

Comments concerning the draft revision (September 2006) of the Readability Guideline, chapter 3, section 5 ('Testing of multiple language versions')

by Simon Andriesen, Managing Director of MediLingua BV (Leiden, The Netherlands)

Brief introduction

MediLingua is one of the few providers of readability test services in The Netherlands and deals a lot with patient information leaflets that have been translated into Dutch, German, French as well as other languages of the European Union. Testing represents around one third of our activities; medical translation accounts for the rest. Most of our medical translation work, which we do into around 30 different languages, concerns medicines, medical research and health in general; less than half of it is about medical devices. We are frequently contracted to do 'third-party review' of translations that have been done elsewhere. In many cases these translations leave a lot to be desired (which is probably why we are invited in the first place because our customers suspect this already). Fortunately, there are also review projects when we can just sign-off a perfect high-quality translation. Nevertheless, medical translation is a difficult process, which frequently results in language versions that are simply not good enough.

We are aware that several other readability test providers are responding to the invitation to provide comments to the current draft Readability Guideline. As medical translation is one of the major activities of our company, and in order not to duplicate the efforts of others, we feel it is appropriate for us to focus on the translation aspects of the guideline. Translation of leaflets is an activity that is often not done in a professional way, perhaps as a result of the lack of translation-competence or understanding in regulatory affairs departments at pharmaceutical companies. Another reason may be that until recently there was no legal requirement concerning the readability of leaflets; as long as a leaflet was translated, this was assumed to be sufficient. The recently introduced requirement of readability testing is therefore very welcome.

Comments

Translation is specifically discussed in Section 5, Chapter 3, of the current draft Readability Guideline. In the 6 paragraphs of this section, future users of the Readability Guideline should find clear instructions on how to deal with translation of patient information leaflets. They should learn how to make sure that translated versions of a readability-tested leaflet will be as ‘legible, clear and easy to use’ (to use the terms from European Directive 2001/83/EC, article 59(3)) as the original version. Below, we will analyse and discuss these paragraphs one by one.

Paragraph 1, sentence 1

1) In the first sentence of paragraph 1 reference is made to ‘easy to read’.

The draft Readability Guideline uses different expressions, and in order to make the text more consistent, we recommend to follow the terms from the Directive and to rephrase it to ‘easy to use’.

2) In the first sentence of paragraph 1 reference is made to ‘EEA languages’.

As it may not be clear to all future readers of this Guideline what the abbreviation EEA stands for, we recommend to change ‘EEA languages’ into:

‘all languages of the countries of the European Economic Area (the member-states of the European Union, plus Iceland, Norway, and Switzerland)’

In fact, this requirement concerns only the language or languages of those EEA countries where the package leaflet will be on the market. Sentence 1 of paragraph 1 would then run as follows:

‘The package leaflet should be legible, clear and easy to use in the language(s) of the country or countries of the European Economic Area (the member-states of the European Union, plus Iceland, Norway, and Switzerland) where the medicine will be on the market.’

Paragraph 1, sentence 2

3) It is very unlikely that there is any evidence to support that ‘it is normally sufficient to undertake patient consultation in one EEA language’.

We frequently deal with translations of patient information leaflets and of medical information in general and know that it is certainly not safe to assume that a translation is as good as the original. Often this is the case and sometimes a translation is better than the original. However, the quality of a translation may be considerably lower than that of the original.

As it is required to readability-test only one language, we recommend to formulate this requirement without these justifications, which are not helpful and probably lead to questions. As this section is inconsistent in its use of terms referring to readability testing (patient consultation, test, tested and modified, user consultation, retested), we recommend to consistently use the term ‘readability testing’.

Sentence 2 of paragraph 1 would then run as follows:

‘Readability testing must be done on one of the language versions of the leaflet.’

Paragraph 2

3) As it is allowed to test any of the other EEA languages, we recommend to add the following sentence at the end of this paragraph:

‘In case the leaflet has been readability-tested in another language than English, it is therefore necessary to translate this language version into English before scientific assessment.’

Paragraph 3

Both the current version (1998) and the revised (2006) draft version of the Readability Guideline state that it is sufficient to perform a readability test on just one of the official languages of the member-states of the European Economic Area (EEA). For practical purposes this is understandable and it may be assumed that the industry is thankful for not having to spend the cost of a readability test times the number of languages concerned. For the sector providing readability test services this is also good news - contradictory as this may sound - as ‘we’ are

already rather busy and not too eager to test 21 languages (which would be the case for an EEA-wide product launch) instead of one.

Having said that, testing just one language version of a leaflet and then translating the tested version into one or more other languages does not guarantee that all these translated versions will have the same level of readability. On the contrary, this is often not the case. In fact, it is the wording and the way sentences are structured that cause most of the problems that are identified during readability testing of patient information leaflets. And that is what easily, and therefore frequently, goes wrong during the translation process.

As far as translation is concerned, perhaps something can be learned from the sector of medical devices. In the EC Directive 93/42/EEC (commonly referred to as the Medical Devices Directive, or MDD) it is specified that ‘Each device must be accompanied by the information needed to use it safely’ and ‘Instructions for use must be included in the packaging for each device’.

The accompanying EU Medical Devices Guidance document (MedDev 2.5/5 Rev.3, February 1998) states that ‘the manufacturer should have procedures for ensuring accurate translation of e.g. labelling, instructions for use and product claims in marketing material’ and ‘These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation’.

What this means is that a manufacturer of a medical device is not only legally required to provide translations of the user’s instructions, but also that he has to make sure that these translations have been done professionally. The manufacturer of a medical device has to be able to show that the translations have been done by a translator or translation company with proper credentials, and that it has been carefully checked by a person or company with similarly proper credentials. This requirement is often met by having on file a signed statement by a reputable translator, translation firm, local office of the marketing authorisation holder, or third party with good credentials. For patient information leaflets for medicines a similar clause could be formulated to make the requirement stronger. On top of that, we would suggest the possibility of performing a small-scale readability test or at least a thorough check of the translated version. This could be inserted at the end of the third paragraph of chapter 3, section 5 of the current draft:

‘The marketing authorisation holder is required to have procedures for ensuring that also the translations of a readability-tested leaflet are legible, clear and easy to use. It is

recommended to perform a thorough check of the translation and it is suggested to perform at least a partial readability test, with a limited number of test participants.'

Paragraph 4, sentence 1

The instruction for the writer of the leaflet 'to ensure that the package leaflet can be translated (...) in a clear and understandable way' leaves too many openings for different interpretations. What presumably is meant here is that the original text must be free of typographical and grammatical errors and of ambiguities, and that it must be written in such a way that the content will be clear to translators and that translators will not have to solve textual problems. In other words: the leaflet must be written 'with translation in mind'. A good way to assess if this is the case, is to have the leaflet translated into one language, and specifically instruct the translator to report what was unclear or wrong. Translators often improve texts by not inserting errors from the source text into their translation, and they do this without mentioning it, if only because it may take more time and effort to describe what was wrong or weak, than it takes to just correct the problem. The disadvantage of translators fixing problems is 1) that the source text is still not optimal (with potential problems for the readers of the original text), and 2) that some translators may solve a specific textual problem in a different way than other translators, and as a result the different language versions of the same leaflet may no longer be the same.

Paragraph 4, sentence 2

This sentence is not clear, as it will be hard to translate 'the outcome of the user consultation' into the other languages. What presumably is meant here is that the textual changes, resulting from the readability test, that have been incorporated into the leaflet, will also be used as a guideline to update the existing translations. However, as many of the changes resulting from a readability test concern the wording or the structure of sentences, it is not always necessary to make exactly the same changes in the translations.

Paragraph 4, sentence 3

It may not be clear for all readers what is meant by ‘strict literal translations’ and future users of this guideline may appreciate specific instructions about how to manage the translation process. In the translation world it is generally accepted that as long as a source text is of high quality, an experienced translator will be able to produce a good translation. Automated translation systems would probably generate ‘strict literal translations’ containing ‘unnatural phrases’, but such systems are not generally used in the translation of this type of documents.

The expression ‘allowing for regional translation flexibility’ could be abused to incorporate information in a certain language version of a leaflet that is not part of the original version. What presumably is meant is that it is understood that translated sentences do not necessarily follow the word order of the sentences in the original version.

Paragraph 4, sentence 4

As the word ‘faithful’ is a normal English word, it is not clear why ‘faithful’ is between quotation marks. In other languages this concept is often left in English (probably for lack of a proper translation) and because of that it is often written between quotation marks.

Paragraph 5

It is unclear what the role is of ‘the Member States/European Medicines Agency’ who need to be consulted concerning ‘the responsibility for the production of faithful translations’. We recommend to delete this paragraph as it does not seem to provide new information.

Paragraph 6

As the QRD template has recently been updated more than once, it is better not to speak about ‘the old QRD template’ and ‘the new QRD template’. Also, the sentence is unclear or grammatically not correct (‘there is no need to be retested’), and therefore we recommend rephrasing it as follows:

‘If a readability test has been performed on a package leaflet in an older version of the QRD template (see Chapter 1, Section A, section 10 of this Guideline) it is not required to test the leaflet again after it has been adjusted to a later version of the QRD template.’

We also recommend to provide clear instruction concerning the use of the most recent version of the template, as a new version may be published without specific notice:

'As any language version of the QRD template may be revised without notice, the marketing authorization holder is advised to download the template in the required language(s) any time a package leaflet is written or revised.'

General comments and Conclusion

In conclusion, we recommend that the text of Chapter 3, Section 5 of the draft Readability Guideline be revised along the lines of the comments presented in this document.

In general, we would recommend to restructure the guideline in such a manner that writers of patient information leaflets will find clear instructions concerning what to do to make a leaflet 'legible, clear and easy to use', and that, likewise, persons or organisations performing readability tests will find clear instructions concerning how to perform such tests. Alternatively, it could be described what criteria the regulatory agencies use in assessing readability test reports.

MediLingua BV
Simon Andriesen, Managing Director
Poortgebouw, Rijnsburgerweg 10
2333 AA Leiden
The Netherlands
Phone: +31-71-5680862
E-mail: simon.andriesen@medilingua.com
Web: www.medilingua.com and www.leesbaarheidstest.nl