

**COMMITTEE ON SAFETY OF MEDICINES  
WORKING GROUP ON PATIENT INFORMATION**

**MINUTES OF THE FIFTH MEETING – Monday 8 November 2004  
10.30 am at Market Towers**

**Working Group**

Ms Melinda Letts (Chair)  
Ms Helen Barnett  
Dr Keith Beard  
Ms Katherine Darton  
Mr David Dickinson  
Nicola Gray  
Ms Wendy Harris  
Professor Jennifer Hunt  
Dr Rosemary Leonard  
Ms Eileen Neilson  
Professor Theo Raynor  
Lady Carolyn Roberts  
Ms Joanne Shaw  
Mr Paul Woods

**MHRA**

Dr June Raine  
Miss Shirley Norton  
Mrs Jan MacDonald  
Dr Sue Harris  
Dr Julia Coombes  
Mrs Beryl Keeley (Secretary)

**1. Apologies and announcements**

Apologies had been received from Dianne Berry, Helen Darracott, Jackie Glatter, Dinesh Mehta, Kristin McCarthy, Alison Blenkinsopp and Patricia Wilkie.

The Chair reminded members that the proceedings and papers of the meeting were confidential. The Chair also reminded members that they should declare any interests in any matters under discussion.

**2. Minutes of fourth meeting on Monday 13 September**

The minutes were agreed as a true record (Paper 05/01) with the following amendments:

- In section 6.1, “lottery” should read “National Lottery Charities Board”
- At the end of section 6.2, add “It may be useful to link into DH research on providing health information via digital TV”.

**3. Matters arising from the minutes**

MHRA introduced Paper 05/02 updating the Group on matters arising from the minutes of the fourth meeting.

### **3.1 Update on implementation**

The Group noted the response to the consultation on early implementation of changes to European legislation as they affect patient information (MLX 309). Some members expressed concern about early implementation of the legislative change introducing the requirement for user testing since this may be difficult for companies to achieve in the limited time available.

### **3.2 Risk communication**

The Group noted the final version of the guidance on risk communication in the PIL. They advised that reference should be made to constant denominators as an option for use in circumstances where it had been shown to be helpful and where the incidences were of a similar order. They also advised that the guidance should be subject to user testing.

The Group welcomed the publication on the MHRA website for Ask About Medicines Week of the pilot version of the supplementary information leaflets. They advised that further work was required on presentation to improve readability, and that user testing should be undertaken. They were keen for the leaflet thereafter to be put on the NHS Direct and Ask About Medicines websites.

## **4. Accessibility**

MHRA reminded the Group that accessibility of the information in the PIL was the third main part of the initial work areas identified by the Group. The reviews of the various individual areas where people have special needs would be brought together, in order to identify common themes for further work.

### **6.1 Medicines for children**

Nicola Gray introduced the subject of information on medicines for children (Tabled Paper I). She emphasised that the term “children” covered a diverse group of individuals at varying stages of development, and explained that at around age 14 children can consider the consequences of health related action and by 15 they can make independent decisions. Available research and policy statements on what children want to know about medicines were also reviewed. These emphasised that children need information about medicines and education to support their progressive adoption of responsibility for medicine use. The National Service Framework for Children would support this.

Members of the Group made the following points:

- Compliance can be a problem so information about the consequences of not taking the medicine can be important.
- For young children the information should be aimed at carers (discussed at the previous meeting).
- PILs are not tested on children and can be difficult for them to use. However, there is little evidence available on this. For chronic conditions, PILs should aim

to help the child to learn to manage their condition. For OTC products, PILs for products likely to be used by teenagers should address their likely concerns.

- Information needs to take account of the lifestyle of the age group concerned and their likely questions.
- The Children's BNF will be a useful data source when available, and the Medicines Information Project is also keen to use this to develop material for children.
- An AS level module on medicines had been developed for use in schools and this had been reviewed by CSM.

The next step would be for MHRA to bring together the access elements to develop themes. These would then be explored with the relevant authorities. The advice would also be used to inform current initiatives such as European developments and the Children's BNF. This would be a priority for the next year of work.

## **6.2 Health literacy**

Dr Michael Horah of the Department of Health presented a report to the Group on the work of the Department of Health in promoting health literacy among disadvantaged groups, and the *Skilled for Health* programme (Tabled Paper II). This is linked to a wider *Skills for Life* programme jointly run with DfES. The materials developed are suitable for use in a variety of areas such as by healthcare staff. Promoting health literacy would also be included in the forthcoming Health White Paper.

Members of the Group made the following points:

- Health literacy empowers patients and would benefit a wider group than just those with low educational skills.
- Redesigning of services to make them more navigable and responsive to the needs of patients would also help.
- A major part of the Skills for life programme is aimed at those whose first language is not English. This was welcomed since the need for interpreters can be a barrier to delivery of effective health information and care.
- This work should link into similar ongoing work in the NPSA on patient safety.

This work would be implemented through support from the NHS University to all PCTs to fund health literacy programmes as part of a much wider national programme. MHRA would consider the need for involvement in future developments arising from this programme.

## **7. Delivery of PILs**

MHRA informed the Group that there was no further progress to report since the last meeting on issues relating to the delivery of PILs. This would be discussed in more detail at the next meeting.

## **8. Readability guideline**

MHRA introduced Paper 05/00 setting out proposals for a new guideline on usability of PILs. This had been developed following the discussion at the last meeting. The

UK is taking the lead on revision of the Readability Guideline through the European Mutual Recognition Facilitation Group. Comments were invited from members within two weeks.

MHRA reported that the draft user testing guideline had been made available to trade associations as part of the consultation on early implementation of the legislative changes. There would be a further consultation at a later stage.

Members of the Group made the following points:

- An output focussed definition of user testing should be used to make it clear that the function of the testing was to validate the information by demonstrating that medicine users can understand and use the information. This may lead to a variety of forms of testing and the guideline should not constrain innovation. However, there was already a body of evidence on this form of testing and delay could mean a lost opportunity to improve PILs.
- It should be made clear in the guidance that testing should not include patients already on the medicine. The test populations should include the target patient populations and, where relevant, younger people and older children should be included in the testing.
- The writer could not reasonably be expected always to accompany the tester.
- Concern was expressed that the use of literate adults for testing excluded the 20% of adults who are not literate.
- The Australian evidence on the benefits of use testing was good, and the opportunity to improve UK practice by learning from David Sless at his forthcoming seminar should not be missed.

MHRA agreed to revise the guideline in the light of these comments, the David Sless seminar, and any further comments sent in by the end of November. The MHRA and the Chair would then make a judgement on whether the guidance could be taken forward as written.

## **9. First annual report to CSM**

MHRA introduced Paper 05/04 providing a draft outline report to CSM. This offered an opportunity to communicate the value of the Group's work to date and inform a wider audience. Initially the report would be presented to CSM by Melinda Letts, probably in December. The report would be designed for publication to inform a much wider audience.

Comments were invited by the end of November. The Group agreed that the final report would be approved by the Chair for presentation to CSM.

## **10. Forward look**

MHRA summarised the work of the Group to date against its original workplan and priorities identified at the first meeting. The Group then broke into small groups to discuss priorities for the next year and which areas had been successful and which needed further work from the last year.

MHRA agreed to summarise the proposals in the form of an outline plan for circulation to the Group and discussion at the next meeting.

**11. Communication of driving warnings**

MHRA introduced Paper 05/05 seeking the Group's advice on warnings in the PIL regarding driving when taking medicines. CSM had asked that the Group be consulted on this issue following consideration of a report by the CSM Working Group on Medicinal Products and Driving.

Members of the Group made the following points:

- This issue needed to be taken in the context of the Group's other work on improving communication in PILs.
- Where other situations may cause hazard, this should be clearly stated e.g. concentration levels and factory work.
- Pictograms were open to misinterpretation and were unlikely to be helpful.
- There was a paucity of good data on this area.
- It may be helpful to start by identifying appropriate categories of products and which drugs should be in each, followed by consideration of the best wording for warning statements for each group.

MHRA requested any further comments by the end of November. The report would be circulated again to the Driving Working Group in collaboration with the Department of Transport. It would also be used to feed into European consideration if this issue.

**12. Dates for 2005**

The attention of members was drawn to Paper 05/06 setting out proposed meeting dates of the Group in 2005.

**13. Any other business**

None

The Chair thanked the members for their helpful contributions.

**The next meeting would be held on Thursday 10 February 2005.**

**Post Licensing Division  
November 2004**