

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

**MINUTES OF THE THIRD MEETING – Thursday 13 May 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  
Mrs Helen Darracott  
Ms Katherine Darton  
Mr David Dickinson  
Dr Nicola Gray  
Dr Rosemary Leonard  
Mr Dinesh Mehta  
Professor Theo Raynor  
Lady Carolyn Roberts  
Mr Paul Woods

**MHRA**

Dr June Raine  
Miss Shirley Norton  
Mrs Jan MacDonald  
Dr Sue Harris  
Dr Jane Moseley  
Mrs Beryl Keeley  
Dr Julia Coombes  
Dr Rafe Suvarna

**Observer**

Dr Peter Carroll (from item 5)

**1. Apologies and announcements**

Katherine Darton from MIND was welcomed to the group in place of Sophie Corlett. Apologies had been received from Jackie Glatter, Wendy Harris, Jennifer Hunt, Kristin McCarthy, Eileen Neilson, Joanne Shaw 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.

The Chair also informed members that Dr Peter Carroll, Medicines Guide Project leader, had been invited to attend for the item on Risk Communication to facilitate liaison between the Working Group and the Medicines Information Project.

**2. Minutes of second meeting on Monday 9 February**

The minutes were agreed as a true record subject to the following amendments:

- The word ‘raised’ was replaced by ‘questioned’ in the sentence in Section 4.2: “Members questioned the inclusion of the draft PIL for Zocor Heart Pro in the Agenda.”
- An additional sentence “Some members expressed the desire for a wider remit.” was inserted after the first sentence in Section 4.1.

### **3. Matters arising from the minutes**

It was agreed that future minutes would use the formula “the Group advised” only in reference to a majority view.

#### **3.1 Item 9 - Casework example - Zocor**

Two members, Professor Alison Blenkinsopp and Dr Nicola Gray, declared personal specific interests in J&J:MSD and left the room.

MHRA informed the Group that an announcement had been made the day before that Zocor Heart-Pro would be made available over the counter through pharmacies. The Agency had taken the views of the Group into account in assessing the PIL and would bring the final version to the Group for information. The manufacturer had worked with wider interests including heart charities in developing the PIL and further patient testing was not envisaged at this stage.

### **4. Minutes of risk subgroup meeting on 5 April 2004**

The chair reminded members that this meeting had been arranged after the February meeting to obtain advice on risk communication from selected members of the Group at an interim stage in advance of presenting proposals to this meeting. All members had been circulated with the papers for this meeting and all contributions taken into account at the meeting.

The minutes of this meeting were agreed by those who had been present as a true record.

Members of the Group commented on the subgroup minutes:

- that the NHS/DH Expert Patient Programme might be another useful resource for consultation
- on the need to initiate consultation with industry on the proposals
- on the need for careful wording in the PIL to reflect statements in the SPC on areas such as use in children and pregnancy to avoid alarm.

### **5. Agreement of revised terms of reference and workplan**

MHRA introduced Paper 03/03 setting out the revised terms of reference and the proposed initial workplan for the Group.

#### **5.1 Terms of reference**

The Group agreed to the proposed change to the terms of reference to recognise the issues of access to current information identified at the second meeting. They also agreed to amend the second term to include “safe and appropriate” use of medicines.

Helen Barnett reported on the discussion at the recent CSM *en college* meeting which considered the work of the Working Group. CSM considered it important that expertise of the Working Group in patient communication should be used as a resource for other initiatives including the Working Group on Direct Patient Reporting (DPR) and the Paediatric Initiative. The Group should also build close liaison with the proposed Agency Communications Directorate. The Group agreed that a new term should be added to reflect the requirement for liaison and co-operation with other relevant CSM Working Groups.

MHRA advised that the focus for the Group's initial work should be on improvements to the PIL. However, this would not preclude involvement in wider activities at a later time. In the interim, liaison with the DPR Group would be promoted through common membership (Helen Barnett, Alison Blenkinsopp and Patricia Wilkie) and specific requests to the Group for advice on patient materials.

The revised terms of reference were accepted. It was agreed that they would be reviewed again at the end of the first year's work. The Group's recommendations for its future work and terms of reference would then be included in each Annual Report to CSM.

## **5.2 Proposed Workplan of the Group**

The Group agreed that the workplan should include joint work with the DPR Group on materials for patient reporting to make best use of the Working Group's expertise in communication with patients. Specific comments on the workplan included replacement of "VI" with 'people with sight loss' and review of the use of the words 'patient' and 'user' to ensure inclusivity of language. The revised workplan would be circulated to members for comment before being sent to the Chair for final approval and then placed on the MHRA/CSM website.

## **6. Risk communication**

MHRA introduced discussion of the papers on risk communication (Paper 03/03). The proposals had been refined following the Subgroup meeting in April.

### **6.1 Headline section**

The Group considered that the section was generally helpful and welcomed the inclusion of the indication as the first bullet point. MHRA confirmed their view that this is permissible under current legislation. The Group advised that, after the planned consultation with patients, medicines where a problem had been identified should be prioritised, followed by a general roll out if the change was well received.

Following a discussion about what constitutes "benefit" of a medicine, it was generally accepted that "benefit" should be used in the context of what the medicine does, rather than how effective it is.

The Group advised that particular care is required on pregnancy statements since an absence of data should not be translated as an instruction not to use the product. This also applied to 'off-label' use in children.

Additional suggestions were made by Group members:

- An encouragement on the package to read the PIL would be useful
- On the format, the guidance should not be prescriptive but allow companies to innovate, subject to user/patient testing.
- The headlines should be consistent with the SPC and BNF advice
- Consistency across all generic products should be encouraged.
- Where relevant the statements should be consistent with any label warnings.
- Inclusion of information on recent safety changes to the PIL could also benefit patients, so long as the date of latest revision was clearly stated.
- If PILs become more widely recognised by health professionals as of value then, if they were available at the time of consultation, it might also be possible to encourage prescribers to discuss the PIL with the patient.
- Designers should be consulted for advice on the effective use of highlighting and boxes to draw attention to particular items

Patient views would be sought at the proposed meeting in July. It was pointed out that industry was already considering suggested that it would be helpful to consult industry at an early stage. This applied to all the proposals and Paul Woods and Helen Darracott agreed to take this forward. It was suggested that companies might prefer an index-based summary as an alternative to this proposal.

## **6.2 Benefit information**

The Group welcomed the revised proposals and advised that the guidance should be clear as to the type of information to be included in this section.

Further points made in discussion were:

- A narrow definition should focus on the key benefits to be observed.
- Since not all patients benefit from a medicine, the statement should clearly relate to the indication, although it may also be helpful to include details of potential lifestyle changes affecting a condition and an indication of when the effects may first be felt.
- This would also allow the section to be more succinct, desirable because the published evidence indicates that 60 words is of benefit.
- A short statement based on the action of the medicine was considered less likely to be promotional since it would be based on the SPC and reviewed by MHRA.
- The inclusion of medical terms could be beneficial for patient education.
- Use of the brand name may be beneficial if it is not excessive and changing between brand and generic names may be confusing to patients.

## **6.3 Statistics**

The Group welcomed the revised proposals. Previous advice had indicated that a mix of ways of expressing information was not helpful and the Group considered that other

options such as the use of a constant numerator or a denominator less than 10,000 could be tested at the patient meeting.

Conveying uncertainty without causing undue alarm was recognised to be a challenge. The Group was advised that describing a factor as “unknown” may cause alarm and should be avoided.

The MHRA also invited views from the Group on what to do if the SPC did not include the type of statistical information required to provide this information in the PIL.

#### **6.4 Dictionary**

The Agency reported that the collection of examples of terms to form the core of a list of accessible terms was ongoing. An Australian list of translated terms had also been provided and this would be reviewed for suitability.

The Group advised that it would be important not to lose precision in the translation and that where appropriate, an indication of the severity of the effect should also be conveyed. In the context of treatment for a condition, patients may have become familiar with the medical terms used and this should be recognised.

Testing by potential users would be important and the use of accessible terms would need to be set in the context of improvements to the readability of information in the whole PIL.

#### **6.5 Supporting information**

The MHRA explained that the proposed material could be provided in a variety of ways including on the web, and in pharmacies and doctors’ surgeries. A core list of Q&As had been identified and a list of issues raised in calls to NHS Direct would also be reviewed for suitable topics to incorporate, although most of these related to specific medicines.

The Group advised that this was a helpful initiative, though ambitious and challenging. It was important that the material addresses the questions that patients want answered in simple terms, and the patient groups could be asked about this at the meeting on 5<sup>th</sup> July. The scope may need to be broadened to support a balanced assessment of the risks and benefits of using medicines and how to use them safely and appropriately.

#### **6.6 Next steps**

MHRA thanked the Group for their advice which would allow the headline and benefit sections of the guidance to be taken forward. On statistics, the Group had indicated factors on which views would be sought at the July meeting. The dictionary would also be further developed for the patient meeting. A broad view would be taken in development of the supporting information although this could be added to at a later stage if necessary.

MHRA indicated that the papers would be revised to incorporate the comments of the Group and reformatted into a draft guideline and examples for the July patient meeting. The proposals would be circulated to the Group for comment in advance of this meeting.

**7. Plans for Patient Meeting**

The MHRA introduced Paper 03/05 setting out plans for the meeting with patient organisations on 5 July. The Group agreed the plans and encouraged the MHRA to proceed as quickly as possible to get invitations out. Careful drafting of the questions to be asked would be required and it was agreed that the material for discussion would be circulated to members for review prior to issue.

**8. Patient Information and European Developments**

MHRA introduced Paper 03/06 updating the Group on progress on the European review of medicines legislation and other European initiatives. Members were invited to provide contributions to a response to the EMEA consultation by 18 June. These would then be collated into a single response from the Group.

**9. Readability and User testing**

MHRA introduced Paper 03/07 and highlighted the late changes to the legislation to Section 59(3) and on harmonisation of the PIL. The European Commission has recognised the need for revision of the Readability Guideline and there would be opportunities for the Group to feed into the review process.

The Group agreed to the proposed work item on the readability guideline and user testing and that MHRA should convene a subgroup meeting in June to take this forward and prepare proposals for consideration by the full Group in September.

**10. Any other business**

Theo Raynor reported that he was leading a team who had won the tender to review the qualitative and quantitative research into the effectiveness of medicines information. This was a 12 month project with a report due next Summer. He offered to circulate the report to the Group when it was available.

MHRA agreed to circulate the paper that went to CSM *en college* meeting on the work of the Group to members.

The Chair thanked the members for their helpful contributions.

**The next meeting would be held on Monday 13 September 2004.**

**Post Licensing Division  
May 2004**