DECISION

No. 6/23.03.2010

on approval of the Guideline on consultations with target patient groups for the package leaflet

The Scientific Council of the National Medicines Agency,
set up based on Minister of Public Health Order no. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.03.2010, in accordance with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law no. 594/2002, as further amended, agrees on the following

DECISION

Single article – The Guideline on consultations with target patient groups for the package leaflet is approved, according to the Annex which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

Guideline on consultations with target patient groups for the package leaflet

Chapter I
Introduction and legal basis

Art. 1. – (1) The European legislation which lies at the core of consultations performed with target patient groups for the package leaflet is regulated through Guideline EC/2009 on the consultations with target patient groups for the package leaflet in accordance with Art. 59(3) and 61(1) of Directive 2001/83/EC, modified through Directive 2004/27/EC.

(2) National legislation in this field includes Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, as well as Scientific Council Decisions (SCDs) of the National Medicines Agency (NMA) No. 12/2007, 21/2008 and 8/2009 – translations and adaptations of the European Guideline on the legibility, clarity and usability on the information on the labelling and of the leaflet of medicinal products for human use and by SCD No. 22/2008 – translation and adaptation of the CMDh Guideline on consultation with target patient groups - Recommendations for bridging.

Art. 2. – (1) This Guideline is not legally mandatory.

(2) Other approaches are acceptable provided are sufficiently grounded.

(3) In case another approach is chosen concerning the methods of consultation with target patient groups, prior consultation with the NMA is recommended.

Chapter II
Purpose for enforcing the consultations with target patient groups

Art. 3. – (1) The purpose of these consultations with target patient groups is to ensure and assess the legibility, clarity and usability of the leaflet.
The main purpose of this Guideline is to provide guidance on how to ensure that the information on the labelling and package leaflet is accessible to and can be understood by those who receive it

(2) The information provided should be accessible and intelligible for users, so that they may use the respective medicinal product in accordance with adequate (safety) conditions.

(3) This Guideline provides information concerning the performance of consultations with target patient groups by compiling and presenting the chapters to be included in the study report.

Chapter III
Enforcement and procedure

Art. 4. – (1) This document comes into force on 1 June 2010.

(2) These recommendations are available for all applications submitted in view of marketing authorisation/renewal through national procedure, submitted following this date.

(3) Companies are encouraged to apply these recommendations as soon as possible for all medicinal products.

(4) 1 year as of the coming into force of this decision, this recommendation is to be enforced for all medicinal products, regardless of their moment of authorisation.

Art. 5. – Information on the consultations with target patient groups should be included in the authorisation dossier, namely in the renewal of the marketing authorisation dossier submitted to the NMA.

Art. 6. – (1) The report on the consultations with target patient groups shall contain a declaration of the company undertaking the test on compliance with Art. 59(3) and 61(1) of Directive 2001/83/EC, amended through Directive 2004/27/EC, and compliance with Art. 28(2) and (3) of Directive 2001/83/EC for medicinal products authorised through the mutual recognition and centralised procedures.

(2) This declaration shall be dated and signed by the reporter(s) and by the quality assurance responsible person, as well as by the representative of the marketing authorisation holder/sponsor.

Presentation of the medicinal product

Art. 7. – (1) Identification data related to consultation shall be presented (the international non-proprietary name of the medicinal product, the marketing authorisation holder/sponsor).

(2) The Pharmacotherapeutic group and the therapeutic indications for the concerned medicinal products shall be mentioned.

Chapter IV
Features of the leaflet layout

Art. 8. – Features such as dimension and font type of the leaflet layout used for testing and the employed font type, blanks, contrast, alignment, titles, colours, the design and organisation of the information shall be mentioned.

Chapter V
Presentation of staff

Art. 9. – (1) The testing of the leaflet may be done by the marketing authorisation holder or by a company contracted to carry out such testing on its behalf.

(2) The dossier containing consultations with target patient groups submitted by such a company contains documents attesting professional training, as well as the qualification of the persons who have performed the study.

Art. 10. – (1) The report on the consultation with target patient groups mentions the name of the company undertaking the testing, the names and qualifications of the persons who have undertaken the testing throughout each of its phases: design, testing proper, verification, coordination.

(2) The testing should be undertaken by an experienced interviewer with good listening, observational and interviewing skills.

(3) Ideally, in view of establishing a direct knowledge transfer, the person in charge of the draft may occasionally accompany the interviewer during the testing process.

Chapter VI
Short summary on the manner of testing

Art. 11. – A short summary on the manner of testing shall be presented, containing the following: the team and its experts, testing premises, city, period when the testing was performed, brief presentation of the working methodology.

Art. 12. – The success criteria applicable to these consultations with target patient groups shall be presented, such as: this method can be considered satisfactory if and only if, following its application, 90% of the test participants are able to find the required information, of whom 90% can show that they understand it.

Chapter VII
Identification of medicinal product characteristics

Art. 13. – (1) Determination and identification of the main and specific characteristics of the medicinal product information are required.

(2) This stage is mandatory in drawing out the questionnaire.

(3) For illustrative purposes, we hereby present a table meant to point out the characteristic aspects of the information related to the information concerning the medicinal product, as well as the mandatory and optional number of questions.

		Route of administration			
		Oral/Parenteral		Topical use	
Field	**Section of the leaflet**	Number of questions		Number of questions	
		mandatory	optional	mandatory	optional
Area of use	**Indications**	1		1	
	Contraindications	1	+1	1	+1
	Warnings	1	+1	1	+1
	Special groups	1	+1	1	+1
Adverse events	**Adverse reactions**	2	+1	1	+1
	Interactions	1	+1	1	+1
Dosage	**Doses**	1	+1	1	
	Application	1		2	+1
	Overdose	1	+1	1	
	Duration of use	1		1	
Handling	**Expiry**	1		1	
	Maintenance				

Chapter VIII
Finding the key-messages in the leaflet

Art. 14. - (1) The key-messages in the leaflet shall be found and presented.

(2) Following identification of the leaflet key-messages, appropriate questions shall be drawn out for each message.

Chapter IX
Questionnaire application

Art. 15. - (1) The questionnaire contains specific and general questions, namely technical questions, as well as questions concerning subjects' positive/negative feedback on the form of the leaflet, as well as on the design and organisation of the information.

(2) This questionnaire shall cover a balance of general and specific issues; a general issue might be what to do if a dose is missed, while a specific issue might relate to a side effect that occurs particularly with that medicine.

(3) Questions referring to all important and difficult issues must be included, particularly those related to specific compliance and safety issues, and strict assessment criteria shall be used (these shall be standardised).

(4) The questions shall reflect any specific issues for safe and effective use and compliance issues related to the medicine being tested.

(5)The avoidance of the serious safety issues caused by the medicinal product throughout the testing of the user's opinions leads to the invalidation of the testing.

Art. 16. - (1) The number of questions employed should be kept to a minimum; normally, 12 – 15 questions will suffice.

(2) If the medicinal product is a part of the following categories:

a) chemotherapy and antibacterial medicinal products

b) medicinal products with complex instructions for use

c) medicinal products raising concerns about safety management

d) Fixed combinations; a minimum of 18 questions is needed to cover safety and compliance issues in their entirety.

Art. 17. – Each question shall point to the related answer in the leaflet.

Art. 18. – There should be a standard number of questions for each section of the leaflet, depending on the route of administration, complexity of information, e.g. indications, contraindications, warnings, special patient groups, interactions, adverse reactions, doses, route of administration, overdosage, duration of treatment, expiry date/storage conditions.

Art. 19. – (1) Questions should be worded in other terms than those used in the leaflet, in order to avoid the "copy-cut" answers, solely based on the identification of word groups.

(2) Questions should appear randomly (not in the order shown in the leaflet).

Art. 20. – Questions involving self-assessment must be avoided (e.g. "According to you, is paragraph X accurate?")

Art. 21. – Questions involving a long list of answers must be avoided (e.g. "Which are the adverse reactions to this medicinal product?").

Art. 22. – There should be about 4 standard questions related to the organisation and the origin of information – syntax, font types, used font, blanks, contrast, alignment, titles, use of colours.

Art. 23. – Questions for each key-message must be supported with arguments.

Art. 24. – The annex should contain the leaflet template through all its phases.

Chapter X
Method and methodology

X.1. Presentation of the method

Art. 25. - The method chosen for user opinion testing must be presented.

X.2. Establishment of the research plan

Art. 26. – (1) The research plan must be established and presented: stages and number of subjects.

(2) A pilot of around 3-6 participants is recommended to test that the questions will work in practice.

(3) At least two tests of further 10 persons each should be undertaken, to review the results and make any necessary amendments to the package leaflet structure.

(4) Tests should be repeated until satisfactory data from a group of at least 10 participants has been collected.

(5) A final test of a further 10 participants should be performed to see if the success criteria are also met in this further 10 (i.e. in 20 participants in total)

X.3. Selection and presentation of the group

Art. 27. - (1) The recruiting methodology should be thoroughly defined.

(2) The selection of the target group needs to be justified.

(3) A small number of participants is needed, i.e. at least 23 participants.

(4) A range of different types of people should be ensured, depending on the age, gender, training level, experience in the use of medicinal products, present level of knowledge related to the disease, who are able to imagine needing to use the medicine

(5) In case of medicinal products meant for rare diseases, the leaflet should more or less be tested in persons who (have) suffer(ed) from the respective disease.

Art. 28. – It should be taken into account that information which can be used by the least able is beneficial for all users.

Art. 29. – Selection of prospective test subjects should focus on the following inclusion criterion: low educational level and training, and corresponding low text comprehension abilities, to ensure an adequate group.

Art. 30. - Selecting the appropriate participants should not overlook the following special target groups:

(a) young people and older people – especially if the medicinal product is particularly relevant to their age group.

(b) new users/people who do not normally use medicinal products, particularly for information provided with new medicines likely to be used by a wide range of persons (e.g. analgesics or antihistamines)

(c) carers may also be an adequate target group (e.g. for medicinal products for Alzheimer's disease, antipsychotics and medicinal products for children).

(d) people who do not use written documents in their working life

(e) people who find written information difficult.

Art. 31. – Participants in such consultations should not be recruited for new testing more often than once every 6 months.

Art. 32. – Groups of subjects should be presented in detail, according to demographic data (gender, age, profession, training level) with the help of charts and graphs.

X.4. Suggestions and recommendations for interviewers and participants

Art. 33. – (1) The interviewing team is recommended to perform an audio and video recording of the interview.

(2) Such records should be kept for no longer than 3 years, in case of NMA request to ensure their authenticity.

Art. 34. – Further recommendations for the interviewer and the person charged with outcome recording:

(a) to allow participants 15 minutes to read the whole of the leaflet.

(b) to use a written set of questions for reference.

(c) to ask the questions orally.

(d) to adopt a conversational manner, allowing ample opportunity for interaction with the participant.

(e) to record, assess/grade the answers to the questions and observe each participant's individual manner of handling the leaflet and of searching the information.

(f) to note such observations which may yield valuable information about how to improve the structure of the package leaflet

Art. 35. – (1) Subjects should be required to become acquainted with the leaflet information in the same way they would prior to taking the medicinal product.

(2) If the time allowed by the interviewer is not sufficient, they should be encouraged to require more time.

Art. 36. – (1) Participants should be required to indicate the location in the leaflet of information related to a certain issue.

(2) The interviewer should score the ease of information location, taking into account the following: the subject has been able to locate the information promptly, the subject has referred to the leaflet, the subject has found it necessary to return the leaflet and how often the question was needed to be repeated, and whether the subject became lost or confused.

(3) Help from the interviewer to locate the text should also be taken into account.

Art. 37. – (1) The required information once located, participants should be required not to read it directly from the leaflet, but to put it into their own words where appropriate.

(2) The subjects' memory should not be tested.

(3) Subjects should not be allowed to read from the leaflet.

(4) The degree of understanding of the information should be graded strictly (e.g. 1 = no answer, 2 = wrong answer, 3 = incomplete answer, 4 = ambiguous answer, 5 = complete and correct answer).

(5) It should be clarified whether the problems encountered relate to the understanding of the text or to the handling of the information.

Art. 38. – As regards the design and organisation of the leaflet information, a grading scale may be used (e.g. ranging from 0 to 10) or a positive/negative assessment.

X.5. Testing time

Art. 39. – (1) The test should be designed to last no more than 45 minutes, to avoid tiring participants.

(2) Should the subjects require longer time, this should be granted.

X.6. Manner of data recording

Art. 40. – (1) The manner of data recorded should be accurately described.

(2) The manner of verbal assessment conversion into scalar responses should be clearly specified.

(3) A result record sheet should be provided for raw data as well as for observations, verbal comments and other types of nonverbal feedback.

X.7. Standardisation

Art. 41. – (1) Pre-established interview performance standards contribute to adequate information quality.

(2) Moreover, this enhances the credibility of such testing and confirms its accurate design, record and reporting.

(3) High quality standards are important to set throughout the entire process.

Art. 42. – Throughout the standardisation process, three levels of interest should be established: location of information, its comprehension and use.

Art. 43. – (1) To locate the information, subjects should be required to indicate where the information related to a certain issue can be found in the leaflet.

(2) Easy location of information should be graded and recorded according to a response scale made up of at least 4 types of responses.

(3) Each of these types of responses should be defined and presented as such.

(4) Correct and efficient record of subject responses can only be achieved in the context of accurate definition and presentation.

Art. 44. – (1) To assess subjects' level of understanding, they should be asked to use their own phrasing in responding to questions related to certain information in the leaflet.

(2) Standardisation of this feature requires a response scale made up of at least 2 response versions.

(3) Each of these must be accurately defined and presented.

(4) Any degree of difficulty in understanding of the information is to be written down in the Result Record Sheet.

(5) Interviewer's help should also be taken into consideration.

Art. 45. – (1) To assess usability of the information, subjects should be required to imagine a particular situation.

(2) A question should be asked next concerning the information from a certain section of the leaflet related to the respective context.

(3) Usability of information can actually be assessed by the subject's ability to answer a question following a few cognitive steps based on the information in the leaflet.

(4) The standardisation of this coordinate shall require a response scale containing a minimum of 2 response variants.

Art. 46. – Regarding questions involving each subject's personal appreciation of the organisation and design of the information – syntax, pattern features, font, blanks, contrast, alignment, titles, use of colours – a grading scale should be used ranging from 1 to 10 (where 1 stands for entirely unsatisfactory and 10 for extremely satisfactory) or an at least 6 graded scale to record personal responses and encode the subjects' feedback in raw scores.

X.8. Data analysis (Statistics)

Art. 47. – (1) The chapter on descriptive statistics should present participants' individual raw scores.

(2) A graphical or tabulated presentation of raw values obtained should be given.

Art. 48. – (1) Results should be reviewed for each round performed.

(2) Presentations may be performed taking into account the range of variables analysed: gender, age, level of education.

(3) Each subject's comments on the tested leaflet draft must be attached.

Art. 49. – The qualitative statistics chapter must describe the manner of raw data coding, their analysis and tabular or graphic presentation.

Art. 50. – (1) Statistic analysis is required by subject, by question and stage.

(2) Emphasis should be placed upon the subjects and questions not meeting the success criterion (90%).

Art. 51. – (1) Following statistic analysis of questions not meeting the success criterion, the leaflet template should be amended by replacing terms, rephrasing or using other methods meant to improve its degree of understanding.

(2) Subjects' suggestions or comments should also be taken into account.

(3) Subjects' comments and feedback should also be presented and further changes to the leaflet template should be justified.

Art. 52. – It will be clearly specified which subject comments have been rejected, as well as the grounds for rejection.

Art. 53. – Following the meeting of the success criterion, an analysis should be undertaken comparing previous stages and the final one which has met the success criterion.

Chapter XI
Conclusions

Art. 54. – The conclusions should:

a) ensure the readability and clarity of the leaflet information
b) ensure proper use of the leaflet by potential beneficiaries
c) convey the comprehensibility of the information and their utility
d) assess the ability to understand the leaflet
e) be compliant with the statistical data recorded
f) be presented in a clear, concise, well-structured manner.

Art. 55. – (1) ANNEX 1, „Checklist and recommendations for assessment of user consultation", is part of this Guideline and should be used as a scale in performing consultations with patient target groups. The points in the list follow chronological steps. Critical deficiencies in one of the criteria result in discontinuation of assessment of the remaining points.

(2) *ANNEX 1* is to be used as reference attached to the Report on Assessment of medicinal products in view of marketing authorisation/ marketing authorisation renewal.

ANNEX 1

Checklist and recommendations for assessment of user consultation

1. Information on the medicinal product

Medicinal product name:	{(Invented) Name, strength, pharmaceutical form}
Name and address of the applicant:	
Name of the company which has performed the user consultation:	
Name of the persons undertaking the research, and their qualification:	
Type of application for authorisation/ authorisation renewal:	{Generic, having a precise medical use etc.}
Active substance:	
Pharmacotherapeutic group (ATC code):	
Therapeutic indication(s):	
Orphan medicinal designation	☐ yes ☐ no

- Report submitted	☐ yes ☐ no
- Justification for not submitting the assessment report:	

☐ extensions of the same route of administration
☐ reference to already existing consultations for the same medicinal product class
☐ reference to already existing consultations on the same safety issues
☐ other justifications _____

- Is the justification for lack of submission of the assessment report acceptable?
Grounds *[assessor's opinion concerning acceptance or rejection of the justification – assessment of justification]*

_____
_

2. Characteristics of the leaflet layout

Are the features of the leaflet template satisfactorily presented? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations
Assessment will focus on whether each of the following items have been presented and analysed when describing the leaflet template: size and font, blanks, contrast, alignment, titles, colours used, design and organisation of the information.

3. Team presentation

Are the assessors presented and the documents attesting their training available?

☐ yes ☐ no

Comments / Further details:

_____

4. Identification of the sections describing the medicinal product

Are general and specific sections describing the medicinal product identified?

☐ yes ☐ no

Comments / Further details:

_____

5. Identification of the leaflet key-messages

Are the leaflet key-messages identified and accordingly presented ?

☐ yes ☐ no

Comments / Further details:

_____

6. Questionnaire design

6.1. Is the X number of questions sufficient? ☐ yes ☐ no

6.2. Do questions cover important (safety) issues in the respective leaflet? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

The following issues should be taken into account in assessing questionnaire design:

- *Has the applicant identified the key-messages on safe use?*

- *Questions cover key-messages, as well as the following fields:*

  =>General impressions on the leaflet;

  =>The section related to the leaflet "diagnosis" (i.e., questions aiming to assess participants' ability to easily and promptly locate information under each section of the leaflet, as well as their ability to understand them properly; the questionnaire should focus mainly on the safe and appropriate use of the medicinal products and on the participant's understanding to ensure safe use – approach of the main safety messages should be ensured);

  =>Aspects such as the information manner of design and organisation.

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

- *Is the location in the leaflet specified for each answer to each question?*

- *Do questions refer to "phrasing issues"? Are the interviewed able to easily understand the text they are reading?*

- *Do questions allow open answers or do they imply multiple choice answers? Interviewed persons should not be provided ready-made answers, which increase the likelihood of positive results. Questions should be open, randomly ordered in order to test patients' use of the leaflet and should not imply the answers. Self-assessment questions should be avoided (e.g. Is paragraph X clear, in your opinion?). Likewise, questions involving a long list of answers should be avoided (e.g. "Which are the adverse events to this medicinal product?").*

7. Method and methodology

7.1. Are the method and the research plan adequately presented?

☐ yes ☐ no

Comments / Further details:

_____

7.2. Number of rounds of consultation, the pilot phase included ____

Comments / Further details:

_____

Recommendations

Assessment of the methodology should take into account the following issues:

- *Does the test rely on different rounds? (at least 2 rounds are required, involving at least 10 participants each: Since this is an iterative process, several rounds may be required to meet success criteria; the test may be preceded by a pilot phase (involving 3 to 6 persons) ensuring the readability of the questionnaire and avoiding major omissions.*
  For example, a satisfactory result is identification in the leaflet of the information required by 90% of adults with basic education, of whom 90% are able to prove they understand the information, which means that at least 81% of the participants, with no exception, can answer each question correctly,.
- *Have there been amendment stages between consultation rounds to maximize text comprehension?*
- *Have the interviewers used live scenarios or demonstrations (e.g. to increase text efficiency, if needed).*

7.3. Is the interviewed population compliant? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

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

- *Is the recruitment method well defined? Is it clear that the composition of the consulted group has been carefully considered? (e.g. as regards such variants as gender, age, level of education, experience in medicinal products use, present level of knowledge on the disease etc.)*
- *What was the consulted group manner of recruitment? Are the recruited persons new users or patients, parents or caretakers?*
- *Is it clear how many people have been involved in the consultation/rounds of consultation?*
- *Is the respective number of people sufficient? (The leaflet should be tested in at least 2 rounds involving at least 10 participants each)*
- *Are demographic data considered in presentation of the group of subjects?*

7.4. Was the interview taken in a well organised/structured manner? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

The following issues should be taken into consideration when assessing interview related aspects

- *Are there precise instructions for the instructor(s)? (e.g. instructions on the performance manner to acquire more information from user consultation, whether help should be provided or not etc.)*
- *Do the interviewers allow the interviewed to specify the location of the information in the leaflet?*
- *Are the interviewed required to phrase their own answer and not rely on their memory?*

7.5. Is the time allocated for answering acceptable? ☐ yes ☐ no

7.6. Is the interview duration acceptable? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

The following should be considered when assessing time-related issues*:*

- *Is it clear how long the consultation has taken?*
- *Were the interviewed allowed appropriate time (for reading and answering the questions)? How long has the interview taken? [The test should be designed in such a way as not to take longer than 45 minutes, in order to avoid tiring the participants]*

7.7. Is the information well recorded and documented? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

When assessing data processing, the following issues should be considered:

- *Is the manner of information recording clear?*
- *Is the information satisfactorily recorded?*

- Was the information satisfactorily processed? (e.g. is it clear in what manner verbal assessments have been turned into scalar responses?)
- Was the assessor provided the leaflets used during the (various rounds of the) consultation?
- Are the reviews to the leaflet explained/justified? Moreover, is it clear which participant comment has been ignored and why?

7.8. Is the quantitative evaluation of the answers acceptable? ☐ yes ☐ no

Comments / Further details:
_____

Recommendations
When assessing the response scoring system, the following issues should be considered:
- How are responses coded? (e.g. 1= no answer, 2=wrong answer, 3=incomplete answer, 4=ambiguous answer, 5=complete and correct answer

7.9. Is the qualitative evaluation of the answers acceptable? ☐ yes ☐ no

Comments / Further details:
_____

7.10. Does the assessment methodology meet a minimum of essential conditions? ☐ yes ☐ no

Comments / Further details:
_____

Recommendations
When evaluating the assessment system, the following issues should be considered:

- The assessment is based on a checklist covering the following three main issues:
The interviewed person has been able to:
⇒ ***find*** *the information (e.g. can the interviewed <u>easily locate</u> dosage related information)*
⇒ ***understand*** *the information (e.g. can the interviewed express the correct dosage and instructions for use <u>in his/her own words</u>?)*
⇒ ***use*** *the information (e.g. "imagine you are in situation X and Y occurs, what are you supposed to do?")*

7.11. Are the general information design principles considered as per the Guideline on leaflet readability? ☐ yes ☐ no

7.12. Does the language include patient accessible descriptions? ☐ yes ☐ no

7.13. Easy text orientation? ☐ yes ☐ no

7.14. Is the use of diagrams acceptable? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

The following issues should be considered:

- Does the report make a clear distinction between quantitative and qualitative results?

- Do the interviewed think that the design and organisation of the leaflet information are satisfactory?

Special attention should be given to the following issues:

- *Syntax (simple language, short sentences, use of markers)*
- *Font characteristics (font size, italic/underlined characters, lower/upper cases)*
- *Organisation of the information (blanks, margins, contrast, left alignment, text presentation in columns)*
- *Titles (consistency of location, highlighting)*
- *Use of colours (existing and appropriate contrast)*

- Pictograms should be an object of consultation, as they are known for their potential to create confusion among patients.

- Do the interviewed encounter difficulties in properly locating and using (if needed) the leaflet information?

8. Data analysis

8.1. Is the methodology compliant with recommendations of the Guideline on the data analysis and interpretation? ☐ yes ☐ no

8.2. Does every question, without exception, meet the 90% criterion of correct answers in location of information? ☐ yes ☐ no

8.3. Does every question, without exception, meet the 81% criterion of correct answers in understanding of information? ☐ yes ☐ no

8.4. Was there any weak point found in the leaflet? ☐ yes ☐ no

8.5. Have such weak points been adequately approached? ☐ yes ☐ no

Comments / Further details:

_____

Recommendations

When assessing the quality/evaluation of the diagnostic, the following issues should be taken into account:

- Are outcomes (as much as possible) related to actual excerpts from the text?
- Has any attempt been made to explain readers' difficulties as resulting from certain such excerpts characteristics (e.g. something was difficult to find because of an ill-chosen title, or a paragraph could not be understood clearly because of a poorly built negation, or the specific information could not be applied properly because of certain unclear terms)?
- Has a second revision of the text been performed?
- Were the weak points of the first round clearly established and approached accordingly? (e.g. questions with a lower score result in amendment to the leaflet => introduction of stylistic changes to facilitate leaflet understanding or elimination of redundant/confusing information)
- Is it clear which paragraphs have been revised, in which manner and in result of which information in the first round?
- Similarly, is it clear what remarks have been ignored in the revision and why?
- Were the changes tested and easier understanding proved?

9. CONCLUSIONS

9.1. Have the main objectives of user consultation been reached? ☐ yes ☐ no
9.2. Is the applicant's conclusion correct? ☐ yes ☐ no
9.3. Overall impression on methodology ☐ positive ☐ negative
9.4. Overall impression on the leaflet ☐ positive ☐ negative

CONCLUSIONS _____

Recommendations

An overall opinion on user consultation and leaflet readability and quality in general should be provided in this section.
The following issues should be taken into account when drawing the conclusions. These should:
1. Reflect patient consultation results thus insuring that the leaflet meets the patients' needs and allows them effective and safe use of the medicinal product
2. Assess the degree of leaflet comprehensibility
3. Determine issues concerning the readability and utility of the information
4. Present potential leaflet changes for its better understanding
- Does the report clearly highlight what specific conclusions of consultation outcomes rely on?
- Do the conclusions correspond to results or, considering actual outcomes are the conclusions too favourable, "too good to be true"?
- Are the conclusions clear, concise and well organised?
- Moreover, have all text revisions incorporated the recommendations and conclusions?