Belgian statements on the European guideline for user consultation

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1 Guidelines

- Guidance concerning consultations with target patient groups for the package leaflet. Article 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC, European Commission, Eudralex Vol 2, may 2006 (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm)
- Guideline on the readability of the labelling and package leaflet of medicinal products for human use rev01, European Commission, Eudralex vol 2, 12 January 2009 (http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol2_en.htm)
- Guidance for the Pharmaceutical Industry on the use of BRIDGING studies to demonstrate compliance with article 59(3) of Council Directive 2001/83/EC, MHRA, December 2006, (http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Usertestingofpatientinformationleaflets/index.htm)
- Further guidance on designing patient information leaflets and how to achieve success in user testing. MHRA March 2007 (http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Usertestingofpatientinformationleaflets/index.htm)
- QRD guidance and checklist for the review of user testing results. Rev 3 – 2007. (See ANNEX)

Information from the applicant regarding the user consultation performed together with the presentation of results, or a justification not performing such consultation, is to be included in the section 1.3.4 of module 1.
If the medicinal product is used in hospitals or the medicinal product is administered by health care professionals and a derogation has been submitted and approved by the Belgian Agency to replace the PL by the SPC, user consultation will not be required.

2 Definition

In the large majority of cases, user means patient. User consultation may include carers (e.g. parents, partners, friends as well as nursing assistants) if the medicine is generally intended for administration by someone other than the patient.

3 Key messages

There must be an adequate balance between efficacy and safety key messages in the user consultation. The most important key messages should be reflected in one or more questions. The total of questions should not normally exceed 15 with a minimum of 12. Those questions are related to safety, efficacy and lay out.

4 Questionnaire: major points to aim at

- Ability to find the information
  - Traceability
- Ability to use the information
  - Comprehension
  - Applicability
- Technical readability: letter format, layout

At least 90% of literate adults must be able to find the information requested in the PL, of whom 90% can show that they understand it, i.e. at least 16 out of 20 participants are able to find and understand the information.

The criteria used to assess whether the questionnaire is answered adequately are included in the user consultation report.

“Open” questions are recommended to closed questions.

5 Number of patients – rounds

Several rounds with a small number of patients are recommended. The PL should be amended with the results between each group. A group of 10 patients minimum should meet the assessment criteria.

A user consultation contains normally details about participants:

- Age
- Gender
- Educational level

The participants selected for a given user consultation should reflect the demographics of users of the medicine in question.

6 Presentation of the results

In order to facilitate the interpretation of results, comprehensive data should be submitted. Both written and graphical reports are welcomed. The graphic should give the results through well-differentiated colours for the different groups of patients.

7 Language

All EU languages are acceptable for the User testing. For national procedures however, the report should be in one of the three official languages in Belgium for national procedures or in English with the cover letter and the conclusion in one of the three official languages.

8 Belgian specific requirements

These requirements were presented and accepted by the Bureau on June 2007.

1. The objectives of the user consultation of the patient information leaflet are the following :
   -improvement of understanding and feeling of security of users
   -reduction of medication errors
   -improvement of compliance
   -improvement of the management of adverse drug reactions

2. The questions addressed in the user consultation must reflect all the **safety issues** that were reported in the clinical part of the dossier and in the risk management plan.

3. Special attention will be drawn on the questions about the use of the drug during pregnancy and/or lactation if there is any risk during these periods

4. When applicable, a User Testing may also include **caregivers eg** whenever the medicine is intended for administration by someone other than the patient : parents, partners, friends, nursing assistants.

5. User consultation will be particularly important if the **risk of administration error** is considered to be high, for example in the following situations :

   -parenteral administration
   -formulation that must be mixed with some other product
   -product must be kept in special conditions (temperature, light)
   -if the dose must be calculated in mg/kg, mg/m^2 or other…
   -if there is a risk by overdosing (intoxication) or underdosing (therapeutic failure).
   -if there is a potential risk of major interactions with other drugs or food.

9 Major objections and user consultation

The Belgian Commission will address major objections for the authorization of products in relation to the user consultation in the following situations:

- Absence of user consultation
- Unjustified bridging
- Key safety messages not evaluated
- Questions not adequate
  Eg closed questions, inadequate balance efficacy / safety, questions not **randomly** mixed
- User consultation report not in accepted language.

ANNEX: QRD GUIDANCE AND CHECKLIST FOR THE REVIEW OF USER TESTING RESULTS

QRD GUIDANCE AND CHECKLIST FOR THE REVIEW OF USER TESTING RESULTS

[Disclaimer: This guidance has been set up to provide practical information on how to evaluate user testing reports which are based on the readability testing method as described in Annex 1 of the EC Readability Guideline. This does not exclude the submission and evaluation of user testing reports based on methods other the one outlined above, for which specific assessment guidance may be issued once experience has been gained

Useful links: More detailed practical guidance can be found in the following documents:

- *EC Readability Guideline [link to be inserted]*
- *"Operational procedure on Handling of "Consultation with target patient groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use [link to be inserted*
- *[MRP/DCP relevant document – link to be inserted]*

PRODUCT INFORMATION

Name of the medicinal product:	
Name and address of the applicant:	
Name of company which has performed the user testing:	
Type of Marketing Authorisation Application:	
Active substance:	
Pharmaco-therapeutic group (ATC Code):	
Therapeutic indication(s):	
Orphan designation	☐ yes ☐ no

- Report provided ☐ yes ☐ no

- Justification for not submitting report:
  - ☐ extensions for the same route of administration
  - ☐ ref to test on same class of medicinal product
  - ☐ ref to test with same safety issues
  - ☐ other _____

- Is the justification for not submitting a report acceptable? ☐ yes ☐ no

Reasons *[assessor's views on acceptability or not of the justification – assessment of justification]*

_____
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1 TECHNICAL ASSESSMENT

1.1 Recruitment

- Is the interviewed population acceptable? ☐ yes ☐ no

Comments/further details_____
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Guidance regarding Recruitment

The following points should be taken into consideration when assessing recruitment methods:

- Is the recruitment method well defined? Is it clear that serious thought was given to the composition of the test group? (e.g. in terms of variables such as sex, age, education, experience with the medicinal product, existing knowledge of the complaint, etc.)
- How has the test group been recruited? Are they new users or patients, parents or carers?
- Is it clear how many people were involved in the test/test rounds?
- Is that number sufficient? (The PL should be tested in minimum 2 rounds of 10 participants each)

1.2 Questionnaire

- Is the number of questions _____ sufficient? ☐ yes ☐ no
- Questions cover significant (safety) issues for the PL concerned? ☐ yes ☐ no

Comments/further details_____
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Guidance regarding Questionnaire

The following points should be taken into consideration when assessing the questionnaire*:*

- Have the key messages for safe use been identified by the applicant

- Do the questions cover the key messages and the following areas:

=>General impressions of package leaflet;

=>"Diagnostic" part of PL (i.e. questions aiming to test whether the participants were able to find specific information quickly and easily in each section of the PL and to verify if they were able to understand this information correctly; the questionnaire should primarily concentrate on safety and correct use of the medicinal product and understanding of the participant to assure safe use –it must be ensured that key safety messages have been addressed);

=>Aspects such as design and layout of PL.

- Is the number of questions sufficient? (too few or too many –e.g. 12- 15)

- Do the questions address "wording" aspects? Can respondents easily understand the text they are reading?

- Do the questions provide open or pre-defined answers? Respondents should not be provided with ready-made answers, thus increasing the possibility of positive results. Questions should be open, should be ordered randomly to see how patients use the PL and should not be leading. Questions that require self-assessment (example: in your opinion, is paragraph X clear?) should be avoided. Questions that require a long list of answers to be given (example: "what are the adverse events of this medicinal product?") should also be avoided.

1.3 Time aspects

- Is the time given to answer acceptable? ☐ yes ☐ no
- Is the length of interview acceptable? ☐ yes ☐ no

Comments/further details_____
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Guidance regarding Time aspects

The following points should be taken into consideration when assessing the time aspects*:*

- Is it clear how long the test lasted?
- Was the time given for respondents to read and answer the questions adequate? How long did the interview last? [The test should be designed in a way to last no more than 45 minutes, to avoid tiring participants]

1.4 Procedural aspects

- Rounds of testing including pilot _____

Comments/further details_____
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Guidance regarding Procedural aspects

The following points should be taken into consideration when assessing the procedural aspects:

- Is the test based on different testing rounds? (minimum two test rounds, each involving 10 participants, are required: As this is an iterative process more rounds may be required in order to satisfy the success criteria; a pilot test (including 3 to 6 persons) could precede to assure the questionnaire is understood and major gaps are precluded. The PL after changes should then be tested on 10 participants in total. However, one single testing round may also be considered sufficient and acceptable on a case-by-case basis)

A satisfactory test outcome for the method outlined above is when 90% of literate adults are able to find the information requested within the PL, of whom 90% can show they understand it, i.e. each and every question must be answered correctly by at least 81% of the participants

- Does it make use of modification phases in-between the testing rounds in order to maximise readability?

- Do interviewers use scenarios or live demonstrations (e.g. in order to increase the efficiency of the test, if appropriate.

1.5 Interview aspects

- Was the interview conducted in well structured/organised manner? ☐ yes ☐ no

Comments/further details_____

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Guidance regarding Interview aspects

The following points should be taken into consideration when assessing the interview aspects:

- Are there clear instructions for the test instructor(s)? (e.g. instructions on how to get more information from the consumers test, whether or not help should be given, etc.)

- Do interviewers let respondents show where information on the medicinal product can be found in the leaflet?

- Do they ask respondents to give their answer in their own words and not to rely on memory?

2 EVALUATION OF RESPONSES

2.1 Evaluation system

- Is the qualitative evaluation of responses acceptable? ☐ yes ☐ no

- Does the evaluation methodology satisfy the minimum prerequisites? ☐ yes ☐ no

Comments/further details_____

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Guidance regarding Evaluation system

The following points should be taken into consideration when assessing the evaluation system:

- Is the assessment based on a check list covering the following 3 basic areas: Whether the respondent was able:

⇒ ***To find*** *the information (e.g. can a respondent <u>easily find</u> the information on dosage?)*
⇒ ***To understand*** *the information (e.g. can a respondent say <u>in his/her own words</u> what the proper dosage and the instructions for use are?)*
⇒ ***To use*** *the information (e.g. "imagine you are in situation X and Y happens, what must you do?")*

2.2 Question rating system

- Is the quantitative evaluation of responses acceptable? ☐ yes ☐ no

Comments/further details_____

<u>Guidance regarding Questions rating system</u>

The following points should be taken into consideration when assessing the questions rating system:

- How are answers evaluated? (e.g. 1= no answer, 2=wrong answer, 3=incomplete answer, 4=ambiguous answer, 5=complete and correct answer)

3 DATA PROCESSING

- Are data well recorded and documented? ☐ yes ☐ no

Comments/further details_____

<u>Guidance regarding Data processing</u>

The following points should be taken into consideration when assessing the data processing:

- Is it clear how the data are recorded?
- Is the way in which they are recorded satisfactory?
- Have the data been processed satisfactorily? (e.g., is it clear how verbal assessments have been converted into graded answers?)
- Has the assessor been provided with the patient leaflets used during (different rounds of) testing?
- Are the revisions in the PL explained/justified? Is it also clear which comment from the participants were ignored and why?

4. QUALITY ASPECTS

4.1 Evaluation of diagnostic questions

- Does the methodology follow Readability guideline Annex 1? ☐ yes ☐ no

- Overall, each and every question meets criterion of 81% correct answers ☐ yes ☐ no

Comments/further details_____-
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4.2 Evaluation of layout and design

- Follows general design principles of Readability guideline ☐ yes ☐ no

- Language includes patient friendly descriptions ☐ yes ☐ no

- Layout navigable ☐ yes ☐ no

- Use of diagrams acceptable ☐ yes ☐ no

Comments/further
details_____

Guidance regarding Quality aspects

The following points should be taken into consideration when assessing the quality aspects:

- Is the report complete?
- Does the report clearly distinguish between quantitative and qualitative results?
- Is the medicinal product and the company concerned clearly indicated?
- Based on EC guidelines, are "diagnostic" questions (see 1.2) scoring satisfactorily?
- Do respondents find the layout and design of the package leaflet satisfactory?
Special focus should be given to the following elements:
- *Writing style (simple language, short sentences, use of bullets)*
- *Type face (font size, italics/underlining, lower/upper case)*
- *Layout (spacing, white space, contrast, left justified, columns)*
- *Headings (consistent location, stand out)*
- *Use of colour (present, adequate contrast)*

- Pictograms should be subject to user testing as it is well known that these can confuse patients.
- Do respondents encounter difficulties in locating and using correctly (if appropriate) the information provided in the PL?

5. DIAGNOSTIC QUALITY/EVALUATION

- Have any weaknesses of the PL been identified? ☐ yes ☐ no
- Have these weaknesses been addressed in the appropriate way? ☐ yes ☐ no

Comments/further details_____

Guidance regarding Diagnostic quality/evaluation

The following points should be taken into consideration when assessing diagnostic quality/evaluation:

- Are the results (as far as possible) related to actual passages of text?
- Is an attempt made to explain that readers' problems arose because of certain characteristics of those passages (e.g. something was difficult to find because of a badly chosen heading; or a passage could not be understood because of a double negative; or specific information could not be applied properly because certain terms were unclear)?
- Was a second round revision carried out?
- Have weaknesses of the first round been clearly identified and addressed in the appropriate way? (e.g. questions that scored low led to modifications on the PL => introduction of stylistic changes to improve readability or removal of redundant and confusing information)
- Is it clear which passages have been revised and how and on the grounds of what observations in the first round?
- Is it also clear what observations were ignored in making the revision and why?
- Have modifications been tested and proved to improve readability?

6. CONCLUSIONS

- Have the main objectives of the user testing been achieved? ☐ yes ☐ no
- Is the conclusion of applicant accurate? ☐ yes ☐ no
- Overall impression of methodology ☐ positive ☐ negative
- Overall impressions of leaflet structure ☐ positive ☐ negative

CONCLUSION/OVERVIEW_____
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Guidance regarding Conclusions

A general view on the user testing performed and on the overall readability /quality of the PL should be provided here *[to be used in the CHMP assessment report – the complete evaluation report of the user testing results can be attached as a reference]*

The following points should be taken into consideration when drafting the conclusions:

Objectives:
1. To ensure the final PL reflects the results of testing with patients to make sure it meets their needs and can enable the patient to use the medicinal product safely and effectively
2. To assess the readability of the PL
3. To identify problems regarding comprehensibility and usefulness of information
4. To describe possible changes in the leaflet in order to improve the readability of the leaflet

- Does the report make it clear on what test results specific conclusions are based?
- Do the conclusions match the results or, given the actual results, is too favourable a picture painted?
- Are the conclusions clear, concise and well organised?
- Have the recommendations and conclusions also been incorporated in any revision of the text?