

COMMITTEE ON SAFETY OF MEDICINE

PATIENT REPORTING OF SUSPECTED ADVERSE DRUG REACTIONS WORKING GROUP

Minutes of the meeting held at 11am on Tuesday, 28 June 2005 in Room CR1, 19th Floor, Market Towers.

Present:

Dr Patricia Wilkie (Chair)
Ms Helen Barnett
Professor Alison Blenkinsopp
Dr Ian Jack
Mrs Carole Myer
Professor Phil Routledge
Mrs Madeleine Wang (for afternoon)
Dr Charlotte Williamson

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

Apologies:

Dr Robin Ferner
Mrs Barbara Greggains
Mrs Barbara Wood

1. Apologies and announcements

1.1 Apologies were received from Dr Robin Ferner, Mrs Barbara Greggains and Mrs Barbara Wood.

2. Minutes from previous meeting on Monday, 16 May 2005

2.1 The minutes of the Working Group meeting held on Monday, 16 May 2005 were agreed as an accurate record.

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

3.1 *Item 5.2:* The Group noted that representatives from COI were organised to attend the meeting to discuss the development of the patient Yellow Card form.

4. Synthesis of qualitative studies of medicines taking

4.1 Dr Charlotte Williamson provided an introduction to a paper by Pound *et.al*¹ that synthesised a number of qualitative studies of lay experiences of medicines taking, and suggested that providing a balanced view of problems with medicines is as important as highlighting the benefits of medicines. Dr Williamson suggested that the Group has so far achieved a balanced approach in the work done so far on patient reporting, care would be needed to ensure the outputs of the Group continued to strike that balance.

4.2 The Group noted the inevitability of ADRs with medicines usage, and supported the view that patients should make decisions about using a medicine in partnership with their prescriber, based on a mutual understanding of the risks and benefits of using the medicine. The Group agreed that in situations where patients had to rely on the support of the healthcare professional, especially in the treatment of complex or serious conditions, partnership would not always be on an equal footing, but that every effort should be made to inform decision making. The Group also noted the recommendation in the supporting paper that people are “unlikely to stop resisting their medicines” and that “safer ways need to be found of administering medicines”.

5. Arrangements for specific pilots

5.1 The Group had previously agreed that there should be main pilots to test reporting mechanisms on wide scale, utilising various reporting mechanisms.

5.2 The Group agreed in principle a proposal from the Regional Monitoring Centres (RMCs) that a comparative study between patients and healthcare professional reporting should be run, and requested further specifics on the study for the next meeting. The Group were advised that the study could be run from current RMC resources.

5.3 The Group discussed other smaller scale pilots that could be run, especially amongst vulnerable or difficult to access patient groups. MHRA undertook to devise a strategy for specialised pilots, based on proposals from Group members.

¹ Pound, P. *et al.* (2005). “Resisting medicines: a synthesis of qualitative studies of medicines taking” in *Social Science and Medicine*, 61 (2005), pp. 133-155.

6. Design of patient Yellow Card form

6.1 The Group welcomed representatives from COI and discussed the design and text for the new patient Yellow Card form. Ideas from the Group were to be incorporated into the further design of form.

7. Evaluation

7.1 The Group considered three papers from Group members on possible frameworks for evaluating the pilots. The Chairman undertook to produce a paper for the next meeting to synthesise the ideas presented into one document.

7.2 The Group highlighted that robust evaluation of pilots is essential, and members expressed a strong preference for evaluation to be undertaken by researchers independent of the MHRA. The Group were also keen that evaluation should ultimately lead to the production of papers for publication. The Group also suggested that adequate resources be made available for evaluation.

8. Update on initial patient reporting pilots

8.1 The Group noted the monthly overview of progress with initial patient reporting pilots, which also included an overview of progress at the half-year mark.

9. Overview of Chairman's visit to FDA

9.1 The Chairman provided an overview of her recent visit to the FDA, including information on the USA's consumer reporting system for suspected ADRs. From the American experience of consumer reporting, the Chairman noted that publicity and promotion was critical.

10. Any other business

10.1 *Market research data.* A paper outlining outcomes of relevant market research conducted in 2003 was tabled.

10.2 *Australian "Adverse Medicine Events Line" experience.* MHRA committed to provide an overview of the Australian experience with patient reporting at the next meeting.

11. Date and Time of Next Meeting

11.1 The Chair reminded the Group that the next meeting would take place on Monday, 18 July 2005 in room CR1, 19th Floor, Market Towers.

**Post Licensing Division
MHRA**

8 July 2005