POSITION PAPER ON USER TESTING OF PACKAGE LEAFLET – CONSULTATION WITH TARGET PATIENT GROUPS (Compliance with article 59(3) of Council Directive 2001/83/EC)

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1. Introduction

Council Directive 2001/83/EC foresees the need for Marketing Authorisation Holders (MAHs) to take account of the views expressed by target patient groups which have been consulted in relation to the acceptability of the package leaflet (PL). Article 59(3) of the directive states 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."*

Guidance has been produced and published by, amongst others, the Coordination group on Mutual Recognition and Decentralised applications (CMDh) which sets out one way in which an MAH can comply with the requirements of article 59(3). This follows closely the performance based method established in Australia in the 1990s and adopted in part by the European Commission in the Readability Guideline from 1998. Although this was the only method outlined in the guidance, it was clear that other methods may well be appropriate and the guidance was considered to be sufficiently flexible to enable other innovative methods to be used and submitted to support applications.

The published guidance (http://www.hma.eu/218.html) also states that it will not be necessary in every case for a full user consultation to be undertaken and that in certain prescribed circumstances a "bridging study" may be prepared to support the PL.

In some cases it may be appropriate to test only parts of the PL; a "focus" test. This may be the case e.g. in a variation where a certain part of the PL has been extensively changed. This may also be required from the National Competent Authorities as a supplement to a full user consultation; e.g. where a certain part of the PL should be retested.

2. Regulatory objectives and assessment process

The purpose of article 59(3) is to ensure that the quality of the patient information is verified and that participants in the consultation (potential patients) can find and understand key messages from the PL which will ensure safe and effective use of the medicine.

The PL is assessed to ensure compliance with the summary of product characteristics (SmPC) and the design and layout is assessed to ensure that the way in which the information is set out in the document is accessible to the reader, easy to read and easy to navigate thereby satisfying article 60 of the directive.

The data submitted in compliance with article 59(3) (consultation with target patient groups) will be assessed to determine whether participants in the test were able to find and understand the key messages for safe and effective use of the medicine in question.
At the end of the assessment process it is the PL which will be subject to approval. The user test or bridging study submitted is not subject to approval but will be considered as supporting data only. The methodology used will be expected to adhere to principles which ensure that the testing addresses the participants' ability to find and understand key pieces of information within the leaflet. In deciding whether or not to approve the PL other factors will be considered over and above the data submitted in compliance with article 59(3). These are referred to as quality criteria and will include but are not confined to:

- Text size and style;
- Language used and its simplicity;
- Sentence construction;
- Navigation tools employed;
- Risk communication tools;
- Signposting to other sources of information;
- Any general feedback provided by the participants on these points in any consultation carried out will be given extra weighting.

The vast majority of applications which have included data in support of article 59(3) have followed the method described in the guidance issued by CMDh.

3. "Australian" method of user testing

The method most frequently employed by MAHs to meet the requirements of article 59(3) is that cited in national and EU guidance documents – namely the "Australian" method.

This involves the following steps:

- Optimising the leaflet for content and design elements;
- Identification of key messages for safe and effective use of the medicine;
- Preparation of a questionnaire which contains open questions based on the key messages and some general questions on overall perception of the document;
- Face-to-face interviews with participants in groups of 10 preceded by a pilot test of around 3 participants. (The purpose of the pilot test is to ensure the questions are appropriate and not as part of the test of the document);
- Collation of the responses and if necessary revision of the PL followed by re-testing;
- Two rounds of 10 participants will be involved in testing the final version of the leaflet;
- Success criteria of 90% of participants being able to find the information required and of these 90% being able to understand the information (overall 81% but in practice 80%). Each question must pass the success criteria for the PL to be considered to have passed the test.

This method is performance based – it provides evidence of how the PL performs when participants search for information contained in the document. It is not a content based test. A content based test would not provide any information on whether or not the leaflet could be understood.

4. Self-completion method

This method of user testing has been undertaken for a small number of MAHs to support their package leaflets.

This involves the following steps:

- Optimising the leaflet for content and design elements;
- Assessment of the PL against a set of quality criteria (see 2 above);
- Identification of key messages for safe and effective use of the medicine;
- Preparation of a questionnaire which contains open questions based on the key messages and some general questions on overall perception of the document;
- Completion of a written questionnaire by participants in groups of 10 or more which is observed by the consultancy firm. How individual participants use the leaflet to find the information is recorded by the contractor through observation. Time taken for completion of the test is usually less than 45 minutes with average times significantly less than 45 minutes;
- Separate discussion between the contractor and the individual participant on their general views of the PL;
- Collation of the responses and if necessary revision of the PL followed by re-testing;
- Two rounds of >10 participants will be involved in testing the leaflet;
- Success criteria of 80% finding and understanding must be achieved. Each question must pass the success criteria for the PL to be considered to have passed the test.

This method too is performance based rather than content based which is an important aspect of the provisions of article 59(3), but some differences to the Australian methodology exist in the way in which the test is executed. These are discussed below.

5. Other methods of User Testing

The literature details other methodologies available and none is excluded for use in providing supportive information. However any method used must be validated suitably and shown to be appropriate to meet the regulatory objectives of achieving a PL fit for purpose. To date, little experience has accumulated in practice with other methodologies.

6. Discussion

In the self-completion method a fundamental difference between this and the Australian method is that participants are asked to write down their responses to the questions rather than respond verbally. This will remove any external negative influences which may occur in a face-to-face interview. The written test replicates the real-life situation where patients will be reading the PL at home without any intervention from a healthcare professional.

However, this different approach to the written test means that the participants do have to be capable independently of reading and answering the questionnaire, using only the written instructions provided. Participants in a user test for the purposes of compliance with article 59(3) should be representative of everyone who might take the medicine, including people with a range of levels of literacy. A testing process which excludes those who are not proficient at writing would not therefore include the full range of people in the target patient group. It will be necessary to ensure in the selection process that participants with a lower writing ability are not excluded. Nevertheless it should be borne in mind that in the

Australian methodology the participants do have to be able to read the leaflet even though their writing ability is not subject to assessment. Also participants could be encouraged to replicate the wording in the patient leaflet as there is no interviewer there to prompt an alternative response. However, in the small number of tests reviewed which follow the self-completion method this has not been shown to be an issue and should not be a barrier to this method being considered acceptable.

Some methodologies include an assessment of the PL against a set of quality criteria which is helpful in giving an independent assessment of the document looking principally at language and design elements rather than consistency of the information with the summary of product characteristics. This is a positive difference which is something not routinely part of the Australian methodology.

One important similarity between the tests is the acceptance criteria. Both the published method and the self-completion method advocate an overall 80% correct response rate for each question posed. The success criteria are a fundamental aspect of the protocol and anything lower than 80% as a benchmark would give cause for concern.

On balance the differences between the test methods would not be considered sufficiently significant to suggest that the self-completion method should not be accepted in the context of submissions made for compliance with article 59(3).

Again it is emphasised to both MAHs and assessors that the user test itself does not gain any independent approval status as part of the regulatory process.

7. Conclusion

The legislation as drafted says only that the PL should reflect the results of consultation with target patient groups. National competent authorities will be approving only the PL as part of the application. Any user test data will be considered as supporting data only and will not in themselves be subject to approval.

Provided a test method is proposed which is performance based, the test is robust in terms of the questions asked and seeks general feedback on the overall quality of the leaflet, methodology which differs from the published guidance should nevertheless be considered acceptable.

From the foregoing, the self-completion methodology should be considered to be an appropriate means of addressing the requirements of article 59(3) and should be acceptable as part of an application to amend the PL.

A user consultation report submitted to the National Competent Authorities should include

- A description of the methodology used to ensure proper readability. If different methodologies for testing the content and the layout respectively have been used, both methodologies should be described
- Questions regarding key information and expected answers to these questions, as well as response gathered.
- Spontaneous comments or suggestions for improvements from testers, if any (no personal data)
- A summary of proposals for improvement of the PL