal documents are intended to perform. Therefore, the text of a directive includes, apart from typical features of specialist texts such as (over)use of the passive, impersonal forms, nominalisations, and specialist vocabulary from a given field. The language of legal texts is, obviously, a challenge for translators: as a specialist language it has certain characteristic features (for further elaboration on such features as precision, vagueness, complexity, conservatism, and specialisation see Tiersma 1999). The reality in which legal texts function is described and reflected in specialist terminology: terms encountered in legal texts and those that refer to a given legal system can have a different meaning from their relevant correspondents in other legal systems due to the absence of an item, activity, or institution (Šarčević 2000). Naturally, all legal systems have their own legal realia or sets of concepts (quite frequently highly abstract ones), therefore it seems substantially difficult to compare terms used in different legal systems. These terms are defined (Šarčević 2000) as system-bound terms (also see de Groot (1999, 206) for *Systemgebundenheit*) because there are so deeply contextualised in a specific legal system. For that reason they are quite often untranslatable or their translation must be descriptive to compensate conceptual gaps. This conceptual incongruity in terminology (Šarčević 2000) may result from the historical evolution of legal systems that led to the development of a conceptual and terminological apparatus pertaining to social, historical, economic or cultural issues vital for a given country and its legal tradition. For this very reason – as Chiocchetti and Ralli (2013, 11-12) aptly observe – legal concepts are so difficult to be transposed from one legal system to another, which results in legal translation being a very complex task.

Since the focus of our considerations in this paper is the language, and specifically specialist vocabulary, of the Medical Device Directive (93/42/EEC) and translation-related problems that occur in the Polish version of this instrument (henceforth MDD), a number of comments pertaining to the specificity of medical terms and challenges they pose for translators as well as the context in which medicine-related directives function seems in order. It is common knowledge that medical translation is one of the types of technical (specialist) translation that is concentrated on medicine and its related fields. First and foremost, due to its being conditioned by the ethical codes of both biomedical research and healthcare, it should be accurate and reliable (Resurreccio 2011), as a translation error may result in serious consequences (for the discussion on quality of medical translation see Karwacka 2014). Thus the priority of the translator is to transfer not only the complex terminological content but also the form with features inherent in specialist translation; this transfer should be devoid of any references to cultural or ideological issues. Resurreccio (2007) claims that this neutrality and objectivity in conveying information gave rise to neutral, impersonal and uniform style

of medical translation. One of problems typical of the English medical language is the fact that medical terminology was constructed out of roots, prefixes and suffixes of Latin or Greek origin (for further elaboration see Kościałkowska-Okońska 2012; problems related with Greek and Latin roots and stems are discussed in van Hoof 1998). Resurreccio and Gonzalez (2007, 230-255) observe two major trends in medical terminology: one towards standardisation (in vitro terminology), the other towards variation (in vivo terminology). The aforementioned Greek and Latin forms and terms are – to a substantial extent – internationalised, and the emerging differences between modern languages are only in spelling. Standardisation pertains also to a variety of international classifications (e.g. the International Classification of Diseases or the Nonproprietary Names of Pharmaceutical Substances, cf. Resurreccio and Gonzalez 2007), yet it must also consider the fact that medical terminology is in a state of flux, changing dynamically and embracing recent discoveries and innovations.

Synonyms are yet another problem, and quite frequently they co-occur – as a ‘mixture’ of both ordinary and specialist language (so called doublets) – in e.g. hospital records or discharge reports. Equivalent names have been used for a variety of reasons, to mention only descriptive, historical or anatomical nature. *Acute anterior poliomyelitis*, formerly known as *the Heine-Medin disease*, might serve as an example of this trend: in the past it was translated into Polish as *choroba Heine-Medina* or *choroba Heinego-Medina*. With the passage of time, it has been more regularly referred to as *polio* (an abridged form of *poliomyelitis*) which is a recognised international term for the disease. Terms adapted from names of physicians or scientists, i.e., eponyms, enhance the usage of synonyms. Van Hoof (1998) introduces a distinction between two types of eponyms, depending on whether the proper noun gives rise to another proper noun (e.g. *parkinsonism/ parkinsonizm*) or whether the proper noun refers to a disease (e.g. *Down’s syndrome/ zespół Downa*) or an anatomical notion (e.g. *islets of Langerhans/ wysepki Langerhansa*).

Finally, another typical and problem-generating feature of medical texts is the presence of abbreviations (shortened forms of words or phrases, usually not capitalised) and acronyms (constructed out of word strings, usually capitalised), particularly in view of the multiplicity of potential meanings. They are frequently and commonly used in medical language to – as van Hoof (1998) claims – save time and space, and to make the language hermetic and understood by professionals only. Those acronyms and abbreviations are not usually explained in medical texts, constituting thus a part of a lexicon of medical professionals (cf. Kasproicz 2010).

The abovementioned problems related with medical language require from the translator a thorough insight not only into the text, but also into its context, in which the text is to function and be effective; this shall be briefly discussed in the following section.

Translating directives: the case of the Medical Device Directive

At present, translation of documentation related with medical devices is a necessity since global healthcare market players tend to apply a number of requirements – to be fulfilled by translators – in proceeding with user documentation (such as e.g. instructions for use) and related materials. Obviously, these requirements may vary from country to country (depending on provisions and conditions imposed by, for instance in Poland, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products [*Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*]). Within the European Union the process of commercialisation of medical devices is stipulated and specified in three directives, namely the aforementioned Medical Device Directive (MDD; 93/42/EEC), Active Implantable Medical Devices Directive (AIMD; 90/385/EEC) and the In Vitro Diagnostic Medical Device Directive (IVDD; 98/79/EC); out of these three the MDD covers the widest range of procedures and products, and for that reason it was selected as exemplary for the analysis in this paper. As far as translation requirements pertaining to these directives are concerned, there is an extensive degree of similarity, yet – in line with general principles of the EU legislation – particular EU member states are capable to establish separate essential requirements for medical devices.

MDD, AIMD or IVDD include dozens of medical or medicine-related words, and understanding them is absolutely essential for successful task performance, and the most essential priority of the translator is the most accurate transfer of the message included in the original text. The sworn translator encounters MDD (or other EU documents that refer to medicine or related disciplines) if research documentation – connected with the task commissioned – pertaining to a medicinal product or a medical device, i.e., the objective of the MDD, is to be made available to the general public (patients, doctors, experts), and products are to be launched on the market. If medicines or medical devices are to be commercialised, then – as the first step – legal requirements must be fulfilled, and the medicines or devices approved of by the Federal Drug Agency or the European Medicines Agency. The second step, as Poland is one of EU member states, entails the necessity to translate legal documents into Polish. As it was mentioned above, these documents are translated by translators within the European Commission and the European Parliament. However, outside the EC and EP context, sworn translators translate medical documentation not only for natural persons who need that for administrative purposes (e.g. death certificates, hospital records, discharge reports, examination results, etc.). They also translate texts for corporate bodies operating on the common European market. Product commercialisation procedures require such documents as, for instance, declarations of conformity, instructions for use (IFU), EC design examination certificates, full quality assurance certificates, product registration documents, patient information leaflets (PILs), or clinical trial protocols. In Poland, relevant provisions of the law require such documentation be translated only by sworn translators to be legally valid; this is where the sworn translator comes into the fore and in this very place can encounter a variety of potential problems. Obviously, it is hardly possible to mention all types of texts; the above short list shows, nevertheless, how varied the tasks for sworn translators are and how demanding in terms of translation they can be.

The classification of medical devices in the abovementioned directives – from Class I to Class III – relies on the degree of risk related with the usage of these devices. Concurrently, requirements for translators are certainly more complex as medical devices belonging to Class I and Class II need to be accompanied by additional certificates, issued by third parties such as notified bodies and registered EU representatives.

It should be stressed that manufacturers of medical devices and medical products need to have production-related documentation, including declarations of conformity, full quality assurance certificates, instructions for use, etc., translated in official languages of a given country where the commercialisation process takes place. The range of the product within the EU determines the range of languages into which the product documentation and supporting materials are to be translated. Thus translation even into all 24 official languages of the EU may be necessary for one product to comply with essential provisions of the MDD, AIMD or IVDD, which is a prerequisite to have the CE labelling.

In this context the sworn translator faces a huge challenge. On the one hand, enterprises operating on broadly understood healthcare markets should consider potential benefits for the performance and success of their products resulting from good translation. On the other hand, wrong, inappropriate, low-quality or simply incompetent translation can ruin the reputation of an enterprise or even, which is far worse, do harm to the final user and, eventually, result in serious legal consequences. For instance, if certain items from the original version of the directive are omitted in translation – most probably due to the translator's oversight, which *per se* is unacceptable – then the national legislation is to implement and use a slightly different version, and this stands in stark contrast with the principle of identity between documents, and related subordinate provisions may be also different and may bring different legal effects.

Directives are referred to in a variety of documents from such areas as instruction manuals for medical professionals and patients, instructions for use, medical articles, brochures, flyers, medical equipment and software, even glossaries and packaging. For instance, in documents such as EC Certificate Full Quality Assurance System there is a reference to the compliance of the quality system with provisions of Annex II of the directive 93/42/EEC.

It can be safely hypothesised that the MDD, AIMD, or IVDD have encouraged, to say the least, many manufacturers of medical devices to acknowledge and recognise the significance of languages other than the English language and thus have made them understand and appreciate the value and importance of translation and translators in the market of today. It is finely reflected in the very wording of the IVD directive: its Article 4, Section 4 stipulates that “Member States may require the information to be supplied pursuant to Annex I, part B, section 8 to be in their official language(s) when a device reaches the final user.” Moreover, the MDD in Annex I, Article 13.1, states that “Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.”

That is why accurate, competent, and precise translation is an imperative since potential users' knowledge is vital.

The Medical Device Directive imposes certain requirements on enterprises in order to proceed with documentation processing that is performed in several languages, which forces enterprises to provide for the translation of documents. These documents are related with instructions for use, labelling, packaging and, if need arises, supporting documentation. These materials are very important, especially when we consider instructions for use intended for the final user: the safety of application of a medical device that is used in compliance with its purpose and works well is of top priority, and low-quality incompetent translation can have a detrimental effect.

The abovementioned product-related information that the sworn translator faces can be divided into two categories, namely, professional use and patient use. The user information intended for patients (OTC, over-the-counter, relating to products or devices that can be bought without a doctor's prescription) is usually translated into all languages spoken on all potentially available markets, and does not have to result from any regulatory restrictions. As regards devices for professional use only, information pertaining to the safety of application is usually translated since those products are complex, and this level of complexity entails the need for the final users to comprehend all information items relevant for the proper functioning of a device. Consequently, this information is provided in the native language of the user. For that reason, accurate, precise and terminologically acceptable translation is absolutely crucial. It must be underlined that not only does inappropriate, inaccurate or terminologically inadequate translation adversely affect the final user (be it a physician or patient) but also it does breach the directive and its provisions. We are not capable of anticipating the legal consequences of court proceedings in a case when hypothetically a legal action is instigated against a manufacturer, which results from the error made by the user. This error may stem from the user's inability of understanding, e.g., instructions for use in a foreign language. The damage to the reputation and business operation of the manufacturer would occur anyway, regardless of the potentiality of being liable in legal terms. Therefore, we could say good translation, no matter whether it is legally binding a specific manufacturer as to a specific product, is a profitable investment.

Sworn translators do refer to and consult the translated versions of EU instruments in order to remain in line with the versions transposed into their national legislations, thus directives are for them one of the sources of relevant and necessary information. The terminology, and specific terms in particular, used in directives form certain guidelines for translators (notwithstanding some terminological problems). Translating medicine-related texts requires from the translator to be knowledgeable about the field to the extent available and possible in case of persons who are not physicians themselves (or experts from other related fields such as, e.g., pharmacy, biology, biochemistry, physiology, etc.). If the translator fails to understand the text – and violates the first and most important principle of translation – they will not be able to translate it correctly. As obvious as it may seem, there are instances when this understanding of the translator's role is somewhat distorted... In addition to the knowledge of the field and specialist terminology, the translator must also have an understanding of the context in which a given text functions. The ideal path seems to be

the one proposed by O'Neill (1998, 76) when the text is first translated by the translator and then verified in terms of substance and terminology compliance by an expert (e.g. a physician), or the text is translated by a physician, and then is 'polished' in terms of stylistics and language by the translator. This seems to be the best, or most effective option when it comes to successful and high quality translation of medical texts. Specialist knowledge, apart from the translator's own motivation to develop it, should be accompanied by information mining in the form of having access to and using any sources of information, starting from specialist dictionaries, glossaries, books, databases, articles and online information.

As stated previously, directives (and MDD in particular, for the purposes of this article) are valuable sources of information on the terminology used and specific solutions that may be considered necessary not only by translators themselves, but also by either natural persons or corporate bodies commissioning translation tasks. For that reason it would be interesting and worthy to have a brief insight into the way the MDD is translated into Polish so as to verify whether it can truly be a valuable source of information for the sworn translator, or rather its translation should be treated with caution. The examples provided in the remainder of the article are taken from the Polish translation of the MDD. The subject of assessment are not broadly understood language problems (errors, of semantic or syntactic nature, quite a substantial number of which can be found in the aforementioned directive and would need separate and further research) but only specialist terms as they pose the biggest challenge for translators who may be translation experts but are not experts in medicine.

MDD in translation: a comparison

To illustrate terminological problems addressed above, examples of specific terms occurring in the directive shall be provided. The methodology applied shall be a micro-comparative study: the study is limited to one instrument only, and only specific equivalents used are subject to comparison. It aims at addressing potential translation gaps and terminological inconsistencies encountered in the translation of the MDD, which will allow us to assess the efficiency of the transfer of terms from one language to another. The micro-comparative study is focused on the ways specific medical terms were translated into Polish; these terms are extracted from the original and compared with their translated equivalents in the Polish version of the directive. As a way of signalling terminological problems occurring in the MDD and potential consequences both for translators who refer to the MDD as one of information sources and translation users, those examples of 'problematic' translations in the Polish version of the directive shall be briefly discussed, and tentative categorisation of translation inconsistencies shall be also presented which reflects the nature of those problems. Numbers of articles and sections of the MDD are provided, respectively.

Example 1: inconsistency

The first example concerns *medicinal products*: this term is used as early as in the preamble to the Directive and occurs quite regularly throughout the entire document. In the Polish version *medicinal products* are inconsistently translated at times as *produkty lecznicze*, but sometimes as *leki gotowe*. The more relevant

option would be the former, since *produkty lecznicze* in contrast to *leki gotowe* cover an entire range of products, and not only medicines or drugs, and thus are closer to the meaning range of the English term. This is reflected in the very wording of the subsection (Art. 1, Section 5) where medicinal products include also products ‘derived from blood as covered by Directive 89/381/EEC’.

Example 2: omission

In Article 1/ Section 2(c) the words *calibrator* and *control material* are missing and, quite surprisingly, were not translated into Polish at all: this omission may yield grave consequences since no calibration (thus no obligation imposed on the manufacturer) can possibly make substantial volume of equipment useless. The absence of *control material* may result in the understanding that no controls or control groups are required to perform valid clinical trials in this particular case.

Example 3: terminology

In Article Section 5(a) *in vitro diagnostic devices* were translated as *wyroby diagnostyczne in vitro* whereas the usual and most frequently applied term in this context is *wyroby medyczne do diagnostyki in vitro*. The same problem occurs in Section 5(e) in this Article where *blood products* were translated into *produkty z krwi ludzkiej* which seems slightly awkward and stylistically deficient, as the standard term is *produkty krwiopochodne*. The same section can also ‘take pride in’ two other examples, namely, *plasma* translated as *plazma ludzka* instead of *osocze* and yet another problem with *blood cells of human origin* emerging as *komórki krwi pochodzenia ludzkiego* instead of *komórki krwi ludzkiej*.

Example 4: terminology

Article 1 Section 5(f) applies *transplanty* for *transplants* where *transplanty* are very rarely used in Polish in this specific context as *przeszczepy* or *przeszczepione narządy* are incomparably more common, not to mention the fact that the Polish translation sounds stylistically deficient and is not used as a relevant term.

Example 5: misunderstanding

In Annex 1, Section II, Subsection 7.2 another serious problem cannot go unnoticed as the meaning of the original sentence is distorted due to the translator not having properly understood the original. The sentence:

The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients (...)

was translated into Polish as:

Wyroby muszą być projektowane, produkowane i pakowane w sposób minimalizujący zagrożenie powodowane skażeniem i pozostałościami po osobach zajmujących się transportem, przechowywaniem i używaniem wyrobów oraz po pacjentach (...)

where the term *residues* is applied to refer to components or ingredients of medical devices that can have an adverse effect on the persons involved in transport and on the patients. This sentence may be understood as if persons involved in transport as well as patients were responsible for contamination and leaving any kind of residues behind, which obviously is a nonsense. A better option would be to use

w stosunku do or wobec/ w przypadku osób zajmujących się transportem (...) oraz wobec/ w stosunku do/ w przypadku pacjentów.

Example 6: terminology

In Annex 1, Section 9, Subsection 9.2 we see *the volume/pressure ratio* translated almost literally as *objętość/współczynnik ciśnienia* whereas a better, more frequently occurring and certainly more context-fitting option would be *współczynnik ściśliwości* since the clause does not refer to general pressure but to properties of devices relevant in cases where their application does involve pressing the device (or the product) onto e.g. a surgical site (in procedures that require the usage of haemostatic materials such as haemostatic sponges, bonewax, etc.). These are instances where *współczynnik ściśliwości* of the product or device is essential for the patient's performance.

The same subsection 'houses' another example similar in nature to *transplanty*, namely, *implants* were translated into *implantaty* instead of *implanty*. This probably results from the translator's misspelling, yet the final effect is not satisfactory, to say the least, and the term is not really used in Polish medical texts.

Example 7: terminology

Another example that shows certain deficiency in the knowledge of medical terminology can be found in Annex IX, Section III, Subsection 2, Rule 5 where *the ear drum* ('ympanic membrane' in medical terminology) was translated as *nabłonek bębenka*. From the medical point of view *bębenek* as a bodily organ does not exist; on the humorous side one may venture a conclusion that maybe the translator followed *młoteczek*, *kowadełko* and *strzemiączko* (being part of the ear) and found *bębenek* matching with the aforementioned, yet the proper name for this part of the human ear is *blona bębenkowa* and the phrase refers to *nabłonek błony bębenkowej* or simply to *blona bębenkowa*.

The findings of the above study corroborate a seemingly obvious truth: while translating medical or medicine-related texts the most important factor is the subject specialist knowledge, without which the translator – even understanding words – is not capable of comprehending terms included in the text, the textual context and the processes, to which a given text refers. This specialist advanced knowledge of the field is a substantial determinant both for the process and for the product of translation (and translation competence is reflected in the process and the product of translation, which has been empirically verified by e., the PACTE group [2009, 209]). The language level of those texts is not substantially varied in terms of style, use of register or of complex grammatical structures; it is terminology that occurs to be the major 'enemy' of the translator.

Concluding remarks

From the above examples we can explicitly infer that terminological deficiencies and inaccuracies in the text substantially affect the perception of the translation. Yet, the underlying danger is that those imperfect renderings may adversely affect the quality of texts produced by sworn translators. There is an apparent tendency to enter a – once translated – phrase or term into a database, and subsequently such term becomes an

equivalent that is almost automatically chosen and applied, yet not always verified. It seems surprising that even though translation solutions suggested are wrong and faulty (or even misspelled), they are still to be found in the texts that – as mentioned above – are to serve as a source of reference and information. Undoubtedly, an increasing awareness, on the part of sworn translators, as to the possible drawbacks of the translated version is a factor facilitating the development of professional experience and competence, yet in the long run badly translated – in terms of terminology – legal instruments can be even detrimental to the well-being, or even health, of patients or final users of medical devices. Thus translators should be more careful and less reliant on the directive, and on the reliability of the terms used in the Polish version. This presumably should lead to the increasing awareness of the importance of personal professional competence, ability to search for and find relevant and credible information in e.g., parallel texts, such as papers in medical journals, medical databases. This will also lead to demythologisation of directives, whose translated versions are sometimes – unfortunately – treated as an invaluable source of truth.

One of potential remedies to this problem might be a changing role of the sworn translator to be more active in the institutional sense: to officially inform on and indicate errors, monitor modifications introduced and verify resultant effects through the administrative powers of professional associations. Thus, such blunders would not be seen in official versions of documents transposed into Polish legal regulations.

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