

**MINUTES OF THE MEETING HELD ON 20 OCTOBER 2003 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 Peter Day  
Professor Gabrielle Hawksworth  
Professor Ronald Jones  
Dr Agnes McKnight  
Professor Peter Noyce  
Professor Stuart Pocock\*  
Professor James Ritter  
Dr Harriet Scorer  
Mr Robert Stevenson  
Professor Cameron Swift  
Professor Roger Walker  
Dr Elizabeth Williamson

**Secretariat**

Mrs Lavinia O'Brien (Deputy Sec)  
Mr John FitzGerald (Vet. Co-ord.)  
Mrs Yvonne Muhammad (Asst. Sec.)  
Mrs Karen Salawu (Asst. Sec)

**Legal Adviser**

Mr Simon Rogers

**MHRA**

Mr Jeremy Mean\*

**Invited presenters**

Mr Norman Duncan\*  
Professor Alasdair Breckenridge\*  
Dr Diane Benford\*

**Apologies**

Professor Edzard Ernst  
Professor Veronica James  
Dr Christine McCartney  
Professor Gordon Murray  
Professor Philip Routledge  
Professor Herbert Sewell  
*\*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 Dr Elizabeth Williamson (Pharmacist, University Lecturer in Pharmacognosy, Centre for Pharmacognosy and Phytotherapy at the London School of Pharmacy) to her first meeting.

## **2. APOLOGIES FOR ABSENCE**

- 2.1 Apologies for absence had been received from the Commissioners indicated above. Mr Roy Alder, Dr June Raine and Mrs Sue Jones of the Secretariat also sent apologies.

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

- 3.1. Following a discussion the minutes of the meeting held on 5 September 2003 were agreed, pending some amendments.

## **4. MATTERS ARISING**

- 4.1. Para 5.2. The Commissioners' comments to the Shipman Inquiry had been collated and the paper had been forwarded to the Inquiry. VMD reported that the CVO and the RCVS and BVA had responded individually to comment from the veterinarian viewpoint.

## **5. THE CODE OF PRACTICE**

- 5.1. A presentation was made to the Commission relating to an ongoing review of the Code of Practice in relation to Conflicts of Interest.

## **6. Open meetings at the Committee on Toxicity of Chemicals in Food, Consumer Products and Environment (COT). A Presentation by the Secretary**

- 6.1. A presentation was made by Diane Benford, scientific secretary to the COT, based at the Food Standards Agency.

- 6.2. The following points were raised in discussion:

6.2.1 Every other meeting of the COT was held in public. The open meetings dealt with normal Committee business and were advertised in relevant publications and on the website but not in the lay press. COT initially posted a list of agenda items on the website then two weeks before the meeting the final agenda was published. Members of the general public could apply for invitations but few people had attended meetings thus far.

6.2.2 Confidential items on COT agenda were usually dealt with at a specific time, for example at the end of the meeting. The meeting was then closed to members of the public who were asked to leave. COT had not had to deal with data, which was commercially sensitive.

6.2.3 No specific arrangements were in place for dealing with the minutes of an open meeting. Once the draft minutes were agreed and finalised they were put on the website.

6.2.4 Experience in the All Wales Medicines Strategy Group was that the public were allowed to attend but not ask questions. Meetings were advertised in the local media and 30/40 people attend at each meeting. NICE open meetings had also worked very well. These meetings did not deal with confidential data.

6.2.5 All licensing decisions in USA were made in public but the legal adviser explained that under UK legislation (section 118 of the Medicines Act 1968) there was a general prohibition on disclosure of information submitted to the MHRA as part of a licence application.

## **7. Proposals to review the advisory committee structure for medicines in the MHRA**

7.1. Professor Breckenridge presented the paper. He outlined the background to the review and the proposals for the new structure. He explained that the proposals were only in relation to medicines. The Commissioners agreed that, overall, there was a need for change. The main points raised in discussion were as follows:

7.1.1 It was thought that the proposed title of the new decision making body “The Commission on the Safety of Medicines” (CSM) could easily be confused with the current CSM. MHRA wanted to retain “safety” in the title but it was thought that this could be a good opportunity to include a reference to “quality” and “efficacy” in the title of the new Commission.

7.1.2 The new Commission, with only 10 members, might be too small. It would not have the broad base of expertise of the current Commission. In addition not everyone would be able to turn up at every meeting – and with only 10 members some meetings could be reduced to 5 or 6 people.

7.1.3 If all members of the new Commission were required not to have personal interests would enough people be found? It could also mean that there would be no industry input. MHRA confirmed that the new Commissioners would be recruited under Nolan principles.

7.1.4 The new Commission was to be the decision making body and this needed to be set out clearly – who was going to be on it and the role of the Therapeutic Advisory Groups (TAGs). It was important that the new structure retained the powers of the current Commission as set out in the Medicines Act. MHRA confirmed that there were no plans to change the regulations.

7.1.5 The new Commission would provide advice to the MHRA Board and Ministers. Commissioners were also able to provide advice on an individual basis.

7.1.6 The role of the TAGs needed to be set out clearly. If they were set up as a group of experts there needed to be a procedure for obtaining advice from people with clinical and medicinal expertise, prescribing GPs, generalists and lay people. MHRA proposals were that a number of TAGs would be set up which would include a range of people and that there would be “cross-TAGing”.

7.1.7 There was a perception of a considerable workload for new core Commission. The new Commission needed to be in a position to effectively take on board the vertical relationships of the Chairmen of the TAGs. MHRA envisaged that the new Commission would meet once a month but under the new structure much of the groundwork would be carried out by the TAGs. The new structure would need to remain a flexible process with advice being sought from where it was needed. The role of the new Commission would be to pull the advice together.

7.1.8 Appellate Body: It was important that Industry didn't suffer as a result of the new structure. The current legislation only made provision for a “person appointed” to collect information and Commissioners were concerned that more opportunity should be given for discussion. The legal adviser explained that a change to allow the appointment of more than one person would not involve primary legislation.

7.1.9 MHRA proposals envisaged that if a company disagreed with a MHRA licensing proposal, the issue would go to a TAG first, where a decision might be made to have a clarification meeting. These meetings have been remarkably successful and it was thought that this should be amplified in the paper that goes out for consultation as it would do a lot to allay concerns voiced by industry and help divert the “two bites of the cherry” issue.

7.1.10 A mechanism needed to be in place for Veterinary issues to feed into the new Commission. MHRA were proposing that the VPC would disband and veterinary issues would be taken to the new CSM. A veterinary expert would be one of the CSM “group of 10” and a special TAG would be set up for veterinary products.

## **8. Other agenda items**

8.1. The Commission agreed to defer discussion on two papers and two tabled papers until the next meeting.

## **9. Up-date on 2001 Review**

9.1. VMD reported that the European Parliament had looked at common opinion and produced 70 to 80 suggested changes. Briefing for MEPs covered two issues, scope and data protection period, where the UK felt it was important to maintain the common position. A Council Working Group meeting was scheduled for 28 October

2003. Reactions to proposed changes for both veterinary and human use would be discussed.

9.2. It was possible that this could run past the time scale for EU enlargement. Action was being taken to try to minimise this risk. However, if it did happen, new member states would have members on each committee and would have a vote in ratio with their size.

#### **10. Update on VMD issues**

10.1. A debate on veterinary prescriptions following the Competitive Commission Report was being held in House of Commons on 20 October 2003.

#### **11. Any other business**

11.1. The Chairman drew members' attention to two tabled papers for information, an article in March 2003 issue of DTB on the withdrawal of certain Yasmin advertising material and the Commissions collated response to the Shipman Inquiry. Copies of the MCA Annual Accounts were also available.

#### **12. Date of next meeting**

12.1. The date of the next meeting was Friday 7 November 2003