

**SUMMARY OF THE COMMISSION ON HUMAN MEDICINES MEETING HELD
ON THURSDAY 14th JANUARY**

Information is being withheld, under Section 43 of the Freedom of Information Act 2000, on the grounds that information regarding the issue under consideration and advice from the CHM remains confidential at the date of this summary and will remain so until a final decision has been taken. There is no overriding public interest to release such information in advance of the regulatory process being completed. Any request for future information should be made direct to the MHRA (via info@mhra.gsi.gov.uk) and will be considered in accordance with the FOI Act.

LICENSING

NEW DRUGS *(not previously licensed in the United Kingdom)*

The Commission considered and advised on a medicine which acts as replacement therapy for two rare hereditary conditions in which bile is not produced as normal.

ABRIDGED *(Applications for new licences for known drug substances which rely in part on previously submitted data or on data submitted by other licence holders).*

The Commission considered and advised on:

- a medicine indicated for the symptomatic relief of seasonal allergic rhinitis and chronic urticaria
- a medicine indicated for relief of mild to moderate pain
- a medicine for the treatment of pulmonary hypertension

PRE-HEARING *(The Commission considers the company's written data a month before the potential oral hearing and decides whether or not the data have resolved the questions put to the company)*

The Commission considered and advised on:

- a medicine indicated for the management of pain and fever associated with common colds, influenza, headache and teething in children aged 3 months to 3 years and for the management of fever in babies who develop fever following vaccination at 2 months
- three applications for an inhaler indicated for the management of asthma

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PHARMACOVIGILANCE (*The process of identifying and responding to drug safety concerns arising with marketed medicines*)

The Commission was informed that there was a 2.4% increase in the total number of spontaneous reports received in the time period January to December 2009 compared to the same time period in 2008. In the year to date, 47% were from the healthcare profession, 41% from the pharmaceutical industry and 12% from patient reports.

PAPERS/ OTHER ITEMS

The Commission considered and discussed papers on the following:

1. The final draft of a European guideline on the investigation of bioequivalence
2. **Update on the sale, supply and administration of medicines by registered midwives**

The Chairman welcomed representatives from the Department of Health (DOH) and the Nursing and Midwifery Council (NMC).

DOH reminded Commissioners that they had previously deliberated on the proposals to update and expand the midwives' list and went on to say that midwives are required to work with women both in hospital and in the community. Their exemptions under medicines legislation are therefore important to them.

Turning to the paper before the Commission, DOH noted that when Commissioners considered the proposals previously they had agreed to the removal of several medicines which were no longer relevant to current midwifery practice. They also noted there had been some concerns expressed by commissioners about certain aspects of the proposals and these were addressed in the paper. Specifically, the midwives' list had been re-arranged so that the medicines intended for the mother were separated from those intended for the baby.

The Commission noted that miconazole had been removed from the proposals because it was no longer indicated for neonates. DOH acknowledged that the list had become out of date. However, the NMC explained they were now required to review their standards of practice every three years. As the midwives' list formed part of the standards, they will be included in the three year cycle.

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The NMC also explained that a review would look at the relevant standards and establish if there were any changes in practice. As part of the review process, the NMC will consult with a range of key stakeholders which would include members of the profession and other professionals such as obstetricians, neonatologists and pharmacists. In response to a question from a Commissioner, the NMC said the criteria used to establish if practice was still relevant included NICE guidance, policy changes and relevant research.

The Commission went on to consider the proposal for adding Diclofenac to the list for the relief of moderate to severe pain. They noted the comments made in relation to this proposal by the Royal College of Obstetricians and Gynaecologists. In particular, the suggestion that alternative NSAIDs might be considered such as Brufen or Indemethacin. The DOH said that Diclofenac was not offered to everyone but it was the drug of choice for a small number of women suffering, for example, from the effects of episiotomy. It was a very useful agent for women in severe prolonged pain. In response to a query about the duration of administration it was confirmed that use was normally for no longer than 48 hours after birth. Diclofenac is used in hospitals so it seemed appropriate to also offer it in the home setting.

On the proposal for Carboprost this has been included as it is used as a component of management of post-partum haemorrhage (PPH). Whilst PPH does not occur frequently with normal birth it is one of the more common reasons for maternal collapse and need for resuscitation in childbirth.

The DOH told the Commission that they understood the MHRA had sought the views of a member of the Royal College of Paediatric and Child Health about whether or not there was a case for including a medicine for neonatal resuscitation on the list. The NMC had decided, on balance, not to pursue this as they considered it more appropriate to provide basic life support for the baby as recommended by the Resuscitation Council UK. The Commission established that this decision did not interfere with current best practice. The NMC also confirmed that, in future, if practice changed, they would be prepared to review the situation.

There was some discussion about the current range of analgesics available to midwives namely, Pethidine, Diamorphine and Morphine. Commissioners noted that Morphine was less effective than Diamorphine and asked how midwives chose between the two in practice. The DOH and NMC explained that these medicines were not used extensively but the drug of choice depended on local custom and practice. Commissioners noted that availability of the drug throughout the UK may also be a factor as in some areas there is a shortage of Diamorphine. The NMC said the need for Morphine could be considered at the next appropriate review of standards. The NMC confirmed that the protocols midwives use for these particular medicines are concordant with those used by doctors.

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Commissioners observed that the midwives list as drafted needed to be tidied up. For example, there was a question about whether the references to Lignocaine should be amended to Lidocaine. Commissioners agreed to work with the Agency and NMC on the changes that were necessary.

The Commission had agreed to act as the focal point in relation to the additional work which needed to be undertaken following the Commission's previous consideration of the proposals. Commissioners agreed to support the revised list in principle and that it should be reviewed in three years time.

In summarising the Commission's views, the Chairman said that the Commission endorsed the list completely. The Commission was keen to support the NMC in future and would be happy to be involved in any future reviews which the Council undertake.

3. The Commission made the following lay appointment to its Expert advisory Groups:

Anti-Infectives/HIV/Hepatology

Mrs Polly Robson

Mrs Margaret Shotter

Biological & Vaccines

Professor Clive Mulholland

Mrs Polly Robson

Cardiovascular/Diabetes/Renal/Respiratory & Allergy

Mr Phil Willan

Chemistry, Pharmacy & Standards

Mrs Carol Knott

Medicines for Women's Health

Mrs Margaret Shotter

Dr Katherine Darton

Oncology & Haematology

Professor Clive Mulholland

Paediatric Medicines

Ms Lynn Hagger

Pharmacovigilance

Mr Phil Willan

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4. The Commission appointed the following professional members to its Expert Advisory Groups:

- **Dr Catherine L C Tuleu** PhD, Cert Ed, MRPhamS to the Paediatric Medicines EAG
- **Professor Rudolf W Bilous** MD FRCP – to the Cardiovascular/Diabetes/Renal /Respiratory & Allergy EAG
- **Professor Martin N Rossor FMedSci** - to the Neurology , Pain & Psychaitry EAG
- **Dr Christopher Verity** MA FRCP FRCPCD DCH to the Neurology , Pain & Psychiatry EAG

5. The following appointments were made to the Anti Infectives, HIV and Hepatology Expert Advisory Group:

- **Dr Sanjay Bhagani** BSc MB ChB FRCP
Consultant Physician in Infectious Diseases/HIV Medicine, Royal Free Hospital
- **Professor David Dockrell** MD FRCP
Professor of Infectious Diseases, University of Sheffield Medical School
- **Professor Kevin Moore** BSc MB BS PhD FRCP
Professor of Hepatology, Royal Free Hospital
- **Dr Philip N Monk** MB ChB MRCGP FFPD MFTM RCP (Glasgow)
Consultant in Health Protection , Health Protection Agency, Leicester
- **Professor Robert C Read** MB ChB, M.D, FRCP, FMedSci
Professor of Infectious Diseases and Hon. Consultant, University of Sheffield

Procedural Items

In addition, the Commission completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes and European updates. Professors Ashby, Darbyshire, Park, Pirmohamed, Smyth and Weller and Dr Forfar declared interests in one or more agenda items but this did not debar them from taking part in the proceedings.

- i. A list of Commissioners and invited experts who attended the meeting is at **Annex A**.
- ii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

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- iii. The meeting started at 10.15am on Thursday 14th January and finished at 4.25pm.

The next meeting will take place on **Thursday 11th** and **Friday 12th February 2010**.

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ANNEX A

MEMBERS ATTENDING:

**Sir Gordon W Duff MA BM BCh PhD MD (Hon) FRCP, FRCPE, FFPM (Hon)
FMedSci FRSE**

Florey Professor of Molecular Medicine, Sheffield University: **CHAIRMAN**

**Professor Deborah Ashby OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCP
Professor of Medical Statistics and Clinical Trials, Imperial College, London & Co-
Director of Imperial Clinical Trials Unit,**

%Dr Barbara A Bannister MSC FRCP

Consultant in Infectious and Tropical Diseases, Royal Free Hospital, London

Mrs Alison Bowser

Lay representative

***Professor Derek H Calam OBE MA DPhil Hon DSc CChem FRSC FRSA Hon
MRPharmS Hon MBIRA**

Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

Professor Janet H Darbyshire CBE MB ChB FMedSci FRCP FFPH

Professor of Epidemiology and Director of the MRC Clinical Trials Unit, Royal Free
and University College London Medical School; Co-Director of UK Clinical
Research Network

++Dr Michael J Donaghy D. Phil (Oxon) FRCP

Reader in Clinical Neurology, University of Oxford & Consultant Neurologist, John
Radcliffe Hospital, Oxford. (**Vice Chair**)

****Dr J Colin Forfar B.Sc (Hons), MBChB, PhD, MD, MA, FRCP**

Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

Professor Martin J Kendall OBE MD FRCP FFPM (Hon)

Emeritus Professor of Clinical Pharmacology, Birmingham University Medical
School.

Professor B Kevin Park BSc PhD FMedSci FBTS FRCP (Hon) FTBS

Director of MRC Centre for Drug Safety Science, Professor of Pharmacology & Head
of Department of Pharmacology and Therapeutics, Liverpool University

+Professor Munir Pirmohamed PhD FRCP²

Professor of Clinical Pharmacology, Liverpool University, NHS Chair of
Pharmacogenetics and Deputy Director, MRC Centre for Drug Safety Science

Dr Rosalind Ranson MB BS MA MRCP

General Practitioner, London

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Carolyn, Lady Roberts RGN RHV MSc

Chair, The Ethox Foundation-Oxford Centre for Ethics and Communication in
Healthcare Practice. Health visitor

&Professor Rosalind L Smyth FMedSci

Brough Professor of Paediatric Medicine & Head of Division of Child Health, School
of Reproductive & Developmental Medicine, University of Liverpool, Alder Hey
Hospital, Liverpool.

=Dr Angela E Thomas MB BS PhD FRCPE FRCPath FRCPCH

Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Simon Thomas BSc MB ChB MD FRCP¹

Consultant Physician in General Medicine and Clinical Pharmacology at Newcastle
Hospitals NHS Foundation Trust and Professor of Clinical Pharmacology and
Therapeutics at Newcastle University.

Professor Roger Walker BPharm PhD FRPharms FFPH

Consultant in Pharmaceutical Public Health, National Public Health Service for Wales
and Professor in Pharmacy Practice, Cardiff University

Professor Ian V D Weller MD FRCP

Professor of Sexually Transmitted Diseases, University College London Medical
School (**Vice Chair**)

Professor Faith M Williams MA PhD

Professor of Toxicology, Toxicology Unit, The Medical School & Institute for
Research in Environment & Sustainability, University of Newcastle-upon-Tyne

* Chair of the Chemistry, Pharmacy & Standards Expert Advisory Group

+ Chair of the Pharmacovigilance Expert Advisory Group

= Chair of the Biologicals & Vaccines Expert Advisory Group

& Chair of the Paediatric Medicines Expert Advisory Group

% Chair of the Anti Infectives/HIV/Hepatology Expert Advisory Group

++ Chair of the Neurology/Pain/Psychiatry Expert Advisory Group

** Chair of the Cardiovascular/Diabetes/Renal/Respiratory & Allergy Expert
Advisory Group