

GUIDANCE ON THE USER TESTING OF PATIENT INFORMATION LEAFLETS

1 Introduction

From 1 July 2005 new legal provisions exist in the UK for patient information particularly in relation to involving patients in ensuring that the information provided is legible, clear and easy to use¹. This guidance expands upon earlier guidance from the European Commission on user testing of patient information leaflets which has been in use since 1999² and in turn adapted aspects of the work by the Communication Research Institute of Australia³ in this area. It is addressed to marketing authorisation holders and aims to:

- help you decide how and when to apply a user test to PILs which accompany medicines for which you are responsible
- provide information about one way of undertaking a user test
- offer advice on who should be involved in the test process.

2 Legal Basis

All medicines are required by European and UK law to be accompanied by a Patient Information Leaflet (PIL) setting out comprehensive information which is accessible to and understandable by those who receive it, so that they can use their medicine safely and appropriately¹.

European Law now states:

The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible clear and easy to use⁴...The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority⁵.

3 What User Testing Is

Before undertaking a formal user test, you should ensure that at all stages of the development of the PIL the views of patients are considered.

The reason for user testing is to help produce a leaflet that most medicine users can use to take safe and accurate decisions about their medicines.

Diagnostic user testing of patient information leaflets was pioneered in Australia in the early 1990s³, and was recommended in guidelines on Readability in Europe by the European Commission in 1999². It is a performance based, flexible development tool which identifies barriers to people's ability to understand and use the information presented, and indicates problem areas which should be rectified. It is particularly useful as part of a leaflet development process. If testing reveals barriers to understanding, carefully considered changes to the leaflet will be needed to improve it.

4 MHRA's Criteria for Assessing PILs Which Have Been Subject to Consultation with Target Patient Groups

This guidance includes an annex describing one method of diagnostic testing of PILs. This is included for illustrative purposes only, and other performance-based methods are equally valid. In approving PILs, MHRA will not require any particular method of testing to have been used, but will look for evidence that people who are likely to rely on the leaflet can find and appropriately use the information.

As the MA holder, you are advised to ensure that you have:

- Clearly defined before the test what the **most important information** is – for example, what the medicine is for, the dosage and any significant side effects and warnings.
- Reflected in the test sample **populations who are particularly likely to rely on the leaflet** for the medicine in question (these may include carers).
- Provided **credible evidence**, for example data gathered from test participants to a clear protocol
- Provided evidence that test participants can **find and appropriately use the information**.

Where it is intended to market a medicine in the UK, any user testing undertaken should be on the English language version of the patient information leaflet.

5 When to Undertake a User Test

- While user testing of PILs is in its infancy, MHRA expects all PILs submitted for approval to have been user tested unless the MA holder can provide a full justification for exemption.
- Exemption will depend on the submission of appropriate justification, which:
 - might include standard formats and company standard operating procedures (SOP) for writing and testing PILs (including those of commercial sub-contractors).;
 - must demonstrate that PILs prepared according to that company's SOP and in a proven leaflet format have performed satisfactorily in a valid user test as described above.

In the event of revision of a company's SOP, future applications may not be able to rely on tests for a similar PIL tested according to the old SOP.

Over time, as knowledge and experience grow, it is likely that not all PILs will need to be user tested. Rather, some PILs may be able to rely on testing applied to PILs for similar products. Examples of when this might be considered acceptable include:

- Line extensions for the same route of administration
- The same safety issues identified
- The same drug class
- The same pharmaceutical form
- The same patient population
- The same format of PIL

Each case will be judged on its merits and more than one of the criteria above may apply.

- There will still be circumstances where a user test is always required. These are likely to include but will not be restricted to:
 - New chemical entities
 - Medicines which have undergone a change in legal status
 - Medicines with a novel presentation
 - Medicines with particularly critical safety issues.

MHRA reserves the right to request a user test where there is any doubt regarding the usability of the information presented with an application.

6 Implementation

- All applications which include a PIL and are submitted for assessment to the MHRA will be considered against the criteria in section 4 of this document.
- The guidance affects all new applications for marketing authorisations submitted on or after **1 July 2005** which are affected by The Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations [SI 2004/3224.] This will apply in all areas of MHRA work (new MAs, PLPIs and herbals).
- There will be a transitional period for existing marketing authorisation holders to comply with the new requirements. Applications in these circumstances will be submitted directly to the Product Information Unit.
- There will be a final date for all leaflets to comply with requirements to reflect user testing and the changes in the order of the information presented, by **1 July 2008**.
- Assessment policy will be to expect user testing to have been undertaken and the data to be submitted as part of the application or for a full justification for the absence of the test to be provided by the applicant.

Medicines and Healthcare products Regulatory Agency

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1. The Medicines (Marketing Authorisations and Miscellaneous Amendments) Regulations 2004 number 3224 [SI 2004/3224]
2. Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use (European Commission September 1998).
3. Sless D. & Wiseman R. (1997) *Writing about medicines for people: Usability Guidelines for Consumer Medicine Information* (2nd edition)
Canberra: Australian Government Publishing Service
4. Title V of Council Directive 2001/83/EC (as amended), Article 59(3)
5. Title V of Council Directive 2001/83/EC (as amended), Article 61(1)
6. This guidance builds on experience gained with the European Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use which adapted some aspects of the work by the Communication Research Institute of Australia.

ILLUSTRATION - One Way of Undertaking a Test of a PIL

The method described covers one-to-one, face-to-face, structured sets of interviews, involving at least 20 participants reflecting the population for whom the medicine is intended⁶. As indicated above, other performance-based methods are equally valid, and MHRA will judge applications on a case by case basis.

1 Performing the test

- Testing of PILs may be done by the MA holder or a suitably qualified agency on its behalf.
- It should be carried out by an experienced interviewer with good interview, observational and listening skills.
- Ideally the writer of the PIL will carry out the interviews, or occasionally accompany the interviewer during testing, to enable direct transfer of learning.

2 Recruiting Participants

- Ensure a range of different types of people who are able to imagine needing to use the medicine.
- If the medicine is intended for a rare illness, then where possible test the leaflet among people who actually have the illness. You may need to exclude people who have previously taken or are currently taking the medicine.
- Remember that information which can be used by the least able will be beneficial for all users. Try and include:
 - particular age groups such as young people and older people – especially if the medicine is particularly relevant to their age group
 - new users or people who do not normally use medicines, particularly for information provided with new medicines likely to be used by a wide range of people (e.g. analgesics or antihistamines)
 - people who do not use written documents in their working life
 - people who find written information difficult.
- Recruit participants from wherever is most relevant and practical. For example you could use:
 - older people's lunch clubs
 - self-help groups
 - patient support groups
 - community centres
 - parent and toddler groups.

- If you use the NHS to identify subjects or provide premises, you will have to get ethical approval.

3 Sample Size and Use

- Only small numbers of participants are needed. The aim is to meet the success criteria in a total of 20 participants. The important thing is not to re-test participants whom you have already tested. You can achieve this by undertaking:
 - A pilot of around 3-6 participants to test that the questions will work in practice. As you gain experience, you may be able to use just two or three participants in the pilot test.
 - Next, at least two rounds of 10 people each, reviewing the results after the first round and making any necessary amendments to the PIL
 - Repeat tests until you have satisfactory data from a group of 10 participants
 - A final test of a further 10 to see if the success criteria are also met in this further 10 (i.e. in 20 participants in total).

4 Success Criteria

A satisfactory test outcome for the method outlined above is when 90% of literate adults are able to find the information requested within the PIL, of whom 90% can show that they understand it.

If you use a different method of testing, different success criteria may be appropriate. MHRA will consider these on a case-by-case basis.

5 Test Protocol

- You are advised to:
 - Draw up a new protocol for each product
 - Include questions that address all the important and difficult issues, and use rigorous assessment criteria
 - Include a set of expected correct answers
 - Design the test to last no more than 45 minutes, to avoid tiring participants
 - Ensure that the questions reflect any specific safety and compliance issues related to the medicine being tested. Testing is most beneficial when the questions relate to areas where patients' fears are greatest, such as side effects. Avoiding serious safety issues with a medicine during user testing of the PIL would invalidate the test.
- The interviewer should:
 - Use a written set of questions for reference
 - Ask the questions orally
 - Adopt a conversational manner, allowing ample opportunity for interaction with the participant
 - Ask participants, once they have located the required information, not to repeat it parrot-fashion but to put it into their own words where appropriate.
 - As well as recording the answers to the questions, observe how each participant handles the leaflet and searches for information, noting, for example, whether people become lost or confused. This will yield valuable information about how to improve the structure of the PIL.
- The questions should:
 - Adequately cover any critical safety issues with the medicine.

- Be kept to a minimum; usually 12 -15 will be enough, though more may be required in special cases, e.g. if there are significant safety issues to be investigated
- 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.
- Be phrased differently from the text of the leaflet to avoid “copy-cat” answers, based merely on identifying groups of words
- Appear in a random order (i.e. not in the order the information appears in the leaflet).

Copies of the protocol(s) including the questions asked, the responses offered, the interviewer’s written observations and the different versions of the PIL tested must be submitted to the MHRA for review.