

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

**MINUTES OF THE SECOND MEETING – Monday 9 February 2004
10.30 am at Market Towers**

Working Group

Ms Melinda Letts (Chair)
Ms Helen Barnett
Dr Keith Beard
Professor Dianne Berry
Professor Alison Blenkinsopp
Ms Sophie Corlett
Mrs Helen Darracott
Mr David Dickinson
Ms Jackie Glatter
Dr Nicola Gray
Ms Wendy Harris
Professor Jennifer Hunt
Dr Rosemary Leonard
Ms Kristin McCarthy
Mr Dinesh Mehta
Ms Eileen Neilson
Professor Theo Raynor
Lady Carolyn Roberts
Ms Joanne Shaw
Mr Paul Woods

MHRA

Dr June Raine
Mr Jeremy Mean
Mrs Jan MacDonald
Dr Sue Harris
Ms Shirley Norton
Mrs Beryl Keeley
Dr Julia Coombes
Dr Rafe Suvarna
Ms Amanda Williams (part)
Dr Joan Pallett (part)

1. Apologies and announcements

- 1.1 Members who had been unable to attend the first meeting were welcomed. Apologies had been received from Dr Patricia Wilkie.
- 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.

2. Minutes of first meeting on Friday 14 November

The minutes were agreed as a true record.

3. Matters arising from the minutes

None.

4. Agreement of revised terms of reference and workplan

MHRA introduced Paper 02/02 setting out the revised terms of reference and the proposed initial workplan for the Group.

Terms of reference

- 4.1 The Group agreed the proposed change to the terms of reference to recognise the issues of equity and access identified at the first meeting. Some members expressed the desire for a wider remit. Members advised that the terms should also include advice on information to patients to support the PIL, within the regulatory framework, and how the current version of the PIL can be made available to patients. This was especially important where a PIL has been updated to provide new safety information. However, it was recognised that wider communications on new safety issues for a medicine were outside the remit of the Group, although the principles of risk communication were anticipated to be common.

It was agreed that revised terms of reference incorporating the requested changes would be circulated to members for agreement after the meeting.

Proposed Workplan of the Group

- 4.2 The Group agreed that the meeting with patient groups should be separated from the business of the May meeting. Members advised that this meeting would require careful planning and linking to a communications plan to ensure that relevant patient groups are made aware of the Group's work and that they have adequate time to prepare and contribute to the work of the Group. Consideration should be given to encouraging attendance from organisations representing the perspective of young people and children. Information about the Group and minutes of meetings will be made available on the CSM website and MHRA will look to issue press releases as appropriate occasions arise to further publicise the Group's work.

Members questioned the inclusion of the draft PIL for Zocor Heart Pro in the Agenda. Information to patients when a product first becomes available OTC following a reclassification was considered to be an important aspect of the Group's remit to advise MHRA on key cases.

- 4.3 The Group advised that the workplan should be refined to provide a longer term perspective and to specifically address how the terms of reference will be fulfilled. It was agreed that the workplan would be recast to address the issues raised and circulated to members for comment.

5. Risk communication

- 5.1 MHRA summarised the findings of a review of the literature of risk communication (Paper 02/03). Members of the Group advised that the evidence to date on the benefits of pictorial representations of risk for elderly people was mixed.

A newspaper article on communicating uncertainty was drawn to the attention of members at the request of Patricia Wilkie (Tabled paper IV).

5.2 **Dr Peter Bennett** of the Department of Health presented a review of the individuality of responses to risk and factors affecting the interpretation of risk information (Tabled paper II). **Professor Dianne Berry** presented an overview of communication of risk in the PIL and pointers for good practice (Tabled paper V). In response to questions, Prof. Berry advised that there was little evidence available on how risks interact where patients are on multiple medications. There was limited evidence on communication of risks to adolescents but very little on younger children. Age had been shown not to be an independent factor for risk evaluation. All individuals vary in their understanding of risk and interpretation of the seriousness of a risk is linked to personal values and individual assessment of the personal impact of the event. Training for health professionals in risk communication would help the patient: prescriber interaction. Much of this benefit could be derived from general training on communication but there were also issues specific to risk.

5.3 MHRA introduced the discussion of factors affecting good communication of risk under five headings (Paper 02/03A). The advice provided would feed into the development of models of good communication for evaluation with patient groups and then into UK guidelines, which could then be put forward for consideration at a European level.

(i) General aspects of risk perception:

5.4 The Group advised that trust in the source of information was important. Kitemarking was one way of achieving this, though if this undermined plurality it could be counter-productive. “Generic” information on classes of medicine may be considered more trustworthy than company PILs for individual medicines. The current NHS Direct Online “Information Partners” initiative, which kitemarks voluntary sector websites, may provide opportunities for building trust in patient information, since the NHS and voluntary organisations are both trusted sources. It was recognised that PILs needed to be available to support treatment discussions between the prescriber and the medicine user (NPSA had evidence that the availability of information at the time of consultation in secondary care provided a significant benefit) and that, although this is already possible via the Electronic Medicines Compendium, prescribers may be reluctant to take the time to download them. Companies would find it helpful to be provided with information on where to access general guidance on good communication on health issues. On categorising risks in the PIL, e.g. according to the action required, the Group advised that any approach would need to be tested in patients.

(ii) Putting risks in the context of benefit

5.5 The Group agreed that it was critically important to include information in the PIL on the benefits of taking the medicine to allow patient to balance the risks against the potential benefits. Providing an explanation of the rationale for taking the medicine can help to increase adherence, in terms of both dose and length of time taken. For certain products this may also need also to include the risk of not taking a medicine for

the condition and the likelihood of the treatment failing to work (loss framing). Where a product is indicated for a number of complex conditions it may be necessary to refer to further sources since space in the PIL is limited.

(iii) Conveying statistical information and uncertainty

5.6 The Group advised that presentation of absolute numbers for probability, e.g. 1 in 100, was the most widely understood technique. A constant denominator should be used. Other methods such as Number Needed to Treat/Harm, comparative and community scales and logarithmic measures were much less widely understood. It is helpful to include the range of probability (95% confidence interval) where this is known. The provision of uncertain information was considered to be preferable to withholding the data but where the estimated range is very broad this may be difficult for patients to interpret. The impact of positive or negative framing should also be considered.

(iv) Use of language and literacy

5.7 The following points were made:

- **Graphics:** The Group advised that the use of graphics is not necessarily effective and the PIL may not be a good medium for pictorial representations because of the size and format.
- **Elderly:** The Group advised that the elderly are not a homogeneous group and that good practice in communication is applicable for all ages. Educational level is a much better predictor of understanding than age.
- **People with learning disabilities or mental illness or who are very young:** Thought needs to be given to how they can find the information and how easy it is for them to understand.
- **Carers:** Where the information is being read by a carer, the information is likely to be interpreted with added caution.
- **Standard terms:** The Group supported the development of a dictionary of commonly understood terms to use to describe medical conditions. The Plain English Campaign may also provide useful advice.
- **Headlines:** The Group advised that a section or box with the key ‘headline’ messages may be of benefit to patients but any approach would require validation. Information on the US practice of including key information in a black box should be evaluated. For long term users of a medicine, it is important to be able to identify where changes in the risk information have occurred.

(v) Further information sources

5.8 The Group supported the development of supplementary guidance material outside the PIL to aid patients in understanding the risk information in the PIL. The Group urged that the current prohibition emanating from the European Commission on including website addresses in the PIL should be reviewed.

Prioritisation of work

- 5.9 The Group advised that there should be a stocktake of the available evidence to define those issues where there was already good evidence and which would not require further work. Work could then be concentrated on the remaining areas.
- 5.10 Putting risks in the context of benefits was identified as the first key priority and there was also support for the use of simple language with a standard dictionary of terms and for supporting materials on understanding risk and generic information on medicines. The MHRA would now develop proposals further. Any additional suggestions should be sent to the Secretary.

6. The life cycle of a PIL

MHRA summarised the stages in the development of a PIL by the company and the review procedures of the Agency (Tabled paper III). The contributions of Paul Woods and Helen Darracott to the paper were acknowledged. The group considered that this provided helpful insight and a pointer to opportunities for intervention.

7. European legislative changes

MHRA summarised the outcome of the negotiations on changes to the European medicines legislation as they affect PILs (Paper 02/05). Interpretation was not yet available on how changes, such as the facility to request Braille versions, would be applied. The Group agreed that the changes affecting PILs may be appropriate for translation into UK law earlier than the expected implementation date in late 2005. The importance and urgency of introducing appropriate use of user testing was emphasised. The Group agreed to discuss the issues in more detail at the May meeting. MHRA also summarised the current status of discussions between the EMEA and European patient organisations and their recommendation on product information (Paper 02/05A) and the Group asked to be kept informed.

8. Safe disposal of medicines

MHRA summarised a proposal for a statement on disposal of medicines in the PIL, and the issues involved (Paper 02/06). NPSA welcomed any initiative to remove unwanted medicines from the home for safe disposal to reduce the chances of accidents. The Group recognised that all disposal methods had environmental implications. The Group advised that the inclusion of information on disposal in the PIL should be supported. This would require further discussions with other stakeholders such as pharmacists, and other options such as information on the packaging or a dispensing label should not be ruled out. The wording to be used in any statement would require careful consideration and may also include a reference to out of date medicines.

9. Casework example - Zocor

- 9.1 Two members, Professor Alison Blenkinsopp and Dr Nicola Gray, had declared personal specific interests in J&J:MSD and left the room.
- 9.2 MHRA requested the views of the Group on the draft PIL for Zocor Heart Pro (Paper 02/07), recognising that no decision had been made on the reclassification application and that changes may be required as a result of the consultation should it be approved. The Group advised that the repetition of Zocor Heart Pro through the leaflet appeared promotional and that the presentation of information on side effects should be rethought since this was not all located in one place and included no numerical estimates of risk.
- 9.3 It was agreed that in order to elicit general principles and provide specific advice on important cases, more time would be required for discussion of future casework.

10. Meeting dates for 2004

MHRA drew attention to the list of diary dates for 2004 (Paper 02/08) and advised that meetings were planned in May and September. The additional dates provide flexibility. One of these dates would be allocated for the patient group meeting and other proposals may arise following further consideration of the workplan.

12. Any other business

There was none and the Chair thanked the members for their helpful contributions.

12. The next meeting would be held on Thursday 13 May 2004.

**Post Licensing Division
February 2004**