

COMMITTEE ON SAFETY OF MEDICINE

PATIENT REPORTING WORKING GROUP

Minutes of the meeting held at 11am on Friday, 15 October 2004 at Market Towers,
London SW8 5NQ.

1. Apologies and announcements

1.1 Apologies were received from Ms Helen Barnett, Mrs Madeleine Wang and Mrs Barbara Wood.

2. Minutes from previous meeting on 21 September 2004

2.1 The minutes of the working group meeting held on Friday, 21 September 2004 were agreed.

3. Matters arising from minutes of meeting on 21 September 2004

3.1 *Item 2.3:* The MHRA reported that patient reporting was expected to be featured during 'Ask About Medicines Week' (AAMW). The Chairman will provide a report at the next Working Group meeting on coverage.

3.2 *Item 6.3:* MHRA undertook to re-circulate the list of the groups that participated in the MHRA's focus group with patient representatives on 5 July for information before the next meeting.

4. Discussion on current issues

4.1 The Group discussed the issues raised in the recent BBC 'Panorama' broadcast on SSRIs in light of the references made to direct patient reporting of suspected adverse drug reactions.

4.2 The importance of patient views on adverse reactions was underlined and it was noted that the direct patient reporting initiative was a recommendation made in the *Report of an Independent Review of Access to the Yellow Card Scheme*, published in May and immediately accepted by the Health Minister. The MHRA has a strong commitment to gaining the patient's perspective of their experiences of adverse drug reactions to better inform decisions made about medicines safety.

5. Proposed pre-pilot information gathering project for patient reporting

5.1 The Group considered a proposed pre-pilot information gathering project, aimed at:

- a. assisting with the development of patient reporting forms,
- b. gaining an understanding of the types of information that patients might give in relation to suspected ADRs (to ensure compatibility with current systems and databases),

- b. collecting information to inform the development of pilot patient reporting projects in 2005, to ensure the patient perspective is built into pilot studies from the outset.

5.2 The survey group would be the several hundred members of the public who have directly contacted the MHRA in the last year to report their experiences of suspected adverse drug reactions. People would be asked to choose from a selection of proposed patient reporting forms, and complete the form based on their experience. They would also be invited to complete a questionnaire about the form, and about how they would like to report drug reactions in the future. To safeguard privacy, people would be contacted first, and asked if they wish to be part of this study. People would also be provided with a copy of their initial correspondence.

5.3 The Group suggested that this exercise should also be run prospectively, so that people who write to the MHRA regarding drug reactions in the future are also invited to participate in the study.

5.4 On the testing of forms, the Group suggested that when designing the final patient reporting form to be used in the future, market/social researchers should be engaged to assist. This was flagged as a project for 2005.

5.5 The Group suggested that feedback was very important, and that people who took the time and effort to communicate should be provided with feedback on the outcomes of the exercise from the MHRA.

5.6 The Group agreed that the pre-pilot project be undertaken, and provided feedback on the design of the proposed forms to be used.

6. Anonymised case details of suspected ADR reports submitted by patients via NHS Direct

6.1 The Group considered the anonymised case details of suspected ADR reports submitted during the NHS Direct-based pilot project into patient reporting of suspected ADRs.

6.2 The Group noted that the quality of the reports generated by the pilot compared well with reports received via the Yellow Card reporting scheme.

6.3 The Group discussed the concept of “seriousness”, as the NHS Direct reports carry a seriousness indication. The Group discussed whether seriousness or severity should be included in patient reporting mechanisms.

7. How pilots should be run

7.1 The Group discussed how pilot studies could be run, in order to provide important information in the development of a reporting scheme that would be easy to use and to access, and provide meaningful information for improving medicines

safety. Engaging with and involving stakeholders (including patient and carer organisations) during pilots was seen by the Group as vital.

7.2 It was agreed that each member would consider preparing a half-page plan on recommended pilot projects for the next meeting.

8. International experience of patient reporting of suspected ADRs

8.1 MHRA provided a comprehensive compilation of literature on the international experience of patient reporting of suspected ADRs as background information. The Group noted that on the basis of international experience, there is no one system that can be seen to represent “best practice”, that the concept of direct patient reporting is still relatively new and that international experience and evaluation is quite limited.

8.2 The Group noted that in the Australian experience, “noise” created in drug safety monitoring systems that allow patients to report directly was not much greater than that created through systems that only allow medical professionals to report.

9. Publication of proceedings from Working Group

9.1 The Group agreed that the full minutes from Working Group meetings should be published.

9.2 A specific Patient Reporting of ADRs Working Group webpage was being created, and would be under the CSM website. Minutes from Working Group meetings would be published on the webpage. A specific email address would also be created to facilitate public communication with the group.

9.3 A short briefing note outlining the direct patient reporting of suspected ADRs initiative in overview would be prepared and circulated to Working Group members before the next meeting.

10. Future meetings

10.1 The Group agreed that meetings should be held on a monthly basis until June 2005, when the required meeting frequency would be reviewed.

10.2 MHRA would circulate proposed meeting dates for 2005 to Working Group members before the next Working Group meeting. When confirmed, these dates would be published on the Working Group webpage.

11. Any other business

11.1 The Group agreed that a second clinical pharmacologist should be appointed to the group. With the Chairman, MHRA will explore options.

11.2 For the next Working Group meeting, the Chairman proposed that Dr Andrew Herxheimer be invited to present the findings of his research into patient reporting of ADRs, and make recommendations on taking the initiative forward. The Group also expressed desire to invite a representative from the devices side of MHRA to address the Working Group on patient reporting systems for medical devices. As the NPSA are also looking to implement a system of direct patient reporting of adverse incidents, the Group also expressed their desire to learn more about the NPSA's plans.

11.3 The Chairman advised that the next Working Group meeting would be held at Market Towers on Tuesday, 16 November 2004.

**Post Licensing Division
MHRA**

26 October 2004