

**COMMITTEE ON SAFETY OF MEDICINE**

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

Minutes of the meeting held at 11am on Monday, 16 May 2005 in the MHRA Board Room, 16th Floor, Market Towers.

## **1. Apologies and announcements**

1.1 Apologies were received from Professor Alison Blenkinsopp, Mrs Carole Myer and Mrs Madeleine Wang.

## **2. Minutes from previous meeting on Wednesday, 23 March 2005**

2.1 The minutes of the Working Group meeting held on Wednesday, 23 March 2005 were agreed as an accurate record.

## **3. Matters arising from minutes of meeting on Wednesday, 23 March 2005**

3.1 *Item 4.2:* The Group suggested that there was no reason for members of the public to have any awareness of the “black triangle scheme”, as the scheme had never been promoted more widely than to healthcare professionals.

3.2 *Item 3.4:* Mrs Barbara Wood undertook to update the BMA’s GP Committee on developments in patient reporting through the Yellow Card Scheme, and provide feedback to the Group.

3.3 *Item 3.3:* Dr Charlotte Williamson expressed concern at the delay by the Working Group Secretariat in despatching the paper provided on risk communication, as the paper was despatched with the routine Working Group mailing. Dr Williamson expressed that Group members would have found it useful to have received the paper at an earlier stage. In the future, the MHRA undertook to despatch material considered by Group members to be of an urgent nature in addition to routine mailings.

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

4.1 MHRA provided an overview of progress with initial patient reporting pilots, and noted that the number of patient reports received continues to be encouraging. The Group also noted the diversity of medicines on which patients have submitted reports, with some herbal remedies also reported.

4.2 The Chairman requested that statistics on patient reports be more clearly detailed on the CSM’s monthly pharmacovigilance statistics.

4.3 The Group asked for clarification on how patient reports would be used. MHRA advised that patient reports would be used in the same manner as healthcare professional reports with regard to processing reports onto the pharmacovigilance system and signal detection. Patient reports are given the same priority as healthcare professional reports and entered onto the pharmacovigilance system within set timeframes. On signal detection, MHRA advised that patient reports will be included in the current signal detection process alongside healthcare professional reports from end of June 2005. Individual reports are scanned and saved onto the pharmacovigilance database, to be available when specific medicines are assessed. The MHRA also advised that the developing MHRA IT systems will see the Agency’s capacity for signal generation enhanced. MHRA also explained that these new systems will enable MHRA to more effectively incorporate other information including published literature into the pharmacovigilance system.

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

5.1 The Group considered the draft version of the new patient Yellow Card reporting form, recently redesigned on the basis of the outcomes of user testing.

5.2 The Group noted the colloquial nature of the language of the form, and asked for justification of why this style of communication is recommended by COI. Advisors from COI will be asked to attend the next Group meeting. The Group also looked at the draft form in close detail, and provided feedback for redesigning the form.

## **6. Any other business**

6.1 Proposed agenda items on developing arrangements for pilots and proposed framework for the evaluation of pilots were deferred to the next meeting.

6.2 The Group noted the papers provided for information – “One year with ADR consumer reports” which provided an overview of the Danish experience of patient ADR reporting, and “Developing an assessment tool for evaluating community involvement”, a paper provided by Dr Charlotte Williamson.

## **7. Date and Time of Next Meeting**

7.1 The Chair reminded the Group that the next meeting will take place on Tuesday, 28 June 2005 in room CR1, 19th Floor, Market Towers.

**Post Licensing Division  
MHRA**

20 June 2005