

**COMMITTEE ON SAFETY OF MEDICINE**

**PATIENT REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS  
WORKING GROUP**

Minutes of the meeting held at 11am on Monday, 18 July 2005 in Room CR1, 19th Floor,  
Market Towers.

**Present:**

Dr Patricia Wilkie (Chair)  
Ms Helen Barnett  
Professor Alison Blenkinsopp  
Mrs Barbara Greggains  
Dr Ian Jack  
Mrs Carole Myer  
Professor Phil Routledge  
Mrs Madeleine Wang  
Mrs Barbara Wood

Dr June Raine  
Mr Shaun Fiddes  
Mrs Kavita Chadda  
Mrs Shelly Gandhi  
Dr Suzie Ekins-Daukes  
Mr Stephen Fawbert  
Mr Andrew Black (Secretary)

**Apologies:**

Dr Robin Ferner  
Dr Charlotte Williamson

## **1. Apologies and announcements**

1.1 Apologies were received from Dr Robin Ferner and Dr Charlotte Williamson

## **2. Minutes from previous meeting on Tuesday, 28 June 2005**

2.1 The minutes of the Working Group meeting held on Tuesday, 28 June 2005 were agreed in principle, subject to amendment of paragraph 7.2.

## **3. Matters arising from minutes of meeting on Monday, 16 May 2005**

3.1 *Item 5.3:* The Chairman asked Group members to forward specific ideas for pilots to the MHRA.

## **4. Presentation: Professor Munir Pirmohamed on “Adverse Drug Reactions in Hospitals”**

4.1 Professor Pirmohamed (Professor of Clinical Pharmacology at Liverpool University, member of CSM and Head of the Mersey Regional Monitoring Centre) provided the Group with a presentation on research into adverse drug reactions in hospitals, and suggested that on the basis of his study, some 6.5 per cent of the hospital admissions in Liverpool were related to ADRs during the study period. Professor Pirmohamed also provided recommendations on taking patient reporting forward for consideration.

## **5. Developing the patient Yellow Card form**

5.1 The Group discussed the design and content of the revised patient Yellow Card form, to be used for main patient reporting pilots. The Group considered that the term “complementary remedies” was preferred as more accurate than the term “alternative remedies”. The Group also recommended that more information on how the MHRA uses Yellow Card forms should be made available to patient reporters.

5.2 The Group indicated that it was content with the planned title of the new Yellow Card form – “A side effect from your medicine? Report it on this Yellow Card”, and suggested the title could change when public awareness of the scheme increased. The Group also advised that the Yellow Card website and telephone number should also appear on the cover.

5.3 The MHRA indicated it would investigate engaging a telephone-based language interpretation service to assist non-English speaking people to also make Yellow Card reports, via telephone. Professor Phil Routledge also undertook to informally discuss taking forward a patient Yellow Card form in Welsh Language with the Welsh Assembly.

## **6. Proposed framework for evaluation**

6.1 The Group considered a paper prepared by the Chairman which brought together ideas from Group members on developing a framework for evaluating patient reporting pilots. The Group agreed to create a sub-group to develop a coherent and comprehensive proposed framework for evaluation that could be presented to CSM for consideration in September.

6.2 The Group reiterated its advice that evaluation of patient reporting conducted independently of the MHRA/CSM was essential, and that sufficient resources should be made available. In any independent research, the Group suggested that MHRA should have a role to play in monitoring research to ensure that it is delivered according to agreed specifications. The Group were also keen that evaluation should ultimately lead to the production of papers for publication.

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

7.1 The Group noted the monthly overview of progress with initial patient reporting pilots. The Group discussed the classification of reports as “serious” and “non-serious”, and were advised by MHRA that reports are classified by the Agency against the same seriousness criteria as healthcare professional reports. The MHRA advised that the reason for classifying patient reports in the same way as healthcare professional reports was to enable meaningful comparison. The Group emphasised that the way patients classified the suspected ADR experiences (in terms of seriousness) might be different to the classification made by health professionals or the MHRA

## **8. Promoting patient reporting**

8.1 The Group proposed a range of different methods to promote patient reporting, including the use of posters in outlets that stock patient Yellow Cards, the use of advertising, feedback for people who complete reports and other promotional material and methods, including promotion through the media.

## **9. Patient reporting experience in Australia**

9.1 The Group received an overview from MHRA on the “Adverse Medicines Events Line”, the pilot system for patient reporting that is in place in Australia. The Group noted that different approach to patient reporting that has been taken in Australia, with the reporting system based around telephone reporting. The Group noted that formal evaluation of the Australian patient reporting pilot system will be published in the near future.

## **10. Evaluating initial patient reporting pilots**

10.1 MHRA provided an overview of responses to questionnaires completed by people who had reported suspected ADRs through the initial pilot. The outcomes of the questionnaire included details on how easy the initial pilot reporting form was to complete, and what reporting mechanisms people believed should be set-up in the future.

## **12 Any other business**

12.1 *Market research.* MHRA undertook to advise the Group on progress with market research at the next meeting.

**13. Date and Time of Next Meeting**

11.1 The Chair reminded the Group that the next meeting would take place on Tuesday, 27 September 2005 in the MHRA Board Room, 16th Floor, Market Towers.

**Post Licensing Division  
MHRA**

10 August 2005