

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

**Minutes of the meeting held on Tuesday 27 September 2005 in the MHRA Board Room,  
Market Towers**

**Working Group**

Dr Patricia Wilkie (Chair)  
Ms Helen Barnett  
Dr Robin Ferner  
Professor Ian Jack  
Mrs Carole Myer  
Mrs Madeleine Wang  
Dr Charlotte Williamson  
Mrs Barbara Wood

**MHRA**

Professor Kent Woods (items 1-3)  
Mr Jeremy Mean  
Mr Shaun Fiddes  
Ms Kavita Chadda  
Mr Stephen Fawbert  
Mr Andrew Black (Secretary)

**1. Apologies, announcements and introductions**

Apologies had been received from Prof Alison Blenkinsopp, Prof Phil Routledge and Mrs Barbara Greggains.

The Chairman 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 Working Group welcomed Professor Kent Woods, the MHRA Chief Executive, who emphasised the importance of patient reporting for enhancing medicines safety monitoring and for involving patients and members of the public in medicines safety regulation.

In discussion, Professor Woods confirmed that the MHRA was committed to ensuring the pilots were effectively evaluated. Health Ministers had committed the Government to piloting different patient reporting mechanisms to gauge effectiveness, and evaluation was essential to that process. Professor Woods stressed that the Department of Health had well established mechanism for bidding, prioritising and allocating resources for research, and he expected this mechanism to be used for the evaluation of the patient reporting pilots.

Professor Woods thanked the members of the Working Group for making an important contribution to the development of patient reporting, and thanked Dr Wilkie for her leadership.

**2. Minutes from meeting held on Monday 18 July 2005**

The minutes were agreed as a true record, subject to amendment of paragraphs 5.1, 6.1, 7.1 and 8.1.

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

All matters arising were included as agenda items.

### **4. Consideration of proposal for research project to compare patient and health professional reporting**

Dr Robin Ferner introduced a Paper on his proposal to conduct a comparative study between Yellow Card reports on the same suspected ADR completed by patients and health professionals, using patient and healthcare professional reporting forms respectively. The group thanked Dr Ferner for his proposal and agreed to endorse the proposal as a recommendation for the CSM and the MHRA to consider. The group proposed a change of wording so that the study made reference to "encouraging" patients to report, rather than "allowing."

### **5. Update on initial patient reporting pilots.**

The Group noted the monthly overview of progress with initial patient reporting pilots. The Group considered the issue of "black triangle" medicines, and how prescribers would be aware when the status changed. The Working Group advised the MHRA to give consideration to the matter of communicating with patients about the black triangle scheme.

### **6. Overview of agenda item for CSM on 29 September 2005**

The Group considered an overview of the paper on the main patient reporting pilot to be considered at the CSM on 29 September 2005. The Chairman was to provide CSM with an overview of the development of patient reporting, and ask the CSM to endorse the proposed patient Yellow Card form. The Working Group was keen to ensure that the CSM had sight of the Working Group's recommendations for evaluation of patient reporting pilots. MHRA apologised that the paper for the CSM on patient reporting had not been circulated to all members of the Working Group and committed to distribute the paper following the meeting.

### **7. Reporting of suspected ADRs in children and young people**

Mrs Myer introduced a paper for discussion on reporting of suspected ADRs experienced by children. The Group concluded that the development of a separate Yellow Card form for children was unnecessary if the new patient Yellow Card was promoted to children, young people and their parents or carers. The Working Group agreed that a specific pilot aimed at promoting the Yellow Card Scheme amongst children would be advantageous. The MHRA suggested that the CSM's Paediatric Working Group might be best placed to advise on how children's experiences of suspected ADRs might be best captured.

**8. Plans for launch of main pilots on 25 October**

MHRA presented proposals for the launch of the UK-wide patient reporting pilot on 25 October 2005. The Working Group made suggestions on invitees and the draft programme for the event. It was agreed that further comments from Working Group members regarding the launch would be sent by email to the MHRA.

**9. Sign off of the patient Yellow Card form**

The Working Group proposed small amendments to the proposed patient Yellow Card form, mainly in the "protecting personal information" section. The Working Group agreed that with the inclusion of the small amendments, the form was in a finalised state to provide to CSM for consideration.

**10. Consideration of telephone reporting protocol.**

The Working Group noted the proposed telephone reporting protocol, and emphasised their advice that the MHRA staff who would be taking calls should be properly trained.

**11. Acknowledgement letter and leaflet**

The Working Group undertook to provide any comments to MHRA by email on the proposed acknowledgement letter and accompanying leaflet for people who complete a Yellow Card report.

**12. Any other business**

The MHRA informed the Working Group that the Commission on Human Medicines (CHM) would have a different structure of advisory working groups and sub-committees, and this structure would be determined by the CHM itself as one of its first tasks. The MHRA would recommend to CHM that advisory arrangements will need to be in place to ensure that the important work commenced by the CSM Working Group on Patient Reporting would continue under the CHM.

Appointments to newly created CHM working groups and advisory committees would be made via the independent NHS Appointments Commission. Any members of the Working Group who wished to be considered for appointment to the CHM, or to any of its working groups or advisory committees were encouraged to submit an application before 30 September 2005.