

## **MEDICINES COMMISSION**

### **MINUTES OF THE MEETING HELD ON 7 MAY 2004 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 Joe Collier  
Professor Edzard Ernst  
Professor Gabrielle Hawksworth  
Professor Veronica James  
Professor Ronald Jones  
Dr Christine McCartney  
Dr Agnes McKnight  
Mr Graeme Millar  
Professor Gordon Murray  
Professor Peter Noyce  
Mr Cliff Prior  
Professor James Ritter  
Dr Harriet Scorer  
Mr Robert Stevenson  
Professor Roger Walker  
Dr Elizabeth Williamson

#### **Secretariat**

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

#### **Legal Adviser**

Mr Simon Rogers

#### **MHRA**

Miss Maggie Jackman\*  
Dr Gillian Shepherd\*

#### **Apologies**

Professor Peter Day  
Professor Stuart Pocock  
Professor Philip Routledge  
Professor Herbert Sewell  
Professor Cameron Swift

*\*present for part of meeting only*

### **1. ANNOUNCEMENTS**

1.1 The Chairman welcomed Commissioners to the meeting and reminded those present that the business and proceedings of the Commission were confidential and not for disclosure to persons or organisations outside. She also reminded members to declare any interests, whether personal or non-personal (specific or non-specific) in any products or companies concerned with today's papers.

1.2 The Chairman welcomed two new members to the Commission: Mr Cliff Prior, Chief Executive of Rethink and Vice Chairman of the Long Term Medical Conditions

Alliance; and Mr Graeme Millar, of the Scottish Consumer Council.

## **2. APOLOGIES FOR ABSENCE**

2.1 Apologies for absence had been received from the Commissioners indicated above.

## **3. MINUTES OF PREVIOUS MEETING**

3.1 The minutes of the meeting held on 6<sup>th</sup> February 2004 were agreed with minor amendments and signed by the Chairman.

## **4. MATTERS ARISING**

4.1 Para 2.1 - The Chairman had written to both Mr Alder and Dr Raine and asked if they could nominate deputies to attend the meetings if they were unable to attend themselves.

4.2 Para 4.2 - MHRA reported that the Independent Report on the Yellow Card Scheme had been launched on the scheme's 40<sup>th</sup> Birthday on Tuesday 4<sup>th</sup> May. It had been issued for public consultation and a copy of the report and consultation letter was tabled for Commissioners. The consultation period was due to end at the end of July and the Commission was invited to consider the report and its recommendations in more detail at its July meeting. The MHRA would bring the issue back towards the end of the year for further discussion once the consultation period was over and firm proposals were developed.

4.3 Para 5.1.4 - The MHRA reported that a cross-Agency group, led by the Licensing Division was working up proposals for naming policies and that this work would include a glossary for terms such as "plus" and "extra" - it was a significant piece of work but it was being moved forward. The MHRA would report to the Commission in due course.

4.4 Para 7.3.3 - MHRA reported that there were some points relating to committee minutes and confidentiality that were currently being considered. Committee secretariats were already, in practice, producing fuller minutes of meetings, but there were no imminent formal changes being adopted as a result of the kava kava judgement, which had criticised the Agency.

## **5. PAPERS**

**5.1 Annual Reports for 2003:**  
**British Pharmacopoeia Commission**  
**Veterinary Products Committee**  
**Advisory Board for the Registration of Homoeopathic Products**  
**Medicines Commission**

5.1.1 Commissioners expressed their surprise that these reports had been referred to them for information only. The Commission reviewed its role in relation to the reports from the section 4 committees. The MHRA confirmed that the committees were required to send annual reports to the Commission under section 5 of the Medicines Act 1968. The legal advisor confirmed that the information in the reports was relevant to the Commission's statutory function of reviewing the work of the section 4 committees. The Commission may comment on the contents of the reports.

5.1.2 The Commission considered again the issue of declarations of interest in terms of some members whose interests were considerable because they listed all of the work undertaken by their department or university (particularly in the case of Deans, etc.). The Commission considered that this could generate criticism because it might give the impression that other members weren't disclosing all that they should. The Veterinary Products Committee (VPC) had put a note in their report (para 11) drawing attention to the issue of interests and that some of the longer lists of interests related to work undertaken by the organisation as a whole rather than ones where the member had a direct connection.

5.1.3 The Commission sought advice from the Secretariat on the issue but the Secretariat did not feel that they should have any influence over what a member considered he or she should declare or not, and they did not think that they should take it upon themselves to delete any declarations made by members. The Code of Practice gave guidance on what should and should not be declared and it was up to individual members to make their own judgements. The Commission also requested that the lists of interests for each committee should be clearly marked as interests "in the pharmaceutical industry". Other interests (e.g. academic or political interests or associations with pressure groups) were not declared in these lists.

5.1.4 The Commission noted and accepted the reports from the British Pharmacopoeia Commission, the Veterinary Products Committee and the Advisory Board for the Registration of Homoeopathic Products. It suggested a few minor amendments to its own report and asked the Secretariat to make the amendments and send the draft to Commissioners again along with the relevant appendices.

## **5.2 British Pharmacopoeia 2004: Preface British Pharmacopoeia (Veterinary) 2004: Preface European Pharmacopoeia: Approved Synonyms**

5.2.1 The Medicines Commission considered and approved for publication the prefaces for the British Pharmacopoeia 2004 and British Pharmacopoeia (Veterinary) 2004. The Commission also approved the European Pharmacopoeia Approved Synonyms for publication.

## **5.3 Medicines Commission response to the Review of the Advisory Body**

## **Structure laid down in the Medicines Act 1968**

5.3.1 The Chairman had circulated a draft response to the MHRA's consultation letter relating to the review of the medicines advisory committee structure. She thanked those members who had taken the time to respond to the proforma sent out a few weeks before and had used these responses, along with the previous discussions held at meetings, to draft the reply.

5.3.2 The Commission discussed the draft and agreed the main points. In addition, the following comments were made in discussion:

5.3.2.1 The name of the new Commission should not be CSM, as the Commission considered that this would cause confusion with the "old" CSM. This would be at odds with the aim of changing the image and launching the advisory bodies as something new. It considered that the new name should be more descriptive and reflect the issues of quality, safety and efficacy (although a suitable alternative was not proposed);

5.3.2.2 The Commission considered that it could be difficult to get a quorum with as few as 10-12 members, particularly if they were to meet so frequently;

5.3.2.3 The Commission was concerned that the consultation document only suggested one possible structure for the new bodies and that there was no alternative proposal, nor any opportunity to propose an alternative structure;

5.3.2.4 The Commission considered that it was essential to have industry input and that if the main body could not have a member with current experience, then it should consider whether it could have a member with recent experience of working in the industry. Alternatively the industry input could be strengthened at TAG level on the same basis;

5.3.2.5 The Commission considered that a broader membership would allow a wider view and assist in policy making decisions/advice. In addition to a member with experience of the pharmaceutical industry, Committee members suggested that the list could include a lawyer/ethicist, a public health specialist, a veterinary surgeon, a lay/patient advisory specialist and a practising pharmacist.

5.3.2.6 A clear job description was needed for the TAGs, not all would be therapeutic advisory groups, some could be technical advisory groups. If TAGs could have clarification meetings with companies and then hear oral representations on applications, it would still be possible for the new Commission to hear appeals;

5.3.2.7 It was suggested that, rather than have the Chairmen of the TAGs as full members of the new Commission, their places on the Commission could be used to broaden the expertise and have the TAG Chairmen attend the main meetings as expert advisers when necessary;

5.3.2.8 The Commission agreed to keeping the VPC and BPC as they are;

5.3.2.9 It agreed with the principle of having members without personal interests in the pharmaceutical industry but doubt was expressed as to whether enough suitably qualified members without interests could be found. It noted that other interests (such as academic or political interests or associations with pressure

groups) were not being targeted;

5.3.2.10 Lay/patient advisory input was essential and would be extremely useful in providing advice on the best way to communicate with patients. It would be useful to have a forum where these advisers were not surrounded by scientific and medical professionals - perhaps a panel for “switching” would be the best place to assist the move to “self care”;

5.3.2.11 The Commission agreed that the new Commission should continue to recommend appointments to the VPC and BPC although it considered that recommendations to the VPC could only be made if the new Commission had veterinary representation (or have access to advice from relevant experts);

5.3.2.12 The new Commission should continue to hear appeals in relation to veterinary products - but only if it had the right expertise (see 5.3.2.11 above);

5.3.2.13 The Commission was also concerned about the ability to appoint enough toxicologists, statisticians, epidemiologists, etc. for each TAG.

5.3.3 The Chairman agreed to finalise the draft advice with the assistance of one or two members within the next few days.

## **6. Oral Updates**

### **6.1 Update on the 2001 Review**

6.1.1 The MHRA and VMD updated the Commission on the outcome of the 2001 review, which was now for implementation. The final date for implementation was 20 November 2005 for the Regulation and 30 October 2005 for the Directives and it was common UK practice not to implement before the deadline. However, one or two provisions (relating to switching, user testing and readability) were being considered for an early implementation although no firm proposals were available as yet.

6.1.2 The Commission had the opportunity to ask questions clarifying, for example, the likely effect on the change of the definition of investigational medicinal product. Commissioners asked about the definitions of a clinical trial and an investigational medicinal product, and whether n-of-1 trials would be covered by the new directive. MHRA confirmed that guidance on these and other issues was soon to be issued. MHRA confirmed that it was unlikely that any products currently categorised as devices under the present definition would fall to be categorised as medicines under the new definition. But there might be some that change from medicines to devices as some products would not meet the criteria of exerting a “pharmacological, immunological or metabolic” effect. MHRA would however, be looking at products carefully and if there were any public health concerns about reclassification would take steps to retain them under stricter medicines regime.

### **6.2 Update on the Clinical Trials Directive**

6.2.1 MHRA made a presentation outlining the progress and implementation of the new Clinical Trials Directive. The new system was introduced by legislation on 1<sup>st</sup> May 2004

and replaced the old Clinical Trials Exemption (CTX), and Doctors and Dentists Exemption (DDX) schemes. MHRA confirmed that guidance on the scope of the trails covered by Regulations would be placed on the website.

### **6.3 Update on progress of the Joint CSM/MC Working Group on Prescribing, supply and administration of medicines**

6.3.1 The Vice-Chairman reported that the work of this group was now complete and the group had been disbanded. They had completed two major pieces of work in relation to extending prescribing for nurses following requests from the Chief Nursing Officer and the Emergency Care Strategy Team. There may well be a need to reconvene the group at a later date if further requests are made to extend the prescribing powers of other health care professionals. The Chairman of the Medicines Commission thanked the Vice-Chairman for his hard work and the work of all the group members (including two from the Medicines Commission (Professor Walker and Professor James) and the other members of the group from the CSM.

### **7.2 Update on ongoing issues in Veterinary Medicines Directorate (VMD)**

7.2.1 The VPC report on the suspected adverse reactions scheme was about to be presented to Ministers for publication - copies would be distributed to interested Commissioners when it became available.

7.2.2 The issue of residues of Lasalocid in eggs (through the use of feed additives) was a long running issue – resulting from cross contamination of feed and the VRC were taking an aggressive stance with the feed industry in order to try and rectify the situation.

7.2.3 A list relating to antimicrobials authorised for use in humans and animals had been published on the VMD web site. The DEFRA Surveillance Strategy on antimicrobial resistance in animals had been published and copies would be distributed to interested members.

### **7.3 Update on ongoing issues within the MHRA**

7.3.1 MHRA reported that the Agency's new Executive Board had met for the first time in April and the new Governance structure was now fully in place. A project looking at co-locating the Agency was underway. MHRA also reported that a communications strategy would be implemented shortly with a new communications director being appointed and a new in-house unit set up to deal with internal and external communications including media handling.

## **8. Any other business**

8.1 The Chairman asked for all consultation letters to be copied to Commissioners as they are issued.

8.2 The Chairman congratulated Dr Elizabeth Williamson on her appointment as Chair of the Sydney University Faculty of Pharmacy in herbal medicines. She was due to take up this post in January 2005.

8.3. The Chairman reported that she and the Vice-Chairman had had a meeting with Lord Warner earlier in the week and had expressed the views of the Commission on the new advisory structure. She reported that it had been a very positive meeting.

8.4. MHRA reported that an assessment of Buscopan had been completed and CSM had advised that there was evidence of acceptable efficacy.

## **9. Date of Next Meeting**

9.1 Thursday 8<sup>th</sup> July 2004.

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