



Readability Testing of PILs – A New ‘Must’



For a year now, the regulatory affairs departments of pharmaceutical companies have faced a new burden: readability testing of patient information leaflets. Simon Andriesen reports on ‘best practices’ based on some eight months of testing

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Since November 2005 (in the UK since July 2005), manufacturers of medicinal products are legally required to have their patient information leaflets (PILs) readability-tested in order to get their products approved. European Directive 2001/83/EC, as amended by Directive 2004/27/EC, defines that these leaflets should be “legible, clear and easy to use”, and that the manufacturer has to deliver a readability test report (with a positive conclusion) to the authorities. Currently, this requirement is concerned with new or significantly revised products, but eventually, patient information leaflets for most existing products will have to be tested too. According to the (British) Medicines and Healthcare products Regulatory Agency (MHRA), the reason for testing is ‘to help produce a leaflet that most medicine users can use to take safe and accurate decisions about their medicines’.

So, the leaflet has to be legible, clear and easy to use. How readability tests have to be performed and what requirements there are for a leaflet to pass the test were left undefined however. On the basis of the various sources (see Different Criteria) providers of readability test services have extracted their own test method, with most of these based on ‘an example of a method for testing the readability of the leaflet’ that was published by the EC. However, there does not seem to be a consensus on the test criteria to be used.

TEST PREPARATION

Any readability test project begins with a preparation phase, during which the text of the leaflet is carefully edited and checked; spelling or grammatical errors are corrected and sentences are rephrased. This is an important step: approximately 70% of all changes in the leaflet are made during the preparation phase. It is important to make sure that the leaflet complies with the template published by the Quality Review of Documents (QRD) group of the European

Medicines Agency (EMA). This template is available in 25 European languages; the English version is annotated with instructions (for leaflet writers) about what information has to be placed under the various headings. The templates can be downloaded from the EMA website (1). New versions are frequently uploaded and medical writers/translators or regulatory affairs staff should download the most recent template whenever they start working on a leaflet. They also have to make sure they have the correct template: there is one for the central procedure (CP), one for the mutual recognition procedure (MRP), and another for the decentralised procedure (DP).

Part of the preparation is composing a list of around 15 questions that cover the most important parts of the leaflet (especially safety aspects), and deciding on the appropriate answers. A pilot test is then embarked upon with five testers. The results from the pilot test are used to revise the leaflet (text and/or design) and, if necessary, the questions. At this point, everything is ready for the actual test.

PROFILE OF TESTERS

The ‘average person’ does not exist, of course, and therefore we make sure that the two test panels with 10 persons each are balanced regarding sex, age and education. Testers have to be literate in (and native speakers of) the language of the leaflet and should have no problems with reading. It is crucial to make sure that a test group has at least one young person (around 18-22 years of age) and two or three persons older than 60 years. Most medicines are intended for a general population and the leaflets can and should be tested by anybody, as long as they can imagine that they may need to use the medicine at some time in the future. Medicines for a rare disease will in all likelihood call for persons who actually have the disease and their carers (who are often administering the medicines).

Before starting a test interview it is explained to the tester that the aim of a readability test is to assess whether certain information can be found and, if so, whether the information found is understood. We explain that there is no need to learn the text of the leaflet off by heart: testers can refer to the leaflet when answering the questions, just as they would do at home. We stress that we are testing the leaflet for readability and that we are not examining the tester’s memory or reading skills. If there is something the tester cannot find, or does not immediately understand, then it is likely that there is a problem with the text (or the layout) of the leaflet (and not with the tester). If a single tester gives an incorrect answer that does not inevitably lead to changes in the leaflet; however, if a number of testers have the same problem finding or understanding the information, it is a clear indication that there is probably something wrong with the text. A readability test consists of at least two test rounds with a test panel of 10 testers each. In these two panels, the success criteria should be met; if the first test round does not lead to satisfactory results, an extra (third) test round will be necessary. The criteria have to be met in one test round and the results should be confirmed during the next round.

SCORING

After each test round, the answers of the testers are scored so that an overview per question of the number of times the requested information was found can be gained alongside the number of times this information was understood (which is assumed to be the case if testers can rephrase the information in their own words). The speed of finding the information is also scored. This is important, because when testers need too much time to find the information, there could be a problem, even though the answer may be correct.

PASS OR FAIL

A leaflet passes a test round if for at least 90% of the questions the information is located and if in at least 90% of these cases the information is understood. Usually, a questionnaire has 15 questions, and based on 10-person test panels, this means that there are a total of 150 questions per test round. For 90% of these 150 questions (that is, 135 questions) the requested information should be found. However, finding the information is usually not much of a problem. Typically, in only one to three out of 150 questions is the information not found (that is, a score of 98 to 99%).

What is usually more difficult is understanding the information and acting appropriately. Analysis has shown that, during test round one an average of around 93% of the questions was understood and during test round two (after revision of the leaflet) this improved to around 98%. These high scores are most likely the result of text revisions during the pre-test editing and of the pilot test; for comparison, when testing few leaflets without doing any pre-editing or pilot testing, scores have been relatively low (between 67% and 75%).

CONFLICTING CRITERIA

Different test criteria are used. Many test providers use the ‘90% of 90%’ criterion, supported by the Australian authors Sless and Wiseman, who’s 1997 work has greatly influenced the thinking about readability testing (2). It is also supported by the publication *Always read the leaflet* (3).

Approval is not universal however: the *Readability Guideline* (4) does not support the ‘90% of 90%’ criterion. This guideline allows for the pooling of the results of the first and second test rounds. If 16 out of the total of 20 testers (that is, 80%) give the right answer, the leaflet is assumed to be OK. The *Readability Guideline* states that “for questions identified as most important, any failing to achieve 80% of correct responses for these individual questions should be addressed adequately and discussed in the report”. In practice, this would mean that if a first test round has a relatively low score of 70%, for example, and after revision of the problematic sections the second test has a score of 90%, this would be acceptable. In this case, only two test rounds would be necessary, while under the ‘90% of 90%’ criterion a third test round would be required.

The question is ‘who is right?’ The criterion of ‘90% of 90%’ does not mean that 81% of the testers have to understand the leaflet. If 100% of testers find the information (which is often the case), 90% of all these testers have to understand it, not 81%.

If a leaflet is poorly written, it does not matter which criterion are used. For leaflets with an overall score in the lower 80s, using the criteria of the *Readability Guideline* (16 out of 20, or 80%) does not always help. According to that same guideline, there should not be individual questions with a score lower than 80%. As readability tests have questions that score very high, a low overall score of a leaflet implies that there must be specific questions scoring well below 80%. And with a score for specific questions below 80%, this means that certain parts of the leaflet have to be revised, and if that happens, according to the *Readability Guideline*, the leaflet should be tested again.

National authorities, such as the British MHRA and the Dutch CBG-MEB, treat the criteria flexibly. In case of low scores, they would expect to see revisions in the leaflet and a better score during the next round. In general they seem to be more interested in general improvements and an overall learning curve than in the absolute scores.

READABILITY VERSUS EMEA-QRD TEMPLATE?

As already mentioned, leaflets should follow the structure and the standard headings of the QRD template. At the same time, leaflets

Different criteria

Article 59(3) of the Directive states: 'The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.'

Directive 2001/83/EC, as amended by Directive 2004/27/EC (2004)

"Over 90% of literate consumers should be able to find information quickly and easily and 90% of those who find the information should be able to understand and act on it appropriately. Thus, over 81% of literate consumers should be able to use the consumer medicines information appropriately."

Sless D and Wiseman R, *Writing about medicines for people*, Usability guidelines for consumer medicine information, Communication Institute of Australia, Second Ed, 1997

"To have at least 16 out of 20 consumers able to answer each question correctly. However, it is not necessary for the same 16 people to answer each question correctly. It may be necessary to retest several times in order to achieve this level of performance. (...) This means that not every subject has to answer 80% of the total questions correctly. Regardless of the criteria applied, for questions identified as most important, any failing to achieve 80% of correct responses for these individual questions should be addressed adequately and discussed in the report."

Readability Guideline (European Commission, September 29th, 1998)

"A satisfactory test outcome (...) is when 90% of literate adults are able to find the information requested within the PIL, of whom 90% can show that they understand it."

Always read the leaflet, MHRA, 2005

"In order to ensure that those involved can understand and apply the information, the evidence presented [in the readability test report] must demonstrate that they can pick out the relevant information, interpret this and describe the action they would take as a result."

Guidance concerning consultations with target patient groups for the package leaflet, European Commission, May 2006

Standard headings in package leaflets

1. What is X and what is it used for?
2. Before you take X
 - Do not take X
 - Take special care with X
 - Taking other medicines
 - Taking X with food and drink
 - Pregnancy and breast-feeding
 - Driving and using machines
 - Important information about some of the ingredients of X
3. How to take X
 - If you take more X than you should
 - If you forget to take X
 - If you stop taking X
4. Possible side effects
5. How to store X
6. Further information
 - What X contains
 - What X looks like and contents of the pack
 - Marketing authorisation holder and manufacturer
 - This leaflet was last approved at what date?

must pass a readability test – potential conflict between the two requirements however is a problem, to watch for carefully.

During most readability tests the mandatory heading 'take special care with x' (x being the name of the product) leads to questions, such as what 'special care' means. In the interest of readability, it could be advisable to revise this heading. The heading 'taking x with food and drink' can create even more

confusion; many testers think that this is the section where they will read how to take their medicines (before or after a meal, keep under the tongue, chew or swallow whole, with or without water). However, this section is about possible interactions with non-medicinal products and would contain instructions, such as not drinking milk in combination with using tetracyclines, or not using alcohol during treatment with benzodiazepines.

During readability tests, the heading 'important information about some of the ingredients of x' frequently comes up as causing confusion. It is by far the longest heading in the leaflet and because of that it attracts the attention of readers. However, this section is about the relatively unimportant 'other ingredients'. Often just one substance is mentioned, for example lactose, which is of importance for people who are intolerant to lactose. An obvious solution is to recommend changing the heading to 'this product contains lactose'.

A final problem commonly found with the template is that it is intended primarily for patients. Although fine in itself, leaflets for medicines that are administered by a professional (injections, contrast media) also have to follow the structure of the template. While such leaflets contain important information about side effects and contraindications, patients usually do not get to see them. And if they do see them, they will read the instruction to keep this medicine 'out of the reach and sight of children', and to not pass the medicine on to others, 'as it may harm them, even if their symptoms are the same as yours'. In the setting of a readability test, this leads to confusion; some testers assumed they had to inject the contrast media themselves.

THE FUTURE: JUST ONE LANGUAGE?

Manufacturers are happy that the Directive requires only one language version to be readability-tested. Given the cost of a single readability test (€7,000-10,000), a requirement to test all 21 EU languages would be a heavy burden, so it is assumed that the approved leaflet will be properly translated. Alas, this is not a very safe assumption! A leaflet that has gloriously passed a readability test in one language may be poorly translated into any or all of the other EU languages. The content will probably be there (so the translation is technically correct), but it is often the wording that decides if a leaflet is readable or not. Manufacturers must continue to take 'special care' when validating national versions. ♦

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References

1. <http://www.emea.eu.int/htms/human/qrd/qrdtemplate.htm>
2. Sless D and Wiseman R, *Writing about medicines for people, Usability guidelines for consumer medicine information*, Communication Institute of Australia, Second Ed, 1997
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4. *Readability Guideline*, European Commission, September 29th, 1998