

MINUTES OF THE MEETING HELD ON 11 FEBRUARY 2005 AT MARKET TOWERS, 1 NINE ELMS LANE, LONDON SW8 5NQ

Present

Professor Parveen Kumar (Chairman)
Dr Jeffrey Aronson (Vice Chairman)
Dr Lydia Brown
Professor Joe Collier
Professor Gabrielle Hawksworth
Professor Veronica James
Professor Ronald Jones
Dr Christine McCartney
Dr Agnes McKnight
Professor Gordon Murray
Professor Stuart Pocock
Mr Clifford Prior
Professor James Ritter
Dr Harriet Scorer
Professor Cameron Swift
Dr Elizabeth Williamson

Apologies

Dr Susan Bews
Professor Peter Day
Professor Edzard Ernst
Mr Graeme Millar
Professor Peter Noyce
Professor Philip Routledge
Professor Herbert Sewell
Mr Robert Stevenson
Professor Roger Walker

Secretariat

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 Andrew French*
Dr Ged Lee*

**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.

1.2 The Chairman congratulated Roy Alder of the Secretariat, on behalf of the Commission, on his award of a CBE in the New Year's Honours. She commented that it was well-deserved and thanked him for his years of support to the Medicines Commission.

2. APOLOGIES FOR ABSENCE

2.1 Apologies for absence had been received from the Commissioners indicated above. Dr June Raine of the Secretariat also sent her apologies.

3. MINUTES OF PREVIOUS MEETINGS

3.1 The minutes of the meeting held on 4th and 5th November 2004 were agreed.

4. MATTERS ARISING

4.1 Para 1.2 - The Chairman reported that Professors Ernst and Pocock should have received a letter from the Chief Executive of the MHRA, on behalf of Ministers, inviting them to serve a further twelve months until 31st December 2005.

5. PAPERS

5.1 European Pharmacopoeia: Approved Synonyms

5.1.1 The Commission approved for publication the list of supplementary approved synonyms for the fifth edition of the European Pharmacopoeia.

6. Oral updates

6.1 Restructuring the Medicines Advisory Bodies

6.1.1 MHRA reported that, following formal consultation on the proposals to restructure the medicines advisory bodies, preparation was currently under way to draft regulations to implement the changes. Lord Warner announced the basic outline of the new structure on 11th November 2004. The new Commission on Human Medicines (CHM) would have 18 members with a broad range of specialisms plus a Chairman. Two of the members would be lay. The target date for implementing the new system would be late autumn 2005. Commissioners commented that it would be useful to include in legislation, the number of members necessary to achieve a quorum.

6.1.2 There would be three "section 4" committees (set up under section 4 of the Medicines Act) comprising the Advisory Board for Homoeopathic products, the British Pharmacopoeia Commission and a new committee to consider herbal products (a consultation relating to this body was currently underway). The CHM would be

underpinned by a number of Expert Advisory Groups (EAGs), the chairmen of some of these Groups would also be members of the CHM. Several EAGs would be generic – e.g. biologicals, pharmacovigilance and pharmacy / standards – and their Chairs would be members of the CHM. It was anticipated that much of the work would be undertaken at this level. Commissioners expressed some concern about the use of specialist EAGs, in particular that selection of Group members by the Commission, rather than by a more formal process, could give rise to concerns about bias and lack of transparency and suggested that the criteria for selection should be a matter of public record. They also had concerns about the practicality of the proposal for some of the meetings of the EAGs to be “virtual”, i.e. by video- or tele-conferencing. They strongly recommended early pilots of EAGs and new working methods.

6.1.3 Every effort would be made to resolve product application issues through the EAGs but, in the event of an appeal being requested by the company, a different mechanism was proposed. First, there would be a right to a hearing before the CHM; but the company would have to submit the documents on which it wished to rely (currently there is no limit for submitting documents and appeals can continue for years). If the company were not satisfied by the MHRA decision based on CHM's advice, there would be a right to a hearing before "persons appointed" by the Licensing Authority (LA). The LA would appoint a panel of experts; unlike the current arrangements for "persons appointed", when the person appointed tends to be concerned with procedural issues, the panel would also consider scientific issues. MHRA reported that it was considering piloting the new EAG-type of working with current CSM sub-committees before the whole process changed later in the year.

6.1.4 The NHS Appointments Commission would be undertaking the appointments exercises for the new bodies. The Chair of the CHM would be appointed as early on in the process as possible so that he/she could engage in the selection process for members. Ministers had reserved the right to approve the appointment of the Chairmen of these bodies but the members would be appointed by the NHS Appointments Commission. Members of EAGs, and names to be included on a list of experts that may be drawn on as needed, would be appointed by the CHM or the section 4 committee which established the EAG.

6.1.5 In their proposed re-write of veterinary medicines legislation, DEFRA was proposing that the Medicines Act 1968 would no longer apply to veterinary medicines and that there would be separate, free-standing veterinary medicines legislation. As a result of this “divorce”, it was proposed that there would be no veterinary members on the CHM or the other human medicines committees. The Commission expressed its concern about this and said that they considered the veterinary link and input to be extremely valuable and it was essential that there was a direct link. The Secretariat assured the Commission that the veterinary committees would include practitioners in human medicines and that at official level, the constant discourse between relevant Government departments would continue. However, the Commission wished to register its deep concern about this proposal. The Secretariat agreed to take this issue and consider it again.

6.1.6 VMD reported that appeals for veterinary medicines would be slightly different as they would not go to the Medicines Commission or new CHM. The appeals process would be streamlined allowing less time from notice of intent to appeal and the date of appeal. The appeal must be on the basis of the same evidence as the original application. The VMD would take the initial decisions on whether or not to grant an authorisation and any appeals would then be heard by the VPC. Appointments to the VPC would be made as now, by a sift and selection panel, including an independent representative of the Commissioner for Public Appointments, making recommendations to Ministers. Currently recommendations come before the Medicines Commission in the first instance before going to Ministers. This stage had been criticised for its lack of transparency and would not continue as the new CHM would have no role in VPC appointments.

6.2 Proposals for new committee members' interests

6.2.1 MLX 316, a consultation document relating to proposals for interests for members of the new advisory body structure, had been circulated to the Commission earlier. The consultation period was due to end that day and Commissioners were invited to comment.

6.2.2 The proposals were: that the Chairman and members of the new Commission for Human Medicines (CHM) should have no such personal interests in the pharmaceutical industry; and that the Chairmen of the section 4 committees and the new Expert Advisory groups (EAGs) should have no personal interests. The exception to the rule was for the British Pharmacopoeia Commission. This was because the nature of the work of that body was highly technical and it could not be undertaken by members who had no current detailed expertise in industrial manufacture. In addition, its role was to publish technical documents, it did not advise on products or licensing. All other interests would be declared and held on a register and handled through a Code of Practice as now. Declarations of interest would also extend to knowledge of partners' and close family members interests.

6.2.3 The Commission expressed some concern that these new proposals would limit the choice of suitable candidates and thus lower the quality of the advice from the CHM. There was some discussion about particular types of interest such as attending industry-sponsored conferences. The Commission pointed out that Health conferences were now almost always sponsored by industry and that the trend to have such sponsorship for public health events seemed to contradict the new policy for members' interests. The MHRA agreed that different types of interests would be defined as far as possible but, as it was impossible to anticipate every scenario, advice would sometimes have to be given at meetings on how to deal with specific interests declared.

6.3 Freedom of Information (FOI)

6.3.1 The MHRA reported that, since the FOI Act came into force on 1st January, the Agency had received around 80 requests (including around 20 from one individual). Many of the questions had come from Pharmaceutical companies and the second biggest

group has been journalists. It had been particularly difficult dealing with requests asking for “everything the MHRA has on ...”. The requests were currently taking up a considerable resource but the Agency was well-prepared to deal with many of the enquiries and the aim was to publish as much as possible. In answer to some queries, the Agency was saying that they would publish the information on its web site within 20 days so that it would be available to whoever wished to access it.

6.3.2 The Commission asked whether more information relating to the Commission’s work could be made available and asked for clarification of the position relating to confidentiality now that FOI was in place. The Commission was advised that individual members (as opposed to the Commission itself or the MHRA) were still bound by section 118 of the Medicines Act 1968. It was the responsibility of the Commission, acting as a single body, to carry out its functions and it was not for individual Commissioners to reveal documents or information to which they had access, as a result of their membership, to others outside the Commission, without authority. In terms of what might be published, in addition to the summary minutes, which were already available on the MHRA web site, the Commission considered setting up a small group to discuss proposals. Any new proposals would not, however, set a precedent for the new CHM, as it would be up to that body to set its own rules. The Secretariat said that it would discuss the issue of publication of documents for the new structure with colleagues and then perhaps discuss with a few Commissioners.

6.4 2001 Review

6.4.1 MHRA reported that work was underway across the Agency preparing to implement the new proposals from the 2001 Review. Most would not be implemented until the deadlines in October/November but one or two proposals were being introduced early.

6.4.2 VMD reported that it was implementing the proposals from the 2001 review through its re-write of the veterinary medicines legislation which had been issued for consultation. The re-write included implementing recommendations from the Competition Commission and the Marsh Report.

6.5 Health Select Committee

6.5.1 The Chairman thanked all members who had contributed to the submission made on behalf of the Commission to the Health Select Committee (attached as Annex B to the minutes of the November 2004 meeting). The hearings had concluded last week and the report was expected to be published within a month or two. The Government would then consider the report and its formal response. The report would be available and the Commission expressed a wish to consider it when it was published.

6.6 United Kingdom Public Assessment Reports (UKPARs)

6.6.1 From 30th October 2005 the MHRA will be required to make available, Public

Assessment Reports for medicinal products which have been granted a Marketing Authorisation. This requirement comes from Directive 2004/27/EC, part of the 2001 Review. The following proposals will be subject to consultation with the industry shortly.

6.6.2 The UKPAR will be an up-to-date record of the licensing history for a medicinal product, providing information on the data presented in support of licensing applications and the reasoning behind the Licensing Authority's decisions. Each PL will have a separate UKPAR that will be brought up to date following all significant variations (granted or refused). The up-to-date reports will be published on the MHRA website.

6.6.3 UKPARs will be MHRA documents and will have all references to individual assessors and experts deleted, as well as any material deemed to be commercially confidential. As per Directive 2004/27/EC, UKPARs will be made publicly available 'without delay' following grant of marketing authorisations. Applicants will be given the opportunity to comment on whether or not they consider that all commercially confidential data have been removed before release of the report.

6.6.4 The assessment sections of the UKPAR will be created by editing the MHRA assessment reports while the current SPC and PIL will be pulled in from existing databases. Although there is no requirement under Directive 2004/27/EC to produce an overview written in plain language, it may be desirable to include such a summary.

6.6.5 The Commission welcomed the proposals and specifically commented that it would be preferable for the MHRA to use the most open template available in designing its own approach.

6.7 Update on other issues relating to MHRA

6.7.1 MHRA reported that its new Director of Communications formally joined the Agency at the end of January. It also reported that the timetable for moving Hannibal House staff into Market Towers was on schedule for completion by Easter.

6.8 Update on other VMD issues

6.8.1 VMD reported that there had recently been a call to ban the use of organophosphates completely. The Government's position was that there was no need to ban these as they were effective and safe if used in the appropriate way and were vital for animal welfare. The issue was to be subject to further debate.

7. Any other business

7.1 The Commission asked whether there were any plans for the UK Presidency of the EU later this year. MHRA reported that it would be arranging around 14 informal specialist scientific meetings, including a "Heads of Agencies" meeting. The Agency was also working closely with the Department of Health and other Agencies to organise

separate events on nanotechnology and Patient Safety.

7.2 Commissioners were asked to review the list of current interests circulated and to let the Secretariat have any changes as soon as possible.

8. Date of Next Meeting

8.1 13th May 2005.