

**MINUTES OF THE MEETING HELD ON 6 FEBRUARY 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 Peter Day  
Professor Gabrielle Hawksworth  
Professor Veronica James  
Professor Ronald Jones  
Dr Christine McCartney  
Dr Agnes McKnight  
Professor Gordon Murray  
Professor Peter Noyce  
Professor James Ritter  
Professor Philip Routledge  
Dr Harriet Scorer  
Professor Herbert Sewell  
Professor Cameron Swift  
Professor Roger Walker  
Dr Elizabeth Williamson

**Secretariat**

Mrs Sue Jones (Secretary)  
Mrs Lavinia OBrien (Dep Sec)  
Mrs Yvonne Muhammad (Ass Sec)

**Legal Adviser**

Mr Simon Rogers

**MHRA**

Dr Ian Hudson\*  
Ms Sue Harris\*  
Mr Richard Woodfield\*

**Apologies**

Professor Edzard Ernst  
Professor Graeme Millar  
Professor Stuart Pocock  
Mr Cliff Prior  
Mr Robert Stevenson

*\*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 Secretary apologised for having to change the date of the September meeting from 9/10 September to Friday 3<sup>rd</sup> September.

1.3 Commissioners were asked to let the Secretariat have any amendments to the register of interests that had been tabled as this was the information that would be published in the Annual report later this year.

## **2. APOLOGIES FOR ABSENCE**

2.1 Apologies for absence had been received from the Commissioners indicated above. Mr John FitzGerald, Dr June Raine and Mr Roy Alder of the Secretariat sent their apologies. The Commission expressed its concern at the repeated absence of MHRA secretariat members and asked if deputies could attend in their place if they are unable to attend future meetings.

## **3. MINUTES OF PREVIOUS MEETINGS**

3.1 The minutes of the meetings held on 20<sup>th</sup> October 2003 and 7<sup>th</sup> November were agreed with minor amendments and signed by the Chairman.

## **4. MATTERS ARISING**

4.1 There were no matters arising from the 20<sup>th</sup> October minutes.

4.2 Para 5.4 of November minutes – The Chairman reported that she had attended a meeting with the Yellow Cards review team and that the views expressed by the Commission at its meeting in November 2003 had been communicated. The MHRA reported that although the consultation exercise was complete, the review was ongoing and a report of findings would be made available in due course.

4.3 Para 6 – It was reported that a consultation letter concerning proposals for a new medicines advisory committee structure was to be issued within the next few days and that the Commission would be formally invited to comment on the proposals at that time. The Commission expressed concern at not having had the opportunity to comment on this final draft consultation document before it was issued. The Commission sought advice from the Legal Adviser on the procedures being followed. He advised that the consultation was to be conducted by the MHRA on behalf of Ministers. There was no legal requirement for Ministers or the MHRA to consult the Commission on the draft document. The Commission could advise the MHRA and Ministers on the proposals and it was right that the Medicines Commission (and the other medicines advisory bodies) be invited to comment. But it was for the MHRA, on behalf of Ministers, to determine the form of the consultation and prepare the consultation document; they were entitled to

consult on a preferred option. The Commission expressed concern that the document might imply that it had been fully consulted on the proposals and that it approved them. The Commission considered this issue as a full agenda item later in the meeting (see para 6.1 below).

## **5. PAPERS**

### **5.1 MHRA naming policy with respect to umbrella segments of product names**

5.1.1 The MHRA receives applications for product names that may include an umbrella segment. This same umbrella segment is used for other products. The umbrella segment is regarded as commercially important by the industry, particularly in the over-the-counter (OTC) sector, as part of building a brand. MHRA have found some proposals for names unacceptable, and as a consequence decided there was a need for guidance.

5.1.2 The Commission had considered the draft guideline at its July 2003 meeting and suggested a number of changes. The guideline had been amended to reflect this and the Commission was invited to review it again with a view to approving its issue to the industry.

5.1.3 The Commission thanked the MHRA for its work in developing this guideline . It considered the revised guideline and approved its use subject to a number of minor amendments.

### **5.2 The Licensing of Homoeopathic Products – National Rules Scheme**

5.2.1 The MHRA explained that some homoeopathic medicines with product licences of right (PLRs<sup>1</sup> ) have indications for their use, whereas the same medicines, more recently approved under the simplified registration scheme, cannot claim any indications. A preliminary proposal, with the options for new “specific rules” for the regulation of homoeopathic products, was set out in a submission to Ministers in 1998 and agreement was given to explore further the options for changing the licensing arrangements. The objective was to address the inconsistencies for all homoeopathic products. The Commission was first consulted on this issue in July 1999.

5.2.2 A new National Rules scheme has been developed which would allow the marketing of homoeopathic products with a limited range of indications that exclude serious diseases such as cancer. The current simplified registration scheme, which assesses quality and safety but not efficacy, will remain in place. The proposal for current homoeopathic PLRs is that they are allowed to remain in force and companies are allowed to retain all indications that were compatible with the new National Rules

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<sup>1</sup> PLRs were allocated to all medicinal products on the UK market when the Medicines Act 1968 came into force. Over the next 20 years or more, all of these products were reviewed and, if appropriate, given a full product licence with the exception of homoeopathic products, which still retain their PLR status.

scheme. This would mean that they would have to give up the more serious indications or apply to have them considered under the more rigorous kinds of assessment that are used for applications for the licensing of orthodox medicines.

5.2.3 The Commission thanked the MHRA for their work in developing these proposals. In conclusion, the Commission considered that, subject to these reservations, the proposals were pragmatic and it was content for the MHRA to go to consultation.

## **6. Further discussion on the proposals for the future structure of the Medicines Advisory Committees**

6.1 The Commission discussed at length a draft of the consultation document that MHRA were, subject to further minor changes, about to publish. The Commission agreed that change is needed but that it was extremely important to get the restructuring correct. The particular points raised by the Commission included:

6.1.1 The title of the draft consultation letter was misleading as it may imply that the advisory committees were part of the MHRA; in addition, the Medicines Commission, as established under the Medicines Act 1968, is not a “committee”, in contrast to the CSM, which is a Section 4 committee under the Act;

6.1.2 The consultation document gives the impression, implicitly, that the proposals had the agreement of the current advisory bodies, including the Medicines Commission, which was not so;

6.1.3 The model described was geared towards medicines licensing and there was no detailed explanation of whether and how the new Commission would deal with medicines policy issues – (this falls within the existing functions of the Medicines Commission under Section 3 of the Medicines Act 1968);

6.1.4 The consultation letter did not set out any other options. It would be better if specific options were clearly set out;

6.1.5 Other options should be considered – for example, the “Zipped-up model” described by the Vice-Chairman at the Medicines Commission’s meeting held on 7 November 2003. The proposal comprised a main Medicines Commission which combined the functions of the current Committee on Safety of Medicines (CSM) and the current Medicines Commission. This could be achieved by having around 20 members making up the full membership with expertise much as it is now. Half of that number, acting separately, could perform the issues in relation to specific applications as the CSM does now, and the other half, also acting separately, could consider appeals as they do now. It was suggested that the functions only needed to be separated for these two areas of work, and that the remainder of the time the full membership could meet to discuss policy issues rather than discussing them separately as they do now. The model included the TAGs suggested by the MHRA proposals and also the current sub-committees of the CSM. It was envisaged that the CSM half of the body would meet once a month, and the full body every three months);

6.1.6 There is no evidence whether European TAGs are effective. It was suggested that one reason for the approach in Europe may be to ensure a way of

including all member states in the expert advisory structure. The Commission was not convinced that it would be right for the UK structure;

6.1.7 The TAG structure could result in a loss of the breadth of expertise currently within the advisory structure and there would be little opportunity for the development of members. It was also pointed out that specific expertise, such as would be provided by statisticians and preclinical toxicologists, would need to be available within each TAG, and that this would put a huge burden on the limited numbers of specialists in areas such as these. Furthermore, organising meetings of TAGs to suit everyone's diary would be likely to prove difficult, when some members, whose expertise would only be required for an occasional TAG, were not committed to a regular meeting. Members of TAGs who attended only occasionally would have little opportunity to develop the type of expertise that regular attenders at meetings of the CSM and Medicines Commission had the opportunity to do; an important source would thus be lost, or at least weakened;

6.1.8 If TAGs were to be introduced, perhaps one TAG could be tasked with considering medicines policy issues, to meet the criticism that there would be a gap. The Commission, however, favoured policy being a higher priority in the advisory structure making; if the responsibility of a TAG could devalue it.

6.1.9 The points at the end of the consultation letter should be posed as questions and put in priority order – there should also be an open question along the lines of “anything else you can think of?” inviting other comments.

6.2 The Commission agreed that the Chairman should seek to discuss these concerns urgently with the Chairman of the MHRA with a view to having them taken into account in the letter before it is published.

## **7. Oral Updates**

### **7.1 Update on the 2001 Review**

7.1.1 The proposals under the 2001 Review had been agreed and approved in Europe. The final version of the legislation would be published in the Official Journal of the European Union, in March/April. The provisions relating to the European Medicines Agency (replacing the European Medicines Evaluation Agency EMEA) and the Committee on Medical Products for Human Use (replacing the CPMP) would come into force within 20 days of publication. Other changes would be implemented over a period of about 18 months.

### **7.2 Update on ongoing issues in VMD**

7.2.1 In the absence of the VMD co-ordinator, one of the veterinary Commissioners gave a brief report relating to the EU ruling that all medicines for use in food-producing animals must be POM. This creates considerable difficulties for the UK and goes against recent findings in UK reports on veterinary services (e.g. the Marsh report). It was

understood that the Veterinary Medicines Directorate was developing proposals to address the issue and would be going to consult the industry later in the year.

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

7.3.1 MHRA reported that substantive negotiations on the Directive on herbal medicinal products had been completed. In reaching agreement, UK objectives were successfully achieved, in particular, flexibility to take account of evidence of traditional use outside the EU and the ability to add vitamins and minerals, when they are safe and ancillary to the action of the herbal ingredients. The Directive was likely to take effect around March 2004, with a requirement for Member States to put in place traditional use registration schemes by around September 2005. A simplified registration scheme will be introduced for OTC traditional herbal products suitable for use without the intervention of a medical practitioner. The scheme would be based on assurance as to quality and safety. As now, it will still be possible for herbal medicines to get a full marketing authorisation, if it is possible to demonstrate efficacy as well as safety and quality.

7.3.2 The MHRA expected that an extensive communications campaign would be launched shortly to implement the move from using BANs to using INNs (except where INNs were not available and in the case of adrenaline and noradrenaline, for which there are special considerations). The main thrust of the campaign was towards health professionals so that they are in a position to advise patients, but there was also to be included some limited targeted publicity aimed at the public (e.g. posters in GP surgeries).

7.3.3 The courts in the recent Judicial Review upheld the prohibition of kava kava. The judgement made some references to confidentiality of proceedings within committees and the implications of the judgement are being considered by the MHRA.

## **8. Any other business**

8.1 The Chairman tabled a letter she had received from a local pharmaceutical committee concerning training for pharmacy staff in the new NHS. The Commission agreed that the author of the letter should be approached to see if they wished the letter to be referred to the relevant senior officials in the Department of Health.

8.2 The Vice Chairman brought the Commission's attention to the Editorial from the BMJ dated 31<sup>st</sup> January, concerning the new European Clinical Trials Directive, written by Professor Kent Woods. The Vice-Chairman was concerned that it was not clear what would be regarded as a "medicinal product" within the terms of the Directive when determining whether a clinical trial came under this Directive. It would be useful if the MHRA could publish some guidance as to its interpretation. The Commission was informed that the MHRA would be publishing guidance to accompany the national regulations and that this would include interpretation of what was and what was not included.

**9. Date of Next Meeting**

9.1 6/7 May 2004.