

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

**MINUTES OF THE SIXTH MEETING – Thursday 10 February 2005
10.30 am at Market Towers**

Working Group

Ms Melinda Letts (Chair)
Ms Helen Barnett
Dr Keith Beard
Professor Dianne Berry
Ms Helen Darracott
Ms Katherine Darton
Mr David Dickinson
Ms Wendy Harris
Professor Jennifer Hunt
Mr Dinesh Mehta
Ms Eileen Neilson
Professor Theo Raynor
Mr Paul Woods

MHRA

Dr June Raine
Miss Shirley Norton
Mrs Jan MacDonald
Dr Julia Coombes
Mrs Beryl Keeley (Secretary)
Dr Rafe Suvarna
Dr Jon Sisson

1. Apologies and announcements

Apologies had been received from Rosemary Leonard, Carolyn Roberts, Joanne Shaw and Patricia Wilkie. Nicola Gray, Jackie Glatter and Kristin McCarthy were all on maternity leave.

The Chair notified members that Alison Blenkinsopp had resigned from the Group due to other commitments.

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 fifth meeting on Monday 8 November 2004

The minutes were agreed as a true record (Paper 06/01).

3. Matters arising from the minutes

It was noted that the work on accessibility of information for children's medicines should be taken forward in association with the CSM Working Group on Paediatric Medicines. It may be helpful to hear a report of their work at a future meeting.

Members requested earlier circulation of papers to allow time for preparation. MHRA apologised for the late circulation of the papers for this meeting.

Members agreed the appointment of Keith Beard as deputy chair of the Group.

The finalised version of the Seroxat PIL reviewed at a previous meeting was tabled for information (Tabled paper 1).

4. Access to PILs for specific groups

The Group was invited to advise on measures to improve access to the information in the PIL for those with special needs. This followed discussion at previous meetings where the needs of vulnerable groups for information about medicines had been discussed.

Helen Darracott presented information on industry proposals to meet the new legal requirement for provision of the PIL in formats appropriate for blind and partially sighted people (Tabled paper 2).

Members of the group made the following points:

- It is essential that control of the information remains with the company marketing the product who must ensure that their procedures are adequate to ensure it is kept up to date in whatever format it is provided.
- Use of master files of electronic information on each product would allow the format of the information provided to be tailored to the individual patient's needs.
- Not all patients would want to use a patient group as an intermediary to gain access to the information.
- Any service should be resourced to cope rapidly and effectively with reasonable levels of demand from patients.

Eileen Neilson presented information on the current situation on the provision of PILs with medicines by pharmacists and on alternative sources of information. On these points, members of the group made the following comments:

- Focus on a small number of widely used medicines could significantly increase the proportion of cases where a PIL is received.
- It may be helpful to consider options that could provide the PIL at the time of consultation or through other widely available services such as the National Library Service.

MHRA introduced Paper 06/02 setting out proposals for a toolkit of options to increase access to the information in the PIL for vulnerable groups. The Group reviewed proposed European guidance on provision of information for those with sight loss and advised that the guidance should permit a range of options to enable patients to obtain information in the form they find most helpful. The Group felt strongly that companies should be prepared to respond to direct patient requests

without the intervention of a patient organisation and considered that further UK guidance could be provided in the toolkit.

The Group welcomed the toolkit proposal. Members of the Group made the following points:

- An additional group with special needs was hospital patients, who may not always receive information about their medicines at appropriate times. Information is often available on request in hospitals but patients need to be made aware of this.
- The needs of older people for medicines information to suit their particular needs should also be considered.
- A comprehensive database of PILs could promote access to the PIL but should not duplicate work in the Medicines Information Project. Timely updating would be essential.
- The preferred source of information for many patients was their health professional.

The MHRA agreed to convene a subgroup meeting to take the proposals for a toolkit forward for review at the next Group meeting.

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. It was hoped that this could be discussed in more detail at a future meeting.

8. Guidance on user testing and usability

MHRA introduced Paper 06/03 outlining progress on the development of guidance on user testing and usability and discussion of these issues with industry and at European level.

Members of the group agreed to provide any comments in writing and made the following points:

- The industry was very keen to receive guidance on implementing the new legislative requirements.
- It was important that the published document made clear that it was guidance, not direction, and that well justified alternative methods would be considered.
- It may be necessary to review the guidance at the end of the year in the light of the development of European guidance and experience to date.
- The level of expertise of testers will be instrumental in ensuring that testing does secure improvements in the usefulness of the information.

MHRA agreed to revise the guideline in the light of comments received.

9. First annual report to CSM

The Chair reported that progress was being made on the Group's report to CSM. This was being taken forward by the MHRA and the chair as agreed at the last meeting. A copy of the report would be provided to members in due course.

10. Workplan

MHRA introduced Paper 06/05 setting out a draft workplan prepared following the brainstorming discussions at the last meeting. Medication errors were a Ministerial priority area and the group was invited to consider whether any additional work should be initiated in this area. Members of the group advised that:

- High profile error cases represented only a small proportion of the actual problem.
- Other areas that were particularly important to look at were OTC and complementary/alternative medicines, self medication and medication in care homes.
- NPSA had initiated research on medication errors in care homes and was working with the MHRA on identified issues where labelling and information were involved.

The proposals for a further patient consultation were welcomed. This would be taken forward in the context of the Agency's proposals to increase patient involvement in medicines regulation. Further details on this would be provided at the next meeting.

Members of the Group suggested that general initiatives to increase the understanding of medicines among children were needed, such as development of materials for inclusion in the school curriculum. This was outside the remit of the Group.

The UK would hold the EU Presidency for the second half of the year, affording an opportunity to increase the focus on patient information.

MHRA agreed to revise the draft workplan in the light of these comments and email it to members for further input with a view to finalising it before the next meeting.

11. Update on Risk communication proposals

MHRA introduced Paper 06/06 setting out progress on taking forward the group's proposals on risk communication.

Supplementary leaflet

MHRA reported that the leaflet had been revised following pilot testing in consultation with David Dickinson. Further comments on the revised version were invited within the next two weeks. MHRA was asked to consider the need for some form of retesting of the final print format, and to prepare proposals for evaluation and review of the published leaflet.

Guidelines

MHRA reported that the need for further support for the proposals on headlines was being explored. The Group supported testing.

Directory of terms

MHRA stated that this had gone through several iterations with advice from individual members of the Group. Members advised that further work was required to ensure that the terms were both accurate and easy to understand, and suggested the Plain English Campaign as one potential source of advice. It was agreed that an informal group would be convened to take this forward before the next meeting. MHRA would propose a process to gain approval for future additions to the list.

12. **Example case**

MHRA introduced Paper 06/07 inviting comments on the PIL for Nurofen for Children. There were two key messages to be conveyed in the PIL following the reduction in the minimum age for treatment – that the maximum number of doses in babies aged 3-6 months is 3 and that early professional advice should be sought if the child's condition gives cause for concern.

Members agreed to provide detailed comment in writing and made the following general points:

- Sentences were too long and there were too many capitals and long words (e.g. formulation)
- 'If symptoms persist' is not readily understandable

NPSA reported that there was a potential for confusion between use in children and adults. The use of a descriptor such as 'oral syringe' could also help to reduce the potential for errors by health professionals administering this product.

13. **Any other business**

None

The Chair thanked members for their helpful contributions.

The next meeting would be held on Thursday 12 May 2005.

**Post Licensing Division
March 2005**