

**COMMITTEE ON SAFETY OF MEDICINE**

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

Minutes of the meeting held at 11am on Wednesday, 23 March 2005 in room CR1, 19th Floor, Market Towers.

## **1. Apologies and announcements**

1.1 Apologies were received from Dr Robin Ferner, Mrs Barbara Greggains, Dr Ian Jack, Mrs Madeleine Wang and Mrs Barbara Wood.

1.2 The Chairman welcomed Professor Phil Routledge to his first meeting of the Group.

## **2. Minutes from previous meeting on 14 February 2005**

2.1 The minutes of the Working Group meeting held on Monday, 14 February 2005 were agreed as an accurate record.

## **3. Matters arising from minutes of meeting on 14 February 2005**

3.1 *Item 3.2:* The Group asked to see a copy of the proposed leaflet developed by the CSM's Patient Information Working Group on understanding risks and benefits of medicines, so they could provide suggestions. The MHRA undertook to provide a copy of the leaflet.

3.2 *Item 9:* The Group agreed that in order to ensure that all members were aware of members' perspectives when they provide comments via email, emails from members should ideally be copied to all Group members.

3.3 *Item 9:* Dr Charlotte Williamson undertook to provide the Group with a copy of information developed for patients on risk by the Royal College of Anaesthetists.

3.4 *Item 9.1(c):* The Group remarked that sending GPs a copy of a completed patient Yellow Card, where the patient asked for it to be sent, would potentially cause extra work for GPs. The Group noted that patients should have the option of providing their GP with details of a suspected ADR, and that the option should remain on the patient Yellow Card form. The MHRA undertook to discuss the implications of this with the RCGP, and the Chairman suggested that the Chairman of the RCGP should also be invited to address the Group. The Group noted that the GP remained at the centre of healthcare provision for most people, even with supplementary prescribing, and was the best person to receive a copy of a patient's Yellow Card report for inclusion on medical records if the patient wished for a copy to be sent.

3.5 The Group noted that links have been made with the National Programme for IT for inclusion of ADR reporting in new NHS IT systems.

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

4.1 MHRA provided an overview of progress with initial patient reporting pilots, and noted that the response continues to be encouraging.

4.2 The Group noted that the concept of black triangle drugs was not well understood by the public and recommended the MHRA consider further the use of the concept for patients, in order to promote patient reporting of suspected side effects associated with these medicines

4.3 The Group asked about how patient Yellow Card reports would be coded onto the ADROIT system. MHRA advised that all reports would be coded against the MedDRA dictionary, which is the standard terminology used by medicines regulators across the world, and the coding that was used by MHRA IT systems. MHRA also advised that there was a process for having the MedDRA dictionary updated if patient reporting highlighted any potential deficiencies. On the coding and processing of patient ADR reports, the MHRA undertook to communicate with other medicine regulators which accept patient reports, in order to understand how patient reports are processed and utilised.

4.4 The Group noted that many patient reports also list other medicines being taken concomitantly with a medicine that they suspected caused the ADR. The Group advised that for future reporting mechanisms, there needed to be adequate provision for patients to list other medicines being taken.

4.5 The Group also suggested that the new contract for community pharmacy presented opportunities to promote the reporting of ADRs, especially via the medicines use reviews and public health campaigns that will be run by pharmacists. The MHRA advised that discussions have been held with the Department of Health and NHS Strategic Health Authorities on the new community pharmacy contract, and would communicate in similar terms shortly with PCTs and the Devolved Administrations.

## **5. Presentation: MHRA Communications**

5.1 Mr Simon Gregor, the MHRA Director of Communications provided the Group with a presentation on the Agency's communications strategy, and noted that patient reporting via the Yellow Card Scheme was an important way to achieve genuine public involvement in the MHRA's work.

## **6. Developing publicity for pilots**

6.1 The Group discussed the importance of supporting upcoming patient reporting pilots with effective publicity and communication. The MHRA advised that a range of supporting publicity material, including posters and small cards would be designed and provided to the Group for consideration once the design of the patient Yellow Card form had been finalised, in order to produce a consistent design and message for supporting material.

6.2 The Group also discussed the value of utilising local and professional press for promotion. The Group recognised the importance of engaging with key stakeholders across the UK, including professional associations and PCTs (and equivalent bodies in Devolved Administrations) before the main pilots commenced.

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

7.1 The Group noted the progress that had been made in developing the new patient Yellow Card form. The Group agreed that once the form had been designed it should be user tested for usability, before submission to the Plain English Campaign, with a view to securing the "Crystal Mark". The Group noted that considering the nature of the information patients are asked to provide on the Yellow Card, the patient Yellow Card form should be designed to be easy to complete, but not be over simplified.

7.2 The Group also noted that the patient Yellow Card would also need to be made available in Welsh.

## **8. Developing arrangements for pilots**

8.1 The Group endorsed the plan to run a nation-wide “limited roll-out” main pilot to test the effectiveness of various reporting mechanisms, whilst running smaller pilots concurrently.

8.2 As previously agreed by the Group, the main pilots would consist of piloting reporting by paper form, the web and the telephone, in order to test the effectiveness of these reporting mechanisms. The reporting forms would be made available in a range of outlets (including community and hospital pharmacies), as well as other local outlets recommended by PCTs. Voluntary organisations would also be invited to stock reporting forms through the ACEVO network.

8.3 The telephone reporting service would be run by the MHRA’s enquiry team, utilising a freephone 0800 number. The web-based reporting form would continue to be located on the Yellow Card website, but would be amended to replicate the questions asked on the paper form.

8.4 The Group also suggested that smaller-scale pilots should also be run, and suggested that a specific pilot with a Mental Health Trust might be useful, as well as a pilot to facilitate reporting in languages other than English. Group members were asked to circulate specific proposals for smaller pilots amongst Group members for discussion at the next meeting.

8.5 The Group recommended that patient Yellow Card reporting forms should also be made available in Citizens Advice Bureaux, health food stores and supermarkets. Information on reporting suspected ADRs should also be included in the Thompson local telephone directory and in patient information leaflets that accompany medicines.

8.6 The Group discussed evaluation of pilots, and agreed that the core question to ask is how can patient reporting contribute to medicines safety regulation? The Group agreed that the main elements of evaluation should be the investigation of the pharmacovigilance and acceptability/accessibility aspects of patient Yellow Card reporting, and that evaluation should be academically supported, perhaps by an existing academic research department with experience in health care research from a social sciences perspective. The MHRA undertook to explore options and report back to the Group. Professor Alison Blenkinsopp undertook to provide the Group with a paper on proposals for evaluation for the next meeting.

8.7 The Group also discussed the potential impact that patient reporting of suspected ADRs would have on healthcare professionals. The MHRA undertook to communicate with the RCGP and RCN to discuss the matter further.

## **9. Any other business**

9.1 *Canadian public opinion survey on post-marketing surveillance.* The Group noted the outcomes of a public opinion survey conducted the Canadian health authorities on post-marketing surveillance of medicines.

9.2 *Market Research needs.* The Group considered a tabled paper from Mrs Barbara Greggains on the market research needs for informing patient reporting pilots. The Group agreed that market research could provide highly useful information, and asked the MHRA for clarification on whether such a study could be made available.

9.3 *April meeting.* The Group decided that the meeting planned for April should be replaced with a user testing session with patient representatives to develop the patient Yellow Card reporting form.

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

12.1 The Chair reminded the Group that the next meeting will take place on Monday, 16 May 2005 in the MHRA Board Room, 16th Floor, Market Towers.

**Post Licensing Division  
MHRA**

1 May 2005