DECISION

No. 21/07.11.2008

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 Order of the Minister of Health No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.05.2008 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 amended, agrees on the following

DECISION

Single article – The Guideline on consultations with target patient groups for the package leaflet is approved, in accordance with 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 the consultations with target patient groups for the package leaflet

CHAPTER I
Introduction and legal basis

Art. 1. – This Guideline is a translation into Romanian and an adaptation of Guideline EC/2006 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 by Directive 2004/27/EC, transposed in Romania through Law No. 95/2006 on the healthcare reform, Title XVII – The medicinal product.

CHAPTER II
Scope

Art. 2. – (1) All package leaflets included in Community or national marketing authorisations should be in accordance with the legal provisions in force.

(2) The information concerning the consultings with patients should be included in the authorisation dossier submitted to the competent authority.

Art. 3. - As regards existing medicinal products authorised for marketing, the need for user consultation covers in principle situations where significant changes are made to the package leaflet, either through a variation or a procedure according to Article 61(3) of Directive 2001/83/EC, transposed in Article 771 (3) of Law No. 95/2006, Title XVII – The medicinal product.

CHAPTER III
Forms of patient consultation

Art. 4. –Articles 769 (3) and 771 (1) of the Law require that the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use; at the same time, these results of assessments carried out in cooperation with target patient groups shall also be provided to the NMA.

Art. 5. - The respective articles do not define the precise method to be used; as a consequence, these provisions permit user testing as well as other appropriate forms of consultation.

Art. 6. – (1) One of the possible ways of complying with the new legal requirement is by performing a ‘user testing’ of the package leaflet.

(2) User testing means to test the readability of a specimen with a group of selected test subjects.

(3) This method is a development tool which is flexible and aims to identify whether or not the information as presented, conveys the correct messages to those who read it.

(4) Testing itself does not improve the quality of the information but it will indicate where there are problem areas requiring rectification in order to attain the settled goal.

(5) The user testing should be part of Module 1 of the authorisation dossier.

Art. 7. – (1) Other methods than user testing may be acceptable provided that the outcome ensures that the information is legible, clear and easy to use so that patients can locate important information within the package leaflet, understand it and enables the user to act appropriately.

(2) Such alternative methodology will have to be justified by the applicant/marketing authorisation holder and will be considered on a case-by-case basis.

CHAPTER IV
Demonstration of patients consultation

Art. 8. - In general, performing the user testing or another justified consultation method will be essential prior to granting or varying any marketing authorisation under either the centralised, mutual recognition, decentralised or national procedures.

Art. 9. – (1) EU Member States and the European Medicines Agency agreed on harmonised Quality Review of Documents (QRD) templates for the package leaflet to ensure that the statutory information appears as intended by the Directive 2001/83/EC as amended, transposed in Romania through Law No. 95/2006, Title XVII – The medicinal product.

(2) Compliance with the QRD templates does not exempt from the obligation to undertake a user test or other form of user consultation.

Art. 10. – A user consultation is mandatory for each applicant/marketing authorisation holder in the following situations:

a) authorisation of a medicinal product with a new active substance,

b) medicinal products whose classification for release has been changed;

d) medicinal products with particular critical safety issues, involving risk.

Art. 11. - When appropriate, the evidence from tests on similar package leaflets may be used, already approved in accordance with Art. 769 (3) and Art. 771

(1) of Law No. 95/2006, Title XVII – The medicinal product; examples of when this may be considered acceptable based on a sound justification by the applicant/marketing authorisation holder are:

a) extensions for the same route of administration e.g. intravenous/intramuscular or oropharyngeal/laryngopharyngea,

b) same safety issues identified,

c) same class of medicinal product.

Art. 12. – (1) It may be appropriate for an applicant/marketing authorisation holder to refer to a representative sample of package leaflets for medicinal products which comply with the legal requirements in force.

(2) The types of package leaflets should be chosen carefully to be representative of one or more of the following considerations:

a) recently approved package leaflets for a corresponding medicinal product,

b) reflect complex issues of risk communication which may need careful handling,

c) medical terminology which requires detailed explanation .

Art. 13. - However, certain package leaflets may require further user consultation to provide reassurance that patients will benefit from the information provided; this is e.g. the case where user consultation concentrates on one particular aspect of a leaflet which may need particular patient attention, e.g. expression of risk of side effects or complex instructions how to administer the medicinal product.

CHAPTER V
Testing of multiple language versions

Art. 14. – (1) The package leaflet should be legible, clear and easy to read in Romanian in case of medicinal products authorised through the strictly “national” procedure, and in all EEA languages from the countries aiming at the centralised, decentralised and mutual recognition procedure.

(2) As a matter of principle it is normally sufficient to undertake patient consultation in one EEA language; results of such consultation should be presented in English for the centralised, decentralised and mutual recognition procedure, or in the national language for

national procedures to permit the assessment of the test to be undertaken by competent authority responsible for granting the marketing authorisation.

Art. 15. - In the centralised, decentralised and mutual recognition procedure, only the English language version of the package leaflet will be agreed during the scientific assessment.

Art. 16. - The quality of translation should be the focus of a thorough review by the applicant/marketing authorisation holder once the original package leaflet has been properly tested and modified.

Art. 17. – (1) 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.

(2) It is important that the outcome of the user consultation is then correctly translated into the other languages.

(3) 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.

Art. 18. - Following the grant of the marketing authorisation, the responsibility for the production of faithful translations will rest with the marketing authorisation holder in consultation with the Member States/European Medicines Agency.

Art. 19. - If user consultation has been performed on a package leaflet in the old QRD template, there is no need to be retested when updating according to the new QRD template.

CHAPTER VI
Presentation of results

Art. 20. – (1) The presentation of results should be shortened to a summary explaining how the consultation was executed and how the resulting package leaflet accommodated any need for change.

(2) The summary should be in Module 1.3.4 of the application and should have the following structure:

a) description of the medicinal product;

b) consultation or test details, such as:

- method used;
- explanation on the choice of population consulted;
- language(s) tested;

c) questionnaire (including instructions and observation forms);

d) original and revised package leaflets;

e) Summary and discussion of results (subjects' answers, problems identified and revisions made to relevant package leaflet section);

f) conclusions.

(3) All other details should be available on demand.

Art. 21. - The report and the results of the consultation should be presented in English for the centralised, decentralised and mutual recognition procedure or in the national language for national procedures.

CHAPTER VII
Approval by the NMA

Art. 22. – (1) In approving package leaflets the NMA will look for evidence that people who are likely to rely on the package leaflet can understand it and act appropriately.

(2) Any consultation submitted in support of a package leaflet will need to cover the following:

a) Data gathered from users under defined conditions

b) The people who are likely to rely on the package leaflet for a particular medicinal product will depend upon a number of factors and may include carers (e.g. parents, partners, friends, as well as nursing assistants)

c) In order to ensure that those involved can understand and apply the information, the evidence presented must demonstrate that they can pick out the relevant information, interpret this and describe the action they would take as a result.

d) The key information will need to be defined prior to the consultation by the marketing authorisation holder and is likely to include significant side effects, warnings, what the medicinal product is for and how to take/use it.

CHAPTER VIII
Other issues for consideration

Art. 23. - The NMA will have considered other aspects in relation to consultation or user testing and usability of package leaflets and additional guidance is available or under development concerning:

a) Timing of user consultation, submission and assessment within the evaluation procedure;

b) Guidance in relation to usability and presentation of information;

c) Guidance on how user testing should be carried out and what alternative methods are acceptable.