

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

**MINUTES OF THE FOURTH MEETING – Monday 13 September 2004
10.30 am at Market Towers**

Working Group

Ms Melinda Letts (Chair)
Ms Helen Barnett
Dr Keith Beard
Professor Dianne Berry
Mrs Helen Darracott
Ms Katherine Darton
Mr David Dickinson
Ms Jackie Glatter
Ms Wendy Harris
Professor Jennifer Hunt
Mr Dinesh Mehta
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 Rafe Suvarna
Mrs Beryl Keeley (Secretary)
Dr Julia Coombes

1. Apologies and announcements

Apologies had been received from Nicola Gray, Rosemary Leonard, 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 third meeting on Thursday 13 May

The minutes were agreed as a true record (Paper 04/01).

3. Matters arising from the minutes

3.1 Update on implementation

MHRA introduced Paper 04/02 updating the Group on the proposals for early implementation of changes to European legislation as they affect patient information. The Group was invited to provide a response to the public consultation on this (MLX

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309). The Group agreed that early implementation was in the interests of patients and should be supported. It was recognised that the possibility of subsequent further changes to meet European requirements might present problems for companies. While the Group did not wish companies to face unreasonable difficulties, and wished to be apprised by MHRA should such problems arise, the interests of patients were agreed to be paramount.

Members expressed concerns that the timescale was tight and might, if ethics committee approval were required for the use of NHS patients in testing, not be achievable.

- 3.2 MHRA also reported that the EMEA/Patient Organisation working group was currently reviewing the responses to the consultation on their proposals with a view to finalising them for a workshop with stakeholders, to be held in December 2004.

4. Minutes of UTR subgroup meeting on 14 June 2004

This meeting had been arranged after the May meeting to obtain advice from selected members of the Group on user testing and readability at an interim stage in advance of presenting proposals to this meeting. All members had been circulated with the papers for the meeting and invited to contribute.

The minutes of this meeting were agreed by those who had been present as a true record (Paper 04/03).

4.1 User testing guidance

MHRA presented the draft guidance document on user testing that had been developed following the subgroup meeting and circulated to subgroup members for comment (Paper 04/04). Detailed guidance was required because there had been little experience to date on user testing in the UK. Once the guidance was agreed by the Group, this would be put out for consultation as envisaged in MLX 309. Comments were requested from members in the next two weeks.

Members of the Group commented that the guidance should not be overly prescriptive, though important principles such as inclusion of disadvantaged groups should be set out, and that care was needed to allow freedom for the market in user testing to develop. Early review of the guideline was recommended to incorporate learning from practical use.

4.2 Revision of the Readability Guideline

MHRA introduced Paper 04/05 setting out an outline for a proposed new guideline on the patient information leaflet. This would be developed over the next few weeks by the MHRA and there would be opportunities for members to advise during drafting, possibly at a further subgroup meeting. This would then feed into the European review of the Readability Guideline. Members supported this proposal and agreed on the importance of new guidance. Some comments on the outline were offered and written comments were requested in the next two weeks.

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5. Minutes of patient meeting on 5 July 2004

A brief report was given on this meeting. About twenty representatives of patient and voluntary organisations and carers had attended this meeting and provided views on patient information leaflets and the Group's proposals on risk communication. A further session had looked at direct patient reporting of suspected adverse reactions to medicines. The minutes of the meeting had been circulated to members and these were noted (Paper 04/06). It was noted that the prohibition on website addresses in PILs had also been raised as an issue by participants. It was agreed that this point, and a note on who was present and how they had been invited, would be added to the minutes and that they would be sent to attendees. It was further agreed that a summary would be placed on the MHRA website, including a contextual note about the experimental nature of the meeting and a note about how participants' input would be used.

5.1 Risk communication

MHRA introduced paper 04/07 setting out the changes made to the draft guidance on risk communication and the leaflet on side effects following feedback received from those invited to the patient meeting. Final comments on the guideline were requested in the next two weeks. This would then be finalised for inclusion in the report to CSM and then for consultation on implementation.

Possibilities for testing the directory of terms with patient groups and measures to ensure consistency with NHS Direct and the Medicines Information Project were being investigated. The directory would be appended to the guideline when finalised.

MHRA explained that the explanatory leaflet had been reformatted in a second version without the questions in response to a request at the patient meeting. It was hoped that the leaflet could be available for Ask About Medicines Week in November. Further testing would be investigated and it may be possible to seek feedback via the AAMW website. Members were asked to provide any further comments within two weeks.

5.2 Patient reporting

MHRA reported that CSM had established a Working Group, largely consisting of lay and patient representatives. Their first meeting would be on 21 September 2004. Membership and minutes of meetings would be made available on the MHRA website. The Patient Information Working Group would be involved in the communications aspects of the work of the new Group. NPSA advised that co-ordination with NPSA's work on patient reporting of adverse incidents may be beneficial and this would be considered.

6. Accessibility

MHRA introduced discussion of the third major item identified as a priority for the Group, emphasising that the topic was the accessibility of content not access to

leaflets. The topics chosen would stimulate thinking and link to work on the proposed White Paper on the disadvantaged in health care. The key issues for the discussion to identify were:

- whether or not the topics were the right ones,
- what the key problems are, and
- to begin to identify options that would make a difference for patients.

Information on paediatric medicines was an important part of this discussion but, in the absence of Nicola Gray, this would be deferred.

6.1 Sight loss

Theo Raynor introduced the subject of information for people with sight loss. He advised that they are not a homogeneous group and that a range of answers was required to meet their needs. Fewer than 5% read Braille so this was only a partial solution; large print versions of PILs could also help, although with good design many people with some sight loss can use ordinary information sources. Internet solutions could help if designed with sight loss in mind so that voice synthesis and size adjustment software can be used.

Theo reported that he was involved in a joint project with the RNIB funded by the National Lottery Charities Board to investigate how those with sight loss want their information needs met. The results would be available in the next 6 months. They had found that older people with sight loss are often very vulnerable.

Directive 2004/27 included two changes aimed at helping people with sight loss: the name in Braille on the pack and a requirement that the MA holder should make alternative formats of the PIL available. Proposals on this from the RNIB had been tabled (Tabled Paper I).

Members of the group made the following points:

- Elderly people with sight loss often have multiple conditions. They are a high risk group and often not computer literate. Large print would be a good starting point for this group.
- Other ways of making information available include CD, tape and phone lines.
- The PIL is not available at the time of prescription or readily accessible when the medicine is dispensed. However, the PIL and medicine guides are available on the electronic Medicines Compendium.
- NHS Direct may have a role in interpreting the PIL to this group. Digital TV may also be an option. Computer options are not a panacea but do offer opportunities for the future.
- Standards are required for large print PILs and tapes with sophisticated indexing should be available.

Helen Darracott offered to provide information on what industry is already doing for this group of people.

6.2 Other languages

Theo Raynor introduced this topic. For those who have English as a second language, helpful options are to use plain English for the PIL and to provide it in additional languages. One option would be to provide telephone support using a translation service. There may again be a role for NHS Direct in providing this. Pictorial representations were subject to limitations because they could not be comprehensive and had to be accompanied by verbal information to be understood and they were culturally sensitive.

Members of the Group made the following points:

- Any translated leaflets should be based on the UK version and the quality of translation checked.
- Some languages do not have a written form (eg Sylheti).
- Language Line provides a simultaneous translation service.
- British Sign Language should be considered for inclusion, as some people who use this do not read English.
- Simple translation is not enough; cultural differences need also to be considered.
- It may be useful to link into DH research on providing health information via digital TV.

6.3 People with reading/learning difficulties

Carolyn Roberts introduced this topic. Educational level had been shown to be closely associated with treatment compliance. A significant proportion of people of all ages have low literacy or numeracy and this may mean that they are unable to understand the PIL and how to take their medicine safely. Numeracy problems may also compromise understanding of dosage instructions. User testing protocols did not address the needs of this group as it referred to “90% of literate adults”.

Members of the Group made the following points:

- People with reading and learning difficulties are two different populations.
- Links to other initiatives such as SureStart, Health Cities and People First may help to promote health literacy.
- The accessibility topic includes an enormous variety of needs, and a universal PIL interpretation helpline might be a good idea, rather than a proliferation of different versions of each PIL.

6.3 Carers

Wendy Harris introduced this topic. Carers included both formal carers such as care staff and also informal carers such as family and friends. Any of the groups previously considered could include people with caring responsibilities, so there was overlap, but two needs specific to carers were identified:

- A carer would probably not have participated in the consultation where a medicine was prescribed. Important information provided at the consultation when the medicine was prescribed and when it was dispensed may not have been shared with the carer who may also not have received the PIL.
- Carers need training on administration techniques. Particular issues identified were off label use where the PIL may not cover the information needed, what to do if the patient refuses the medication and how to dispose of surplus medicines.

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Most information needs are similar to those of other groups but it would be useful to take advice from a carer organisation such as Carers UK or the Princess Royal Trust for Carers on additional needs. It was recognised that many of the issues raised were outside the power of the Group to resolve.

- 6.4 MHRA thanked the Group for the very helpful advice provided and encouraged members to provide any further thoughts. The legislation does not preclude additional leaflets where these could be of benefit, such as a leaflet for carers, and the need for additional statements in the PIL to alert users to other sources of information would be considered further.

7. **Delivery of PILs**

MHRA introduced Paper 04/08 informing the Group of progress to date on issues relating to the delivery of PILs. This would be discussed in more detail at the next meeting.

Members raised the following points:

- Research findings were reported from a study that showed that 16% of medicines dispensed in two pharmacies were not accompanied by a PIL.
- Any future recommendations would need to take account of dispensing using monitored dosage systems.
- The needs of patients in hospital for PILs should be considered. MHRA advised that some hospitals provided information to patients on the availability of leaflets and how to access them.

8. **First annual report to CSM**

MHRA introduced Paper 04/09 setting out the draft outline of a report to CSM. This would be an opportunity to capture the value of the Group's work to date and an Executive Summary would be included to identify the key messages. Initially the report would inform the CSM and subsequently Ministers of the Group's work to date. Publication would then provide an opportunity to inform a much wider audience.

9. **Forward look**

MHRA introduced Paper 04/10 updating the Group on Ask About Medicines Week 2004 (1-6 November), a proposed user testing seminar and the review of the Agency's advisory committee structure.

10. **Case studies**

One member, David Dickinson, had declared a personal specific interest in GSK and left the room for this item.

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MHRA introduced Paper 04/11 inviting the views of members on two patient information leaflets for important products with public health implications.

On the Seroxat PIL, members provided the following advice:

- Phrases such as “the doctor will decide” and “go back to the doctor and ask what to do” should be revised in favour of phraseology such as the doctor will “advise” and “discuss what to do”.
- The pregnancy and breastfeeding information should be redrafted and made more prominent
- The headline section was not as envisaged in the Group’s guidance and should be reviewed.
- Generally the leaflet was confusing, with important points left without instructions on what to do.

On the Isotretinoin PIL, members advised:

- It would be helpful to provide phonetic advice on pronunciation (this is done in US leaflets).
- The box on page 14-15 includes duplication – it should be short, sharp and focussed.
- The advice on alcohol needs to be practical; for example, it is not clear if it relates to one glass or several. Alcoholics may not recognise their condition.
- If pregnancy is critical the reason for this should be clearly explained at the first mention. It should be in the headline section.
- Side effects were not presented in a logical order. The section was also confusing because some were presented with actions and some without.

Members were requested to send in any further detailed comments by email in the next two weeks.

11. Any other business

The final version of the PIL for Zocor HeartPro, reviewed at a previous meeting of the Group, was tabled for information.

The Secretariat agreed to circulate proposed dates for meetings in 2005.

The Chair thanked the members for their helpful contributions.

The next meeting would be held on Monday 8 November 2004.

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