# Writing and Translation in Expert – Non-expert Communication. Methods, Guidelines and Quality Assessment

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**Summary**
This article consists of two parts. The first section is a rather theoretical approach of what communication between experts and non-experts consists of. It deals with how this form of communication is investigated; it examines how this communicative situation is represented in existing text typologies and which requirements writers and translators have to meet in order to transfer knowledge so it is understandable. In the second section, a specific text type within a real communicative situation is analyzed, in particular the Patient Information Leaflet within the European Public Assessment Report of a medicinal product. This analysis focuses particularly on the external factors of the communication. What is the impact of guidelines and quality assessment on the work of the writer and translator? Do they help the writer and translator in realize the communication as a cognitive process of anticipation and transformation?

## 1. Communication between experts and non-experts

### *1.1 Definition*

Contrary to the concept of *expert*, the concept of *non-expert* is referred to in the literature by a number of equivalents such as: *laymen*, *laypersons*, *laypeople*, the *general public* and *general readers*. This might be the result of attempting to express the concept as respectfully as possible.

A lot of studies define the concepts of *expert* and *non-expert* or *layman* from a cognitive-psychological point of view.

Bromme, Nückles & Rambow (2000:1) define an *expert* as a professional. Bromme, Jucks & Rambow (2004) specify that the expert has generally had an academic education lasting a number of years, that (s)he possesses a certain degree of professional experience and that, on this basis, (s)he is able to successfully manage the requirements of his or her profession (180-181). In addition, Bromme, Jucks & Runde (2005: 93) point out that the expert belongs to a community. This aspect is important in order to define the concept of non-expert.

The *non-expert* or *layman* does not belong to the knowledge community of the expert. However, being a layperson in a given communicative situation does not mean he is not also an expert in another situation. Moreover, the same person can simultaneously belong to different communities or subcommunities. In many cases "experts and laypersons form a temporary problem-related 'community of interest'" (Bromme, Jucks & Runde 2005: 93-94) Bromme, Jucks & Rambow also draw attention to the fact that laypersons often have their own lay theories that can considerably influence the understanding of expert information and the communication with experts. It may happen that laymen use the same words as the expert, but without referring to the same concept. For example, in medicine, the lay concept of diabetes or depression might differ from the professional concept.

Along with the concepts of *expert* and *non-expert*, the characteristics and the problems of *communication* between experts and non-experts are also often studied from a cognitive-

psychological point of view. In this form of communication it is emphasized that knowledge differences exist between the interlocutors. There is a knowledge asymmetry between the expert and the non-expert, and the reference framework or the perspective of the expert differs from that of the non-expert. These differences do not only concern the knowledge of facts and concepts; they also concern structural knowledge, conceptualization, methods of thinking and problem-solving. Bromme, Jucks & Rambow (2004: 181) argue that the knowledge of an expert is problem-oriented, that it is characterized by "situatedness" and "encapsulation", which hampers communication. Theirs and many other studies focus on the expert's perspective. What are his assumptions about the knowledge and the perspective of the layperson he addresses in speaking or writing? How does he estimate the layperson's perspective and the common ground?

These are all rather theoretical cognitive psychological questions. Some of the studies, however, move from the psychological insights to the linguistic realization, in other words, how can the expert in his way of communicating anticipate the layperson's perspective, in other words, how can he adapt the linguistic features of the discourse? And how can the expert's ability to adapt his communication to the layman's perspective be measured? Bromme, Jucks & Rambow (2004: 182) argue that the complex, contextualized, encapsulated knowledge of the expert has to be "unpacked", explicitated and formulated on a less abstract level. Bromme, Nückles & Rambow (2000: 7) even cite some linguistic indicators of conscious listener adaptation such as "explicit introduction of technical terms" and "explicit reference to the listener".

The phenomenon of expert-non-expert communication has been investigated in various knowledge domains: in the domain of medical advice and the health industry (paper written and net based) (Bromme, Jucks & Runde 2005; Askehave/Zethsen 2002) and in the domain of management (Eppler 2004). Experiments have been conducted involving computer experts and architects (Bromme, Nückles & Rambow 2000). Askehave/Zethsen (2002: 28) state that "experts are rarely trained in how to convey specialist information to laymen" and refer for example to incomprehensible tax return forms and insurance policies.

In general, more attention is paid to verbal than to written communication. The advantage of verbal communication – insofar as it concerns a dialogue − is that misunderstanding can be avoided by formulating an additional question as also by using nonverbal signs of non-understanding. On the other hand, the success of expert−non-expert communication not only depends on the expert's competence to anticipate the non-expert's perspective and to adapt his language, but also on a number of external factors such as authority, power structure, and time pressure which can in turn influence the non-expert's perspective. The role of these factors may be more prominent in verbal communication. A good analysis of these factors in the doctor-patient communication was carried out by Peters (2008).

### *1.2 Text types and networks of texts*

Assuming that the most important aim of expert−non-expert communication generally consists of promoting an informed decision or correct action by the non-expert, the topic is well worth of being investigated. Within the field of "writing and translating", I wish to further focus on written communication, which in most of cases is a one-way communication with the exception of the written answering of questions answering on the internet. The first question relates to how existing text typologies within the field of Technical Writing and Translation Studies have included this form of communication.

The interpretation of the expert−non-expert communication as explained in Bromme, Jucks & Rambow (2004: 182), who argue that the complex, contextualized, encapsulated knowledge of the expert has to be "unpacked", explicitated and formulated on a less abstract level, is reflected in Göpferich's typology (Göpferich 2005: 124). In fact, the horizontal line of the graphical representation of her typology shows a reduction of domain specificity and abstraction from progression oriented actualizing texts to didactic instructive texts, the latter being addressed to a broader audience and including school books, handbooks, popular scientific texts, product information, manuals etc.

Similarly, Gläser's classification (Gläser 1990: 50-51) distinguishes between domain internal and domain external communication, largely corresponding to the difference between expert − expert and expert − non-expert communication. Within each type of communication, she subdivides texts according to different types, and does so on the basis of the communicative function. Her classification includes texts with domain specific information, texts aiming at interpersonal contact, directive texts, texts with didactic purpose, popularizing texts and texts affecting behaviour. The latter category is in turn subdivided in instructive texts and directive texts. It is remarkable that a few text types appear in both domain internal and domain external communication: directive texts and texts with didactic purpose. This shows that classifying texts and marking off text types and communication forms is not so easy.

Instead of dividing texts into different types, it is also possible to look for connections between texts or intertextuality. This is the approach adopted by Ostapenko (2007) in her work "Vernetzung von Fachtextsorten" (Making networks of specialized text types) and by Schippel in her article about European networks of text types. Schippel uses the European treaties on EU relations with the ACP-countries as an example and points out how the Cotonou Agreement gives rise to different text types such as EC Communications to the Council of Ministers or the EU-Parliament, Decisions of the ACP-EC Council of Ministers and Regulations.

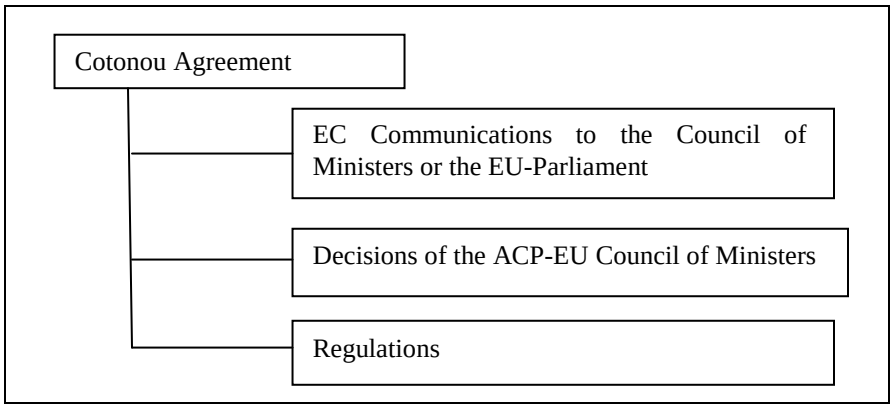


*Figure 1: Schippel (2006:5) – Cotonou Agreement network of texts (own translation)*

The same method of connecting texts of different text types can be applied to the domain of drug information that will be analysed more in detail in the second section of this article. There is the European Public Assessment Report (EPAR) for every authorized medicine. This report encompasses different texts of different text types. The first list includes: a summary for the public, all authorized presentations, a scientific discussion, procedural steps taken before authorization, steps taken after authorization, product information. Product information encompasses on its turn different annexes as presented in figure 2.

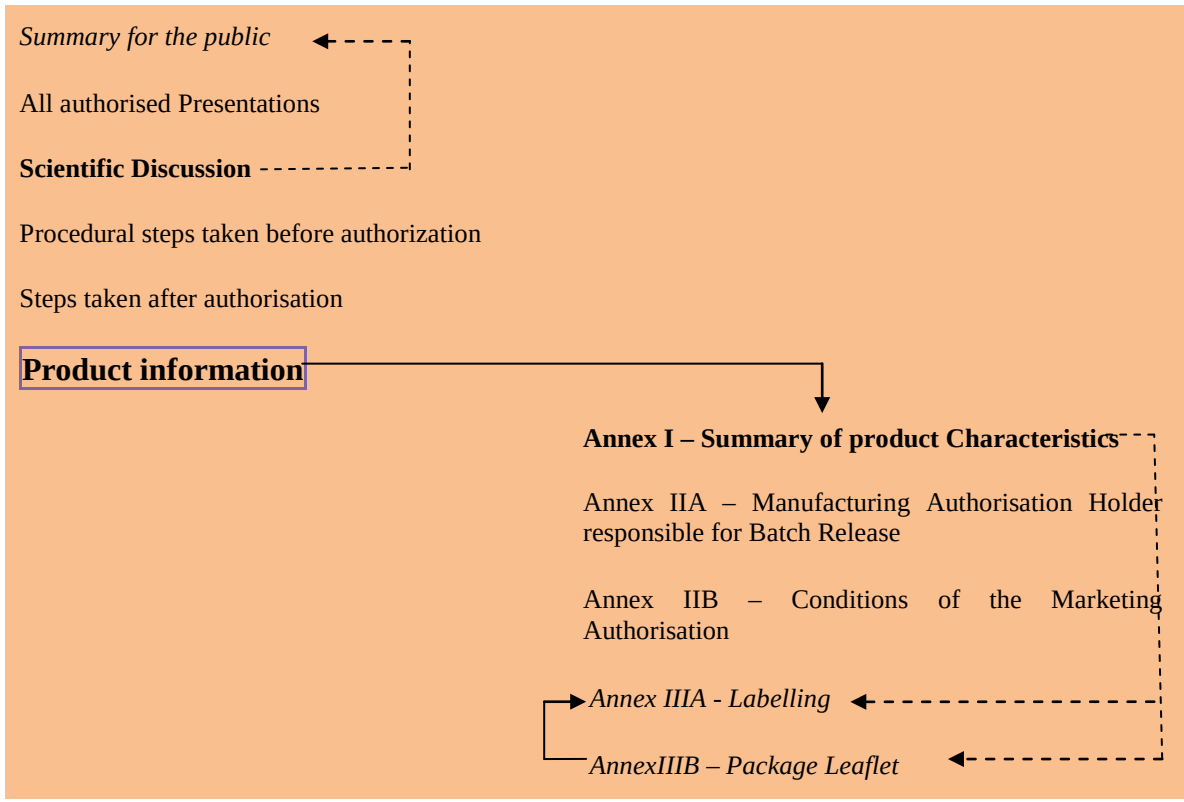


*Figure 2: Network of EPAR texts (see http://www.ema.europa.eu/htms/human/epar/a.htm)*

Within this type of network, communicative connections, intertextuality and dependence become clear. The "scientific discussion" and the "summary of product characteristics" belong to the expert−expert communication and correspond to each other on the level of content, whereas the "summary for the public", the "labelling" and the "package leaflet" belong to the expert−non-expert communication and are also similar on the level of the content. The texts of the expert−non-expert communication are adaptations of the texts of the expert−expert communication; they are inter-generic translations. Within the group of expert−non-expert communication there is also adaption and transfer: the labelling is to be considered a highly abridged form of the package leaflet. The presentation of texts in a network structure puts the writer's and translator's tasks and their required competences into a different perspective.

### *1.3 Translation methods*

The position of the Patient Information Leaflet (abbreviated as PIL) in the network and the task of the writer and translator can be clearly presented in an adapted version of the figure in which Askehave/Zethsen summarize the "skopoi of the texts behind the production of a Danish insert". See figure skopoi

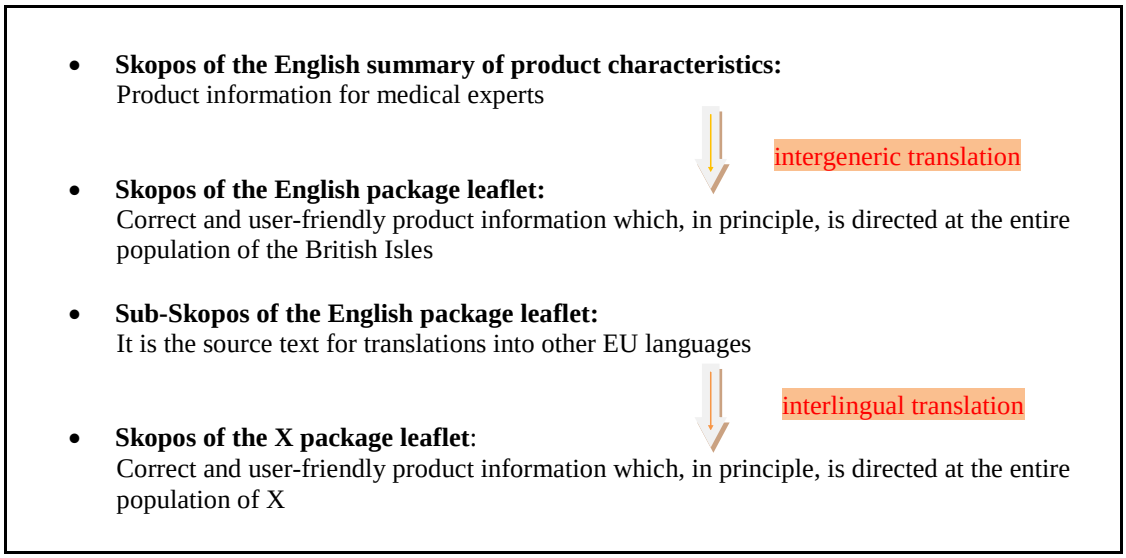


*Figure 3: Skopoi of the texts behind the production of a X package leaflet – Adaptation of Askehave/Zethsen 2002: 25*

The writer of the PIL makes an intergeneric translation of the summary of product characteristics (SmPC) and, in addition, writes his text with a view to interlingual translations. In the most simple communicative situations, the task of the translator is purely interlingual; nevertheless, situations occur in which the English SmPC or other English reports have to be used as a source for a PIL in another language.

Important requirements for the original and translated text of a package leaflet are:
(1) that it fulfills its communicative purpose in the case of a translation: the communicative purpose in the target culture;
(2) that it can be read as an (the) original;
(3) that the communication is as clear as possible, in the case of a translation: that priority is given to clarity of communication over access to the original.

These three points are substantial aspects of (1) Nord's concepts of *instrumental translation*, (2) of House's concept of *covert translation* and (3) of Gutt's concept of *indirect translation*, respectively.
(1) Nord argues that an *instrumental translation* should fulfil its own communicative purpose in the target culture "without the recipient being conscious of reading or hearing a text which, in a different form, was used before in a different communicative action" (Nord 1991: 72)
(2) House's *covert translation* means that the target text is as original for the target text addressees as the source text is for the source text addressees (House 1997: 69). In addition, House introduces the notion of the *cultural filter* that must guarantee that the cultural configuration in the target text is equivalent to that of the source text (House 1997: 70;115-117).
(3) From the perspective of Gutt's translation theory, which relies on the relevance theory, *indirect translation* is – in contrast to *direct translation* – the strategy that is applied when the need to communicate as clearly as possible is given priority over the need to have access to the original meaning, without any explicit interpretation on the part of the

> translator (Gutt 2000: 186). In *indirect translation*, the translator expands and elucidates the text in such a way that implicit information becomes available to the target language audience (Gutt 2000: 194). In Gutt's concept of translation, many texts belonging to the expert−non-expert communication, such as product information and manuals, should preferably not be translated, but rewritten for each audience separately (Gutt 2000: 218).

All three theories on text translation used within the expert−non-expert communication show no real boundary between writing and translating, but rather indicate interaction, interdependence and continuity. When writers and translators are not themselves domain experts, they will perform the role of mediators. Their task will then be to reveal the complex professional knowledge of the expert to the layman in order to promote the transfer of knowledge and make informed decisions possible.

By virtue of their task and role, writers and translators in expert−non-expert communication have to combine various competences. They need domain specific expertise, expertise in communicating with both experts and laymen, because they need to be able to anticipate both perspectives, and finally, expertise in writing and translation.

## 2. External setting of the writing and translation process

Another aspect of the writing and translation process is that while carrying out their task, writers and translators need to take into account external factors such as directives, norms and recommendations and a quality assessment of their texts, which are becoming more and more concrete and formalized. It remains to be seen whether these external factors support the working process of the writer and translator or rather require additional competences. In the second part of this article, I shall deal with advice on text writing and translation on the one hand and quality assessment on the other, together with its impact on the working process of the writer and translator. I shall do this through means of the above mentioned text type, namely the patient information leaflet (PIL) within the framework of European regulations.

### *2.1 Directives and Guidelines*

Writers and translators need to take into account a number of factors that can be found in the following three documents: (1) *The Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004* (European Commission 2004)[1]; (2) *The Guideline on the Readability of the labelling and package leaflet of medicinal products for human use* (European Commission 2009)[2]; (3) *the templates provided by the Quality Review of Documents (QRD) working group* (EMEA 2009)[3].

The *Directive 2004/27/EC* stipulates in Article 59 (1) the structure of the PIL that it "shall be drawn up in accordance with the summary of product characteristics" (a text type belonging to the expert−expert communication), the elements it shall include and the way sections and elements shall be ordered (European Commission 2004, L 135/48-49). Article 63 (2) stipulates general requirements for the writers as well as for translators:

> The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly

[1] In the following text abbreviated as *Directive 2004/27 EC*.
[2] In the following text abbreviated as *Guideline on the Readability*.
[3] In the following text abbreviated as *QRD templates*.

> legible in the official language or languages of the Member State in which the medicinal product is placed on the market.
>
> The first subparagraph shall not prevent the package leaflet from being printed in several languages, provided that the same information is given in all the languages used. (European Commission 2004, L 136/49)

The keywords in this paragraph are "clear", "understandable" and "legible"; furthermore, the translation must provide the same information as the original. However, nothing is said about how the required readability and comprehensibility are to be achieved, and neither is the expected translation method specified.

More detailed information about how to make originals and translations more comprehensible for users are included in the *Guideline on the readability.* The *Guideline on the Readability* (European Commission 2009: 8-10) encompasses recommendations for: (1) type size and font, (2) design and layout, (3) headings, (4) print colour, (5) syntax, (6) style, (7) paper, (8) use of symbols and pictograms. In this context, I shall restrict my contribution to a few recommendations from the sections "syntax" and "style". In the section "syntax" the following relevant recommendations about the length of words, sentences and paragraphs can be found:

> Some people may have poor reading skills, and some may have poor health literacy. Aim to use simple words of few syllables. (European Commission 2009: 9)
>
> Long sentences should not be used. It is better to use a couple of sentences rather than one longer sentence, especially for new information. (European Commission 2009: 9)
>
> Long paragraphs can confuse readers, particularly where lists of side effects are included. The use of bullet points for such lists is considered more appropriate. (European Commission 2009: 3)

In the section "style" important recommendations about the formulation of instructions and the use of medical terms are included:

> When writing, an active style should be used, instead of passive […] When telling patients what action to take, reasons should be provided. Instructions should come first, followed by the reasoning, […] (Euroepan Commission 2009: 9)
>
> Medical terms should be translated into language which patients can understand […] (European Commission 2009: 9)

In addition to the style and syntax advice, the *Guideline on the readability* also includes a long paragraph about translation and the connection between writing and translating.

> During the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way. It is important that the outcome of the user consultation is the correctly translated into the other languages. Strict literal translations from the original language may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand. Therefore, different language versions of the same package leaflet should be 'faithful' translations allowing for regional translation flexibility, whilst maintaining the same core meaning. (European Commission 2009: 22)

This paragraph mentions three steps in the production process of a PIL: first, the original leaflet is drafted; secondly, the user is consulted (cf. 2.2); then the outcome is translated into the other languages. Compared to the detailed writing advice, recommendations with respect to the translation method remain vague. What is meant by "faithful" and by "regional flexibility"?

The only practical information for the translator can be found in the *QRD templates* (EMEA 2010: 16-21) that include standard sentences. These *QRD templates* are available for each of the EU languages and provide standard sentences both to writers and translators. The template contains, for example, a title for each of the 6 sections, subtitles and sentences

expressing medical advice such as: “Please tell your <doctor > or <pharmacist> if …” or “Do not take a double dose to make up for a forgotten <tablet> <dose> <…>” (see fig. 4).

| | |
|---|---|
| 1. What X is and what it is used for | |
| 2. Before you <take> <use> X | |
| 3. How to <take> <use> X | |
| | If you <take> <use> more X than you should |
| | If you forgot to <take> <use> X |
| | If you stop <taking> <using> X |
| 4. Possible side effects | |
| 5. How to store X | |
| 6. Further information | |

| |
|---|
| “Do not take a double dose to make up for a forgotten <tablet> <dose> <…>” |
| “Please tell your <doctor > or <pharmacist> if …” |

*Figure 4: QRD templates – titles of the 6 sections of the PIL, examples of subtitles and standard sentences (EMEA 2010: 16-21)*

The remaining question is how these directives, guidelines and standard sentences contribute to the success of the PIL text and communication with the user. Obviously, there has been progress compared with the past situation. Indeed, harmonizing the structure, explaining scientific terms or translating them into lay terms contribute towards improving the readability and comprehensibility of the leaflet; nevertheless, the quality of text and communication remains far from perfect. How can this be explained?

The writer of the PIL, − often a domain expert with no particular language training − is willing to follow the recommendations in order to meet the requirements of the health agencies. Adaptations made are dictated by external factors and are not the result of anticipating the laymen’s perspective. All too often, the translator of the PIL is faced with a deficient source text, the translation advice is very vague and the standard sentences do not always meet the linguistic norms (suggesting questions not followed by a question mark, for example) and they give rise to unnecessary repetition. As is the case with the writer the translator’s attention is also focused on external regulations instead of communicative competence.

### *2.2 Quality Assessment*

When all is said, it is the consultation with patient target groups that will indicate whether the text is appropriate for communication with the non-expert or not. The obligation to carry out a user consultation is stipulated in the *Directive 2004/27/EC* and the recommendations with respect to the form of the consultation and the way of undertaking a test are described in the *Guideline on the Readability*. Article 59 (3) reads:

> The package leaflet shall reflect the results of consultation with target patient groups to ensure that it is legible, clear and easy to read. (European Commission 2004, L 136/49)

Article 61 (1) of the *Directive 2004/27/EC* states:

> The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority. (European Commission 2004, L 136/49)

This means that the results of assessment are part of the application.

In addition to the *Directive 2004/27/EC*, there is the *Guideline on the Readability* of which a full chapter (Chapter 3) is devoted to consultations with target patient groups. The recommended form of patient consultation is a "user-testing" (European Commission 2009: 20), but other appropriate forms of consultation are also possible. Alternative methodologies will have to be justified by the applicant / marketing authorization holder and will be considered on a case-by-case basis. Performing a user-test or another form of patient consultation is an obligation. The presentation of the data is part of the application and has to follow a prescribed structure. The approval of the package leaflet by the competent authority is a condition for the granting of the marketing authorization.

In appendix, the *Guideline on the Readability* gives, by way of illustration, more details about how to undertake user-testing in a face-to-face interview. I shall restrict myself to a summarizing overview which includes the test performer, the participants, the procedure, the test itself and the success criteria (see fig. 5, next page).

Testing of package leaflets may be done by the marketing Authorization holder or by a service company. Ideally, the questionnaire is drawn up with help of the person responsible for writing the package leaflet. The test must be carried out by an experienced interviewer, occasionally accompanied by the writer of the leaflet.

With regard to the recruiting of test participants, the Guideline stipulates that the selected people should be a representative sample of the population to be treated and in no way directly involved with medicines. Doctors, nurses and pharmacist are therefore excluded. It suggests including particular age groups (young people and older people), new users and non frequent users, people not using written documents in their working lives and people who have difficulty with handling written information.

The Guideline recommends the following testing procedure:

- First, a pilot test of 3-6 participants is recommended;
- Next, repetitive tests until the data from a group of 10 participants are satisfactory
- The last step is to organize of a final test including a further 10 participants to see whether the success criteria are also met by these further 10 participants.

| **test performer** | **MA holder or service company** |
|---|---|
| questionnaire | ideally with help of the PIL writer |
| interviewer | experienced interviewer, occasionally accompanied by PIL writer |
| **participants** | |
| | representative of population to be treated |
| | particular age groups (young and older) |
| | new users and non-frequent users |
| | non-users of written documents in their working life |
| | people who find written information difficult |
| | NO doctors, nurses and pharmacists!! |
| **procedure** | |
| step 1 | pilot test (3-6 participants) |
| step 2 | repeat tests until there are satisfactory data from a group of 10 |
| step 3 | final test with a further 10 |
| **test** | |
| time limit | max. 45 min. |
| nr of questions | 12-15 |
| questions should | reflect all important issues + safety issues and fear factors |
| order | questions appear in random order |
| **success criteria** | info understood by 90% of 90% who found info (16/20) |

*Figure 5: Summary of recommendations as described in the Guideline on the Readability (European Commission 2009: 24-27)*

With respect to the test itself, the Guideline advises designing the test to last no longer than 45 minutes and limiting the number of questions to 12-15. The Guideline stipulates that the questions should cover all important issues, reflect safety issues and fear factors, and that they should appear in random order.

A satisfactory outcome is when the requested information can be found by 90% of test participants, of whom 90% can show that they have understood it. This means that 16 out of 20 test participants should be able to find and to understand the required information.

In order to gain insight into the practical organization of such consultations of target patient groups, a written survey in digital form has been carried out. This survey was presented to the representatives of 45 service companies of different European countries, of which 12 responded. The results of the survey show that the respondents mainly comply with the legislative recommendations. We found only a few exceptions with relation to the procedure, the test itself and the success criteria. With respect to the procedure, in step 2, two companies test a smaller group of participants: only 5-10 instead of 10, and one of the companies does not always organize a final round of testing. In the same company, the test itself consists of less than 10 questions, instead of 12-15. With respect to the success criteria, 5 of the 12 companies indicated that they aim to achieve a result lower than 90%. Surprisingly, when questioned about their average result in the first round of testing, only 2 differ from the 90% or more rule.

We found that several companies also use other test methods as well. How they combine and compare the results of the other tests methods with those of the user testing, and how they present these additional test results to the authorities will be the subject of a next survey.

### *2.3 Quality Assurance?*

In conclusion, what matters is the contribution of this quality assessment to the communication between experts and non-experts. Does user testing assure quality?

At the end of the survey, the respondents were asked for their opinion on the relation between the legislation on readability testing and its implementation. Of the 7 respondents who answered this question, 6 were rather negative. They consider the guidelines "vague", "contradictory", "too general" and they feel that participants' comments on terminology are not followed up by the authorities and that the results of the PIL test are not built into the registration process. One of the respondents also mentioned that there is only limited interaction between the health agencies and the companies. Another respondent commented: "I'm afraid the result of user testing will improve the PIL only to a very small degree. The money spent by the industry (up to 35 000 € for one PIL) does not produce 'excellent' PILs. It mainly serves to meet registration requirements. In order to provide patients with good information, it is necessary to first deal with the differences between patients, contexts, medicines, languages and locations." (translated quote)

## 3. Conclusion

Although directives, guidelines and user testing aim at quality assurance, the improvement of communication does not seem to be satisfactory in practice. Although problems are presented in a report and texts are adapted according to test findings, a fruitful interaction is lacking between the different groups involved in the process: the experts, writers and translators of the pharmaceutical companies, the experts of the service companies and the test participants representing the average layman partner in the communication. Only if the dialogue with the laymen is fed back to the domain experts, the writers and translators in the pharmaceutical industry and to the authorities, can communication with non-experts successfully be improved. Directives and guidelines as well as the recommended quality assessment focus to a large extent on prescriptions, whereas training of the communication competence is required as is collaboration between domain experts, health agencies and people with language and translation competence.

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