

MINUTES OF THE MEETING HELD ON 15 JULY 2005 AT MARKET TOWERS, 1 NINE ELMS LANE, LONDON SW8 5NQ

Present

Professor Parveen Kumar (Chairman)

Dr Susan Bews

Dr Lydia Brown

Professor Gabrielle Hawksworth

Professor Ronald Jones

Dr Christine McCartney

Dr Agnes McKnight

Professor Peter Noyce

Mr Clifford Prior

Professor Philip Routledge

Dr Harriet Scorer

Professor Cameron Swift

Professor Roger Walker

Professor Elizabeth Williamson

Apologies

Dr Jeffrey Aronson (Vice Chairman)

Professor Joe Collier

Professor Peter Day

Professor Edzard Ernst

Professor Veronica James

Mr Graeme Millar

Professor Gordon Murray

Professor Stuart Pocock

Professor James Ritter

Professor Herbert Sewell

Mr Robert Stevenson

Secretariat

Dr Siu Ping Lam

Mrs Sue Jones (Secretary)

Mrs Lavinia OBrien (Dep Sec)

Legal Adviser

Mr Simon Rogers

MHRA

Ms Caroline Brennan*

Dr Patience Holland*

Mr Nigel Goulding*

Mr Richard Woodfield*

Dept of Health

Mr Peter Dunlevy*

**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. Commissioners were also asked to declare any interests in any of the products and companies concerned with the meeting's

papers.

1.2 The Commissioners were advised that the final meeting of the Medicines Commission would be on 8/9 September.

2. APOLOGIES FOR ABSENCE

2.1 Apologies for absence had been received from the Commissioners indicated above. Dr June Raine, Roy Alder and John FitzGerald of the Secretariat also sent their apologies. Dr Siu Ping Lam attended in Dr Raine's absence.

3. MINUTES OF PREVIOUS MEETINGS

3.1 The minutes of the meeting held on 13th May 2005 were agreed with a clarification amendment to para 5.1. The minutes were signed by the Chairman.

4. MATTERS ARISING

4.1 The Chairman reported that she had received a letter from the Minister, Jane Kennedy, thanking the Commission for its Annual Report for 2004 and expressing appreciation of Ministers for the valuable work of the Commission and acknowledging the commitment in time and effort given by individual members of the Medicines Commission.

4.2 Para 6.3 - The Secretariat thanked the Commission for its response relating to the Parliamentary Select Committee's report on the Influence of the Pharmaceutical Industry. The MHRA had submitted its contribution to the Government's response and this was expected to be published before then end of the current Parliamentary session.

5. Educational Session - The new community pharmacy contractual framework and interdependent developments - England

5.1 Mr Peter Dunlevy, from the Department of Health, made a presentation to the Commission relating to developments in community pharmacy in England. The Commissioners had the opportunity to ask questions and seek clarification on a number of points.

6. Papers

6.1 British Approved Names 2002: Supplement No. 4

6.1.1 Subject to the removal of indications under some entries, and clarification of a number of other inconsistencies, the Commission approved this supplement for publication. The Commission was concerned about such a large number of inconsistencies and requested that when the final book is published, that these issues be addressed.

6.2 Update on Tissue Engineering

6.2.1 Tissue engineering is a developing technology which combines various elements of medicines, material science, biology and engineering. Tissue engineered products (TEPs) may be autologous (derived from cells and tissue removed from one person and used in the same person) or allogenic (derived from cells or tissue taken from one person and used in one or more other persons). Tissue engineering and TEPs have typically been used clinically for the treatment of burns or ulcers and in cartilage repair systems. Other more complex areas also expected to be developed further include blood vessels and repair to the central nervous system. There is a range of possible health risks with tissue engineering.

6.2.2 Currently, there is no specific regulatory framework for tissue engineering and TEPs. TEPs fall outside existing devices legislation and many TEPs also fall outside current medicines legislation although some may also fall within the definition of somatic cell therapy. The MHRA had developed a Code of Practice for the Production of Human-derived Therapeutic Products (2002) which has been applied to products falling outside current legislation. However, in May 2005, the European Commission published for consultation, proposals for a Regulation on advanced therapies, including tissue engineering.

6.2.3 The Commission was invited to note developments in this field and to advise on any issues or points arising from the consideration of the European Commission's current proposals. The Commission fully supported the proposal to regulate this area and concurred with the MHRA's response for the UK Government which was attached to the paper, including the need to ensure that proposals related appropriately to the situation of hospital operators. It agreed that a pragmatic approach was needed as this was a new and developing area and that over-regulation should be avoided.

6.2.4 The MHRA understood that the European Commission intended to bring forward formal proposals around October 2006. These would be subject to negotiation, with a reasonable assumption being that they would be likely to be implemented in around 2007/2008. In the meantime there was a case for a "bridging" arrangement to ensure safety for patients, an issue on which the Committee on Safety of Devices had also previously expressed concern. The Commission underlined the importance also of ensuring the safety of relevant health technicians and operators. The Commission suggested that it might be appropriate for a small working group to monitor the developments in this area in order to advise the new Commission for Human Medicines (CHM) in due course. It suggested that membership of such a group should cover a wide range of interests and professions and include patient interests. The Commission suggested that an advisory/monitoring group to the new CHM should include members whose expertise was in this area - it was inevitable that some would have interests in the industry but that it was important to ensure the CHM had up-to-date expert advice in this area.

6.3 Committee on Safety of Medicines (CSM) Annual Report for 2004

6.3.1 The Commission acknowledged receipt of the CSM's Annual Report for 2004 but noted a number of typos. The Secretariat said that they may have been picked up at the proof stage of printing. The Reports were due to be laid before Parliament by early week commencing 18 July.

7. Updates

7.1 MHRA reported that the appointments process for the new advisory bodies, being run by the NHS Appointments Commission, was well under way. The Chairmen for the three main committees were expected to be announced around the end of July and that selection for members (with the assistance of the new Chairmen) would take place during August and September. The appointment of the Chairmen of the three main Expert Advisory Groups (EAGs) would be made at the same time as the members of the CHM and selection of members of the EAGs would be one of the first jobs for the newly formed CHM.

7.2 The events organised by the MHRA during the UK Presidency were underway and many of the Agency's senior team were in Edinburgh hosting the heads of European medicines regulatory agencies meeting. Commissioners had been given an outline of events at the last meeting.

7.3 Dr Brown updated the Commission on developments in veterinary medicines in the absence of the veterinary co-ordinator. She reported that because of the interest from stakeholders, the VMD had had two feedback days to discuss the issue. This followed the release of their consultation document about implementing new veterinary regulations in October 2005. A further consultation document had been issued for response in mid-August relating to fees and medicated feeding stuffs.

8. Date of Next Meeting

8.1 The next meeting would begin at 1pm on 8th September 2005 and was likely to continue the following morning.