

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

**MINUTES OF THE FIRST MEETING – Friday 14 November 2003
10.30 am at Market Towers**

Working Group

Ms Melinda Letts (Chair)
Ms Helen Barnett
Dr Keith Beard
Professor Dianne Berry
Professor Alison Blenkinsopp
Mrs Helen Darracott
Mr David Dickinson
Ms Jackie Glatter
Dr Nicola Gray

Ms Wendy Harris
Dr Rosemary Leonard
Mr Dinesh Mehta
Ms Eileen Neilson
Professor Theo Raynor
Lady Carolyn Roberts
Dr Patricia Wilkie
Mr Paul Woods

MHRA

Dr June Raine
Mr Jeremy Mean
Mrs Jan MacDonald
Dr Gillian Shepherd (part meeting)

Ms Shirley Norton
Mrs Beryl Keeley
Dr Julia Coombes

1. Apologies and announcements

- 1.1 The Chair welcomed all members to the group and members introduced themselves and their roles. Apologies were received from Kristin McCarthy, Sophie Corlett, Jennifer Hunt and Joanne Shaw.
- 1.2 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.
- 1.3 The Group's aim was to be open about the work of the group and summary minutes would be published on the MHRA internet site. Announcements concerning the Group's work would be made when appropriate.

2. Welcome

- 2.1 MHRA reported that Professor Duff, CSM Chairman, had hoped to be present. In his absence, he had asked that his view should be conveyed that information to patients with their medicines was one of CSM's highest priorities and that he was grateful to the Group for their willingness to take this forward. The Group brought together a range of interested parties in the expectation that the Group would be able to engineer improvements to patient information in the UK, within the legal framework.

3. Procedures for the Working Group

- 3.1 The Chair indicated that members should speak through the Chair and notify items for any other business to the Secretary 24 hours in advance of the meeting. The aim would be to make minutes available within 4 weeks and any action required of members in the interim would be noted in the minutes. Papers for meetings would be sent out two weeks in advance to allow time for study, and would include a second copy of the minutes for ease of reference. Correspondence on Group matters should be sent via the Secretary. It was agreed that a quorum for the Group would be six members to include the Chair or nominated Deputy. A Deputy Chair would need to be appointed, in case of the Chair being unable to be present at a meeting, and the Secretary would communicate with members about this.

4. Introduction to the proposed work of the Group

- 4.1 MHRA described the thinking that led to the establishment of the Group by the CSM and the terms of reference agreed by CSM (Paper 01/01). Group members referred to other initiatives and work in this area including the Informed Patient Initiative, the EFPIA guideline on patient information leaflets and Australian work on quality of consumer medicines information. Members suggested potential additional areas of work including access for those with special needs, such as non-native English speakers and visually impaired people, and package labelling.
- 4.2 It was agreed that the work of the Group would begin by focusing on the statutory information, i.e. Patient Information Leaflets. However, the MHRA was participating in ongoing work with other stakeholders on wider access and delivery issues and it was anticipated that the Group would also be asked to consider these issues in due course. The Group would also build on the work of the previous Labelling Working Group. Members suggested that it would be helpful to review the statutory warnings on labelling.
- 4.3 The Group would also be asked to consider individual PILs for significant products, on a case by case basis, to be identified by MHRA and NPSA together. .
- 4.4 It was agreed that the Terms of Reference should be refined to include the issue of equity and access. This was agreed and the Terms of Reference were accepted, subject to this amendment.

5. An introduction to the regulatory perspective

- 5.1 MHRA summarised the current regulatory requirements for patient information leaflets (Paper 01/02 and Tabled Paper III). There were a number of aspects that could be improved within the current legislation such as the inclusion of information about the disease and benefits in the context of health information. User testing was recommended in the Readability Guideline but was little used by companies.

6. Patient Information and Legislative Change – opportunities for change

- 6.1 MHRA summarised the latest situation on the changes proposed to the EU legislation covering medicines as they related to leaflets (Paper 01/03). Of the UK objectives for

this negotiation, a changed order of information had been agreed and a requirement for user testing had been introduced. It had also been agreed that the current legislation allowed for further information, including ‘dos and don’ts’, and that guidance on risk communication would be developed outside the Review. Agreement had not been reached on highlighting new safety information about medicines introduced into the PIL. If the proposed changes were finally agreed in Europe, opportunities would arise for improvement, particularly in terms of the changed order of information and requirements for user testing. There would also be opportunity to develop guidelines on issues considered important by the Group and to try and get them accepted at a European level.

7. The Medicine User’s Perspective (1)

7.1 Patricia Wilkie presented a historical perspective on recognition of the importance of information for patients about medicines and lay and patient involvement (Tabled paper IV). The Erice declaration set out key principles for drug safety information. The involvement of CSM in assessing PILs with applications was also summarised. The following issues were highlighted:

- The role of the PIL in the context of other available information about medicines.
- The need for additional information about medicines and how this may be supplied.
- Different patient and user groups have varying needs for information, e.g. children and adolescents, visually impaired.
- Availability of the PIL before dispensing and in different settings, e.g. hospital, for vaccines.
- The need for special consideration of consumers’ needs for information on OTC medicines to ensure safe use, particularly for new switch products.

7.2 Helen Barnett presented information available to the MHRA on ADRs and other safety information. This information was made available in summary form through changes to the SPC and PIL and MHRA had procedures for public announcements on safety issues when required. She considered that it was important that the Group consider how best this can be made available to patients.

8. The Medicine User’s Perspective (2)

8.1 David Dickinson presented patient views on leaflets highlighting the problems they encounter in getting information on medicines to help them to use them appropriately and safely and presented examples of leaflets where communication of information was poor. He also highlighted particular difficulties in communication of information about risk and the differences between patient and healthcare professional views on what was important in a leaflet, drawing on the work of others present including Dianne Berry and Theo Raynor. Patients indicated four key points of information about a medicine - side effects, dos and don’ts, what it does and how to take it – but different people prefer different orders of priority. A model leaflet was also presented (Tabled paper I).

8.2 Members highlighted how important it was for written information about medicine use to be accompanied by discussion between patient and health professionals. There

were lessons to be learnt from Australian healthcare professional training, which had been developed to address this. Members advised that it was unwise to assume that healthcare professionals communicate information on risk in an understandable fashion.

- 8.3 Members emphasised the importance of identifying what patients wanted to find out in order to address their needs effectively and described the particular challenge of providing information for people with low literacy without inducing a sense of shame.
- 8.4 The need for patient choice in the provision of information was emphasised. An EMEA: patient organisation group was looking at patient information, including information for patients on new safety information via the PIL and publicity.
- 8.5 The Group requested information about the process of production of leaflets in order to identify points at which the process can be influenced to improve the leaflet. Examples of leaflets considered good and poor were provided to the Group to facilitate consideration of the issues (Tabled Paper II).

9. Work Plan for the Group

- 9.1 MHRA introduced the paper on the workplan for the Group (Paper 01/04). The Chair reminded the Group that this was the start of a process to determine what would be the priorities for the Group and deliverables.
- 9.2 Three groups brainstormed the following issues:
- **Risk communication** (reported at Annex A). This group highlighted problem areas to be addressed to improve the quality of risk communication in leaflets and to patients more generally.
 - **User facing issues** (reported at Annex B). This group identified a number of issues concerning the needs of users and patients, the role of PILs in the wider range of medicines information and social issues such as trust, consent and equity
 - **Networking with other initiatives** (reported at Annex C). This group identified other strands of work that may feed into the work of the Group and highlighted the variety of stakeholders involved in patient information.
- 9.3 It was agreed that the Secretariat would write up a draft workplan and email it to members for comment and approval. This would be an iterative consultation process taking place before the next meeting.

10. Casework examples

- 10.1 MHRA reported that the Group would periodically be asked to review specific cases of concern. This would serve two purposes: strengthening the Group's ability to identify principles by consideration of actual cases, and providing advice to the Agency on leaflets where there was particularly important information to convey.

11. Any other business

- 11.1 Professor Raynor reported that the NHS Health Technology Assessment Programme was conducting a systematic review of the role and effectiveness of patient information parallel to the CSM initiative. At the time of the meeting, this was currently out to tender.
- 11.2 The Chair thanked the members for their contributions.
- 11.3 **The next meeting would be held on Monday 9 February 2004.**

RISK COMMUNICATION

PROBLEM AREAS:

understanding risk information
literacy, language, age

communicating changes to risk
trust in source of information
situation: effects on acceptance of risk
holistic presentation of risks (grouping)
critical effects vs total presentation
- patient perspective
support for patients to interpret information

COMMUNICATION OF RISK

General

- Access problem - deprived populations
- Understanding risk as a concept
benefit v risk or
benefit v harm
- Context of benefit critical
- How personalise ? individualise
- Probability for individual/population
- Uncertainty hard to handle
- Framework? User testing
- Just ask!

USER FACING ISSUES

- relevance/selection
- usefulness
- right balance
- pyramid of information (hierarchy)
- presentation simple/not
- user vs patient
- patient consent
- timeliness of PIL
- where is the information held available/access

INITIATIVES

Patient choice consultation

EMEA Working Group

FDA

Expert Patient NSF's

WHO

Med Guides

Industry - EFPIA proposals (Website)
- AESGP

Australia

Doctor Patient Partnership

Paediatric Initiatives

Angela Coulter/Picker Institute

Literature

Wider Government (DTI/DfE)

KEEPING IN TOUCH

