

## **FURTHER GUIDANCE ON DESIGNING PATIENT INFORMATION LEAFLETS AND HOW TO ACHIEVE SUCCESS IN USER TESTING**

MHRA undertook a survey of companies who undertake user testing on behalf of marketing authorisation holders. The survey was carried out between 20 December 2006 and 11 January 2007 and a summary report is available on our website. A number of common themes emerged from the responses. As a result further guidance for MA holders and others who draw up patient information leaflets has been prepared to help achieve quality improvements and success in user testing.

Guidance has already been published in the report from the Committee on Safety of Medicines Expert Working Group on Patient Information entitled *“Always read the leaflet – getting the best information with every medicine”* which is available from our website. This document reiterates some key messages from this publication and puts forward additional advice in the area of patient information.

Quality information depends on two factors – design and layout of the information and the content. Both of these are equally important and need to be given careful consideration before submitting leaflets for user testing. The test will identify problems with the information but will not correct these. The quality needs to be built in prior to testing in order to achieve success.

### **DESIGN and LAYOUT**

The design and layout of the information is crucial in helping patients to find and understand the important messages within the PIL. Before submitting a leaflet for user testing you should take time to review the way in which the information is set out within in the document and take account of best practice in this area in addition to re-ordering the information to comply with the new article 59(1) of Council Directive 2001/83/EC.

Many test houses will offer to review and improve the design and layout of the information in the PIL to ensure a high quality PIL is achieved and there is more chance of a successful outcome in the user test. You are advised to take advantage of these services.

Key points to note:

- Help patients to navigate the information
  - Make sure headings are placed consistently and stand out by using either a larger font or by emboldening the text.
  - Judicious use of colour can help but make sure contrast is good and there are not too many colours which can in itself be a problem.
  - Patients like an index. This is very important if you are using a booklet format which is known to be more difficult to navigate.
- Make sure the text size used is as large as possible and that there is good use of white space. Dense text means patients lose concentration and therefore cannot find the information required.

- Long lists of side effects are frightening and short bullet points have been found to be helpful. Group the side effects by seriousness and make sure that where patients need to take urgent action this is clear.
- Make sure related information is located together and not split over different columns or sides of the leaflet.
- Do not repeat information as this is known to confuse.
- Information which appears before the index or in a box is overlooked by patients so these devices should not be used.

## CONTENT

How the information is worded is equally important in making sure the key messages for safe use can be understood. Before submitting your leaflet for user testing make sure you have considered the way in which the information is written and take account of best practice in this area. Your writing style should be considered in advance of submitting a leaflet for user testing in order to have the best chance of success.

Key points to note:

- Consistency with the SmPC and compliance with article 59(1) must first be achieved (see below, Using Templates)
- Complex language and medical jargon cause difficulty in understanding by patients.
  - Translate all the information into lay language.
  - Make sure you use colloquial English (for leaflets for the UK).
  - Use short sentences and/or bullet points.
  - Many of the phrases in the QRD template can confuse so consider more colloquial terms for the UK.
- Do not use the system organ class arrangement for side effects as patients are unable to follow this logic. Side effects should be grouped by seriousness to enable patients to understand when to take action and what that action should be.
- Make sure risks are communicated clearly to patients. Guidance has already been published in *“Always Read the Leaflet”* and examples of best practice in this area are available. Explanations (including frequency with respect to the side effects) are known to be helpful to readers and can put the risk in context.

## USING TEMPLATES

A template will help to make sure that the information required by the Directive appears in the correct order (article 59(1)). This will not help with design and layout, however, and once you have the text for the leaflet you will still need to make sure that the design and layout of the words produces a high quality document which patients will be able to read and understand.

Findings from the survey indicate that the wordings of many of the headings and subheadings in the QRD template are not well understood by patients. You should make sure that when preparing your mock-up leaflet for testing

you reword your leaflet to ensure that all the information is translated into terms which the patient can understand.

Particular care needs to be taken with the sections in the PIL covering contraindications, warnings and precautions and the side effects sections. These are often very long and written in complex language. Make sure that you have used the guidance above on design and content to help reduce the likelihood of problems arising in testing.

## **CARRYING OUT THE TEST**

Although a method for consulting target patient groups (to comply with the new article 59(3) of Council Directive 2001/83/EC) has been published in *“Always Read the Leaflet”* it is recognised that this is just one example of how this can be carried out. Alternative methods will be considered. Some user test companies have employed other methods. Those who have, recognise the importance of observing one-to-one interviews to help understand how patients navigate the information provided.

Whatever method is used, you must ensure first of all that the key messages for safe use are identified up-front for the particular medicine in question. The key messages for safe use will differ for different active substance so the questions derived from these will also be different.

The participant population to be used will also need careful thought and guidance on this has already been provided in *“Always Read the Leaflet”*.

- People who are familiar with the medicine would not normally be appropriate, although they can be a useful source of advice in the design stage.
- It should be sufficient for participants to imagine having to use the medicine in question but they need not suffer from the condition for which the medicine is indicated.
- Exclusion criteria should include medical, nursing, pharmacy and other health care personnel.
- The participant population chosen should reflect the age range of indicated patient population. Where the medicine is indicated principally for use in a paediatric population parents or carers should be the target population used.

The questions asked of the participants should cover the key messages for safe use. These key messages for safe use are most likely to come from sections 1 – 4 of the leaflet but the distribution and spread of questions will vary from one medicine to another. Although for some medicines there may be a need to ask a question from sections 5 or 6 this would not be usual. Make sure you cover all the key messages for safe use in the questionnaire to be sure of a successful outcome.

Each individual question will need to pass the success criteria set out prior to testing. If one question fails you will need to make changes to the leaflet and

carry on testing until you achieve the success criteria in all questions. Where changes are made to the leaflet we would usually expect you to undertake testing on the final version of the leaflet in two groups of 10 participants unless otherwise justified.

## **PREPARING THE REPORT FOR SUBMISSION**

In putting together the report for submission to the MHRA you should take into account guidance already published and available from the Heads of Agencies website. In addition it is helpful to include the following sections in the report:

- Key messages for safe use.
  - Identify these up-front for the particular medicine
  - Discuss how the questions have been derived based on the key messages for safe use
- Participant selection and demographics
  - Discuss how the participant population chosen reflects the likely patient population for the medicine in question, both in sex and age spread.
  - Discuss exclusion criteria and educational level of participants to ensure bias is removed.
- Report each round of testing
  - Graphical representation works well but if graphs are used they must be clearly labelled and easy to interpret.
  - Each question must pass the success criteria
  - Indicate which questions participants have problems with. This may be in terms of location or understanding or both.
  - If you use subjective criteria such as “easily”, “with difficulty” etc to describe how participants find information, please be aware that we would consider those responses stating “with difficulty” or “with lots of difficulty” to be unsuccessful and that you should discuss how ease of finding the information can be improved by making changes to the PIL.
  - Propose changes to the PIL to address the difficulties
  - Retest and report further rounds
- Discuss any general feedback from the participants on the leaflet and propose changes to address any concerns of a general nature.
- Include all versions of the leaflet.
- We do not need the original data obtained from the interviews – a summary of the verbatim responses will suffice. If we feel we need more information we will ask you for it during the assessment.
- You should not submit data on how each participant performed during the test. The leaflet is being tested, not the participants, and therefore these data are not relevant.

## **INTERPRETATION OF SUCCESS CRITERIA**

Success criteria were published in “*Always Read the Leaflet*”. These state that 90% of literate adults should be able to find the information and of these 90% should be able to understand the information. Over two rounds of 10 participants on the final proposed leaflet we would expect 16/20 participants to have both found and understood the information. Where results fall below this level we would expect revisions to the PIL to be made and further testing to be carried out. Where alternative test methods are proposed different success criteria may be appropriate. Nevertheless, whatever success criteria are proposed each question must satisfy the criteria individually.

## **TIMING OF SUBMISSIONS**

The legal requirement in the UK is that all medicines on the market must have patient information leaflets which comply with both the new order for the information and be supported by user testing by 1 July 2008. The relevant legislation is set out in The Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations 2004 number 3224 [SI 2004/3224]. Both arms of article 59 of Council Directive 2001/83/EC (as amended) must be complied with concurrently. Therefore when you decide to reorder your leaflet text [compliance with article 59(1)] you must at the same time generate data to demonstrate compliance with article 59(3) [consultation with target patient groups]. We do not consider applications which propose changes in only one of these areas to be valid and your application may incur significant delay.

You will need to ensure that your applications are submitted in good time to enable you to have the necessary changes approved by the due date. MHRA is suggesting that to account for assessment time and the time needed to print new PILs you should aim to submit your applications by 31 December 2007.

Further information can be obtained from the Patient Information Quality Unit by emailing [patient.information@mhra.gsi.gov.uk](mailto:patient.information@mhra.gsi.gov.uk)

**MHRA**  
**MARCH 2007**