

MEDICINES COMMISSION

MINUTES OF THE MEETING HELD ON 8 and 9 SEPTEMBER 2005 AT MARKET TOWERS, 1 NINE ELMS LANE, LONDON SW8 5NQ

Present

Professor Parveen Kumar (Chairman)
Dr Jeffrey Aronson (Vice Chairman)
Dr Susan Bews
Dr Lydia Brown
Professor Edzard Ernst
Professor Gabrielle Hawksworth
Professor Veronica James
Professor Ronald Jones**
Dr Christine McCartney
Dr Agnes McKnight
Professor Gordon Murray**
Professor Peter Noyce
Professor Stuart Pocock*
Professor James Ritter
Professor Philip Routledge
Dr Harriet Scorer**
Mr Robert Stevenson
Professor Cameron Swift
Professor Roger Walker
Professor Elizabeth Williamson*

Apologies

Professor Joe Collier
Professor Peter Day
Mr Graeme Millar
Mr Clifford Prior
Professor Herbert Sewell

Secretariat

Dr June Raine**
Dr Siu Ping Lam*
Mr Roy Alder
Mr John FitzGerald** (Vet Co-ord)
Mrs Sue Jones (Secretary)
Mrs Lavinia OBrien (Dep Sec)
Mrs Yvonne Muhammad (Ass Sec)

Legal Adviser

Mr Simon Rogers

MHRA

Dr Alex Nicholson*
Dr David Wright*
Mr Simon Day*
Dr Chris Steele*
Mr Andrew Black*

MHRA Observers

Mr Stephen Fawbert*

Invited Expert Advisers

Dr Michael Gammage*
Professor Robert Kerwin*
Dr Patricia Wilkie*
**present for part of meeting only*
***present on 9th Sept only*

1. ANNOUNCEMENTS

1.1 The Chairman welcomed Commissioners to this historic final meeting and reminded those present that the business and proceedings of the Commission were confidential and not for disclosure to persons or organisations outside. Commissioners were also asked to declare any interests in any of the products and companies concerned with the meeting's papers. The meeting began at 1 pm on Thursday 8 September.

1.2 The Chairman circulated a letter from the Minister, who thanked the Medicines Commission for their valuable work over many years. The Minister recalled that the Commission had been in existence since 1968 and that this was the end of an era. She thanked the current Chairman and members, on behalf of all of the Health and Agriculture Ministers for their valuable service to public health in the UK.

1.3 The Chairman congratulated Professor Gordon Duff on his appointment as Chairman of the new Commission for Human Medicines, which would come into being at the end of October 2005; she had written to him on behalf of the Commission. She also congratulated Professor Philip Routledge on his appointment as Chairman of the new Herbal Medicines Advisory Committee, which would begin life at the same time.

1.4 The Chairman congratulated Professor Elizabeth Williamson, who had recently obtained a Chair in Pharmacy at Reading.

2. APOLOGIES FOR ABSENCE

2.1 Apologies for absence had been received from the Commissioners indicated above. John FitzGerald and Dr June Raine of the Secretariat sent their apologies for 8 September. Dr Siu Ping Lam attended in Dr Raine's place on 8 September.

3. HEARING - Wyeth Pharmaceuticals - Venlafaxine product range: Efexor Tablets PL 00011/0198-0201; Efexor XL Capsules PL 00011/0223-4

3.1 Relevant interests were declared. The company made its presentation and the Commission had the opportunity to ask questions and seek clarification on a number of issues. The Commission considered all of the evidence that it had before it, both written and oral and gave its findings and advice.

3.2 On a more general point, the Commission discussed public concerns about the balance of benefit to harm of medicines in general and antidepressants in particular. The Commission acknowledged that people who had not responded to other antidepressant drugs were usually particularly unwell and were often taking other medicines for similar or unrelated medical conditions. This might increase the risk of adverse effects in some patients. In weighing up the evidence, on the balance between beneficial effects and unwanted effects, patients should be encouraged to discuss any concerns they had with their General Practitioner (GP) at any stage in their treatment. The Commission believed that information of this kind should be clearly communicated to health professionals and patients alike in a variety of ways, in order to get the message across, e.g. in MHRA communications with the press and public, in Patient Information Leaflets (PILs), and in

the Summaries of Product Characteristics (SPCs) for the use of prescribing professionals and GPs in particular.

The meeting continued on Friday 9 September 2005

4. MINUTES OF PREVIOUS MEETING

4.1 The minutes of the meeting held on 15 July 2005 were agreed (with a minor amendment of clarification to paragraph 7.3) and signed by the Chairman.

5. MATTERS ARISING

5.1 Paragraph 6.1 – The Vice-chairman had not been present at the last meeting but reported that the list of British Approved Names published by the British Pharmacopoeia Commission contained descriptive categories that included an indication. These indications were problematic because of inconsistencies. He suggested that there were two solutions: one was to remove the references to indications altogether; the other was to revise them all to ensure consistency, preferably listing licensed indications. The latter would be a time-consuming job and there were no resources to undertake this task. These comments were in line with what the Commissioners had discussed at the previous meeting. Commissioners agreed that something needed to be done to improve the publication and asked the MHRA to communicate the Commission's views to the BPC Secretariat.

6. Papers

6.1 European Pharmacopoeia: Approved Synonyms

6.1.1 The Commission approved for publication the list for the names at the heads of monographs included in Supplement 5.3 to the fifth edition of the European Pharmacopoeia.

7. Educational session: Developments in the Yellow Card Scheme

7.1 A presentation was made updating the Medicines Commission on recent developments in the Yellow Card Scheme including the introduction of patient reporting. The presentation was made by MHRA and Dr Patricia Wilkie, lay member of the Committee on Safety of Medicines (CSM) and Chair of the CSM's Patient Reporting of Adverse Drug Reactions Working Group, attended to answer questions. The Commission had the opportunity to ask questions and seek clarification on a number of points.

7.2 The Commission commented that, although a patient's report of a suspected adverse drug reaction (ADR) could be linked with any corresponding report from a corresponding health professional, there ought to be a stronger message to the public, encouraging them to discuss adverse reactions with their health professionals.

Commissioners acknowledged that this might not always be possible, as there could be a misconception by a patient that by making a report they were in some way suggesting that their GP or other health professional had prescribed the wrong medicine. The MHRA advised that language in the Patient Yellow Card form had been developed to highlight the fact that the Agency was not able to provide patients with individual clinical advice, and that they needed to consult with their healthcare professionals for such advice.

7.3 The Commission expressed concern that, on making a report, patients received only an acknowledgement and no feedback. The MHRA explained that the yellow card system was about detecting signals rather than providing advice about healthcare management and that replies were sent to patients to explain this and encouraging them to seek advice from their relevant health professionals. The MHRA said that it would review the wording on the leaflets and other correspondence to members of the public.

7.4 The Commission asked what was being done to ensure that patient reporting was being encouraged for those who did not speak English. MHRA reported that the pilot of patient reporting had only been launched in January this year and that, although leaflets were being produced in Welsh, other languages were not planned yet. This was because of the difficulty of translating reports received by the MHRA into English.

7.5 The Commission was concerned that, despite widening of the reporting scheme to include new reporters, the numbers of reports received annually had remained constant in recent years, suggesting that some groups were making fewer reports than they used to. MHRA agreed that education was still needed and that some encouragement needed to be given to busy health professionals to understand the public health importance of reporting suspected ADRs through the scheme.

7.6 Concern was expressed that reporting of adverse effects might be manipulated by the submission of fraudulent reports, as had been reported by the Uppsala Monitoring Centre. The MHRA reassured Commissioners that such reporting would be readily detected.

8. Updates from the Veterinary Medicines Directorate (VMD) and the Medicines and Healthcare products Regulatory Agency (MHRA)

8.1 VMD reported that their revision of veterinary medicines legislation was proceeding to time and would be in place for the end of October, as planned.

8.2 VMD had launched a consultation exercise in late July seeking comments and proposals on the review of the distribution category of veterinary medicinal products as recommended by the Marsh report and the Competition Commission's report.

8.3 VMD reported that the Responsible Use of Medicines in Agriculture Alliance (RUMA) was looking to recruit an expert in human medicines and asked the Commission for help. The group was mostly looking at the use of antibiotics and would welcome

input from a GP or other health professional.

8.4 The Commission sought reassurance from MHRA and VMD on the interaction between animal and human medicines and once again expressed concern that there would not be any formal veterinary input to the new medicines advisory bodies. MHRA and VMD assured the Commission that there would continue to be dialogue between the two Agencies in relation to the overlaps between animal and human medicines. The Veterinary Products Committee would continue to have medically qualified members and issues could still be brought to the new CHM, which could recruit a veterinary expert to advise it when needed.

8.5 The MHRA reported that progress was being made to appoint members of the new advisory bodies now that the Chairmen had been appointed. This process would include appointing Chairmen of the three main Expert Advisory Groups (Biologicals, Pharmacy and Standards, and Pharmacovigilance). Induction sessions were being planned for mid to late October before the bodies are formally created. MHRA reported that despite concerns that the stringent code in relation to interests might dampen the response to the appointments exercise, it appeared to have been very successful.

8.6 The Heads of European medicines agencies had had a very successful meeting in Edinburgh in July under the UK Presidency arrangements. Other meetings were due to take place in the coming months and the UK was hoping to get political agreement in principal to the paediatric regulations so that the Austrians could take the work forward during their presidency from January. A major conference on Patient Safety organised by the Chief Medical Officer was due to take place in London shortly and would be widely advertised.

9. Any other business

9.1 The Chairman reported that she had had a reply from Sir Alan Craft on the issue of High Street cholesterol testing that the Commission had discussed some months ago, following an enquiry from him. The Commission agreed that this was not in their remit but were concerned that the questions raised by the Academy of Royal Colleges ought to be taken forward by the appropriate authorities. The MHRA reported that the Devices section of MHRA was looking into the testing of cholesterol as well as the quality assurance of the analyses. There was also a section in the Department of Health looking at the wider public health issue and the educational needs to support this.

9.2 The Chairman announced that this was the last meeting of the Medicines Commission and it marked the end of an important era in drug regulation. The Medicines Commission had been the senior advisory body to Ministers on matters of drug regulation since it was established under the 1968 Medicines Act. She had served on the Commission for 12 years in total, and for the last four years as its Chairman. She said that it had been a great privilege for her and an invaluable educational experience. She thanked all of the members, and the Vice Chairman in particular, for their hard work during their terms of office, and expressed how privileged she had felt to have been their

Chairman. She also thanked the Secretariat for their support and commitment throughout the time of her service and presented them with gifts on behalf of the Commissioners.