



# Quality Control in Medical Translations

Various methods are available to ensure the quality of medical translations – but some are more effective than others

**By Simon Andriesen at MediLingua**



Simon Andriesen is Managing Director of MediLingua BV, based in The Netherlands. He has been involved in writing and translation for over 25 years. His company is fully focused on the translation and localisation of pharmaceutical, clinical trial, biomedical and medical technology information. Simon is also a member of the Advisory Board of the medical track of Localization World, a series of high-level conferences about translation and localisation. He teaches a course on medical-pharmaceutical translation, and is a frequent speaker at conferences about language, medical translation, medical writing and readability testing.

In the medical sector, translation is a small, yet simultaneously big, issue. It is a small issue – almost a non-issue – because compared with the total effort of developing a medicine or medical device, producing (and that is writing plus translating) patient or user information is an activity that does not cost a whole lot and often does not get much attention. It is a big issue when something goes wrong and the reality hits that this type of information should be produced professionally. In this article we will discuss what needs to be translated in the medical sector, what are the required translation quality levels (if any actually exist), how translation quality is usually assessed and how effective these methods really are. Where relevant, a distinction is made between medical translations relating to medicines, and those relating to clinical trials.

## EUROPE – A MULTILINGUAL NIGHTMARE?

Pharmaceutical companies need to make all kinds of information – both for professionals and patients – available in up to the 23 official languages of the European Union. On top of that, there are the languages of several non-EU countries (such as Norway and Iceland), and not-yet EU countries (such as Croatia, Serbia and Macedonia), that will have to be added to the list. Also, not many pharmaceutical companies provide their information in the recognised minority languages spoken in the various EU countries (such as Catalan, Corsican, Frisian and Welsh), but this would add another 30 languages to the list.

And that is only Europe! For clinical research organisations, African and Indian languages are becoming increasingly important as research projects

often include participants in these areas. Both India and South Africa have almost a dozen official languages, and the rate of ‘analphabeticism’ is considerably higher than elsewhere.

Back to Europe, not many people would expect German to be the language spoken by most Europeans as their native language. Of the EU population of almost 500 million 18% speak German as their native language, followed by Italian and English with 13% each. When we include the number of people who can also speak and understand a second language, we have a clear winner: English is spoken by 51% of the EU population (including native speakers), followed by German with 32% and French with 26%.

Providing information only in English, German and French to reach a large part of the European population might be tempting, but for medical information this would be illegal. EU Directives force manufacturers of medicines and medical devices to provide their product information and user instructions in the official languages of the countries where they intend to sell their products. Even for medical devices that will only be used by highly trained professionals, it is illegal to provide the user instructions just in English (although for certain products, and in certain countries, and under certain conditions, manufacturers may be able to negotiate a temporary exception status).

## WHAT IS TRANSLATED AND WHY?

### Medicines

The European Medicines Agency (EMA) and the various national medicines evaluation agencies require that, for medicines, the Summary of Product

Characteristics (SmPC), the Patient Information Leaflet (PIL), and the packaging and labelling texts be made available in the local language. A manufacturer cannot apply for registration without handing over the translated versions of these documents to the European or national regulatory authorities.

### **Clinical Trials**

The EU Directive concerning clinical research (Directive 2001/20/EC) is less strict in specifying the requirements concerning language than the directive concerning medicines, but most countries have local regulations that require at least all information for patients to be translated. In many countries, the study protocol also has to be available in the local language. Even if this is not a strict legal requirement, bodies such as the Medical Ethical Committee (MEC) of the study centres concerned often require the translation of documents as a condition for their participation.

The study protocol describes the background and purpose of the clinical trial, the possible outcomes, the profile and recruitment of patients, and so on. The Informed Consent Form (ICF) is another important document in clinical trials; its purpose is to inform participants in the study – usually patients suffering from a certain disease or condition. Under the Declaration of Helsinki (an initiative formulated by the World Medical Association in 1964, and since then updated frequently), participants must completely understand the information, including the risks associated with using the study medication or treatment. Trial participants have to sign the ICF, stating that they are willing to participate and that they fully understand the information provided. In clinical studies, patient reported outcomes forms (PROs) and questionnaires are key documents; these are either filled in by the participant or by the investigator on the basis of an interview with the participant. Almost without exception, ICFs, PROs and questionnaires always have to be translated.

### **REQUIRED QUALITY LEVELS?**

#### **Medicines**

Guidelines concerning the quality level of translated documents relating to medicines are much more detailed than those for medical devices and clinical trials. Specifically, the quality of patient information leaflets for medicines is discussed in guidelines and other official documents. The EU Directive concerning human medicines (Directive 2004/27/EC) introduced two new language-related requirements concerning patient

information, emphasising that the patient is now central. One is that patient information needs to be available in Braille, or in other formats that are suitable for people who are blind or have reading problems. The other is that patient information has to provide information that is 'legible, clear and easy to use', and the text has to be the result of what the Directive calls 'patient consultations'. In short, it must be established that average users can find and understand the information, and act appropriately. The guidelines state that the source text has to be written in such a way that allows for 'regional translation flexibility', and that translations need to be 'faithful' and should not be 'strict literal translations containing unnatural phrases'.

### **Clinical Trials**

There are no guidelines specifying the quality level of translated documents that are used in medicine studies with human participants. As study centres (such as hospitals) have their own requirements concerning quality and language, the sponsor (a biotech or pharmaceutical company) or the contract research organisation (CRO) is usually required to provide all study documentation in the local language. It is crucial that all patient-reported outcomes (PRO) documents – including questionnaires, instruments and scales – are translated in a way that reflects all nuances of the original. If questions in the questionnaires are not translated the exact same way across all (potentially dozens of) languages, the sponsor runs the risk that the answers to these questions cannot be pooled and parts of the research data become useless.

### **HOW TO PREVENT LANGUAGE-RELATED DISASTERS**

Translation quality varies and depends on the competence of the translators involved. It can happen that translators are asked to translate patient information or other medical documents, even though they have no experience in this field. Many customers too easily trust that a translator or translation provider claiming to be 'specialised in any field' really can do a proper job. And if these vendors also claim to be cheap and promise to deliver within a short period, then this may be attractive. The risk is that the customer can be greatly disappointed – and while this may be true for the independent, general translator, it also occasionally happens with larger translation companies. For the customer, this means that – apart from very carefully selecting translators or translation providers – the quality assessment of translated information is of vital importance.

The patient information leaflet (PIL) for medicines is usually evaluated by regulatory affairs staff in the respective countries, who will check the text for medical correctness and informational usability. The text has to conform to the templates published by the Quality Review of Documents (QRD) group at the European Medicines Agency (EMA). Requirements and guidelines are specified in the *EU Directive on Human Medicines* (Directive EU 2004/27/EC) and in the *EC Readability Guideline*, which was published in 1998. The nature of the information in the Directive is rather general (as can be expected), but unfortunately the Readability Guideline – which should provide details about how to write and test PILs – is also rather vague. A revised version of this guideline has been ‘under consultation’ since mid-2006; it is probably taking so long to turn it into a final version because it still does not provide the guidance that was lacking in the 1998 version.

Let me give a few examples as to why quality of translation is so important.

In an EU-wide registration procedure (with 23 languages), one faulty translation can cause time-to-market delay and, subsequently, a considerable loss of revenue. Why such a revenue loss? Well, it is widely accepted that developing a new medicine costs approximately \$800 million; the patent protection period is limited and sometimes lasts only eight years after the medicine is launched on the market. This means the manufacturer has to recover this investment in the eight years before the patent runs out – in other words, revenues of \$100 million per year. A delay in the registration process of – say – three months, would then cost \$25 million in lost revenues. If this delay were caused by a poor translation, then this would not reflect positively on the career of the Regulatory Affairs Manager who had perhaps selected a lower-cost translation vendor to save a few thousand dollars. After all, the cost difference between a poor translation and a quality translation (including edit and check) of an average 2,000-word PIL couldn't be more than a few hundred Euros per language.

Another example is clinical trial documents; here again, translation quality is extremely important. Apart from the fact that human patients are involved who need to be properly informed, trial results are scrutinised by the authorities, and if they find something that may not have gone according to the rules, part of the research data may not be usable. This may lead to product launch delays and – when the

delay eats into the patent protection window – a considerable loss of revenue.

Translation quality assurance (QA) is key and there are different ways to assess quality of translations. The most commonly used methods are discussed below.

## **READABILITY TEST**

Since 2005, one language version of a PIL has needed to undergo a so-called readability test; this has become a widely used method to deal with the legally required ‘patient consultations’.

During a readability test, two groups of ten ‘average’ persons answer a series of questions. If most participants answer most questions correctly, the PIL is probably clear enough. If more than a few participants have a problem finding the information they need in order to answer a question, there is probably something wrong. The text has to be revised and the test has to be repeated with a new group of, again, ten participants. In most cases, problems with the text will by then have disappeared. A report describing the details of the test then has to be given to the regulatory authorities.

While the readability test is a very effective (albeit costly) tool to verify and improve the quality of a PIL, one weak point is that only one language version needs to be tested; the authorities assume that if one language version passed a readability test, the translations will be equally readable. Everybody involved in translation knows that this is not necessarily the case. Unless such translations are done in a professional way, it is advisable to check very thoroughly and edit these local versions, or even to perform a ‘light’ (and less costly) version of a readability test.

## **BACK TRANSLATION**

The world of medical research – and especially clinical trials – employs an almost unique translation review method, which is hardly ever used in other sectors: the back translation. A back translation is when a translated document is translated (back) into the original language of the source text. The author or trial sponsor can then supposedly verify whether the translation covers the original.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has done a great job in evaluating a dozen existing guidelines concerning the translation of patient-reported outcomes (PROs), and

has formulated a method which includes a double-forward translation, a reconciliation of these translations, then a double-back translation, reconciliation, review and harmonisation. While this can be considered the 'optimum' way to perform linguistic validation, it certainly is a time- and cost-intensive process.

Back translations are usually done because they are required by a Medical Ethical Committee (MEC), or by national authorities. Several points can be put forward against back translations. If there are discrepancies between the original version and the back translation, this may be caused by shortcomings in the source text, or by errors introduced by the 'forward' translator, the editor of the forward translation, the back translator or by more than one of these persons. The back translation process takes a considerable amount of time and effort; the costs are at least the same as those of the original translation, and the outcome is often unclear. Of course, the 'optimum' process – as recommended by the ISPOR – costs much more (up to five times the cost of the original translation).

It can be argued that back translations may be less relevant for languages with an established 'translation infrastructure' (such as French and German), provided that qualified translators have been used for the forward translation. Increasingly, clinical trials are being carried out in countries of Eastern Europe, Africa and Asia. Languages such as Lithuanian, Kurdish, Zulu or Indian may not (yet) have established terminology standards; in such a case, a back translation may indeed be a good way for a sponsor or CRO to check the forward translation. However, there are very few qualified English medical translators who can work from these languages and, for some language combinations, back translation may not be possible without improvising a solution that does not involve a native speaker of the back translated target language.

If back translations are done merely to keep on file, or to satisfy ISO auditors, the effort and cost are a total waste, and the results create a false sense of safety. Only when taken seriously and done in a professional way will a back translation be effective and identify the shortcomings of a translation (although one may still argue whether it is cost-effective).

## **OTHER METHODS**

### **Statistical Review**

Over the past decade several, statistical QA methods have been defined – such as SAE J2450 or the LISA

QA Model. Using these methods, errors are counted, weighed and scored – resulting in a final score that reflects the quality of a translation in terms of numbers of errors. While this may be a good way to assess the performance of an individual translator, it does not say everything about the quality of the translated document, and should not therefore be used as a single QA instrument.

### **Independent Evaluation**

Another method of assessing the quality of translation is for an independent translator to very thoroughly check the translation against the original, and then write a detailed evaluation report. This may take the same amount of time as a back translation, but less time will need to be spent on the good parts, leaving more time to analyse and discuss the problem areas.

### **Additional Edit Round**

Many people agree that an additional heavy edit round can result in at least the same high quality as a back translation would, but at a much lower cost.

### **Parallel Translations**

A great way to make sure a translated document is optimal is to have the source text translated by two translators in parallel. One of these – or a third person – will then have to 'reconcile' the two versions into one that has the best parts of both. As with back translations, the costs are doubled as two persons do the same work in parallel, but in this case the additional cost has a much more direct and positive effect on the quality of the final document than is case with a back translation.

### **Improve Source Text**

Many times, translation quality problems are caused by shortcomings in the source text. A pre-translation edit of the original is always beneficial and every error prevented avoids having to fix subsequent errors in possibly dozens of translations.

### **FIRST TIME RIGHT**

Most people would agree that if the initial translation were done in a professional way – including careful editing – then the quality would be optimal in the first place. Quality assurance methods can then be used to confirm the quality – rather than detecting errors that should not be present in the first place.

*The author can be contacted at  
simon.andriesen@medilingua.com*