

SUMMARY OF THE COMMISSION ON HUMAN MEDICINES MEETING HELD ON THURSDAY 11TH & FRIDAY 12TH FEBRUARY 2010

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 for the treatment of complicated and soft tissue infections and nosocomial pneumonia in adults
- a medicine indicated for the symptomatic relief of hayfever and for the treatment of urticaria

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 for symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis
- a medicine for use in the treatment of patients with ulcerative colitis
- a medicine that inhibits gastric acid secretion indicated for the treatment of gastric and duodenal ulcers
- a medicine for symptomatic therapy in cases of poisoning

VARIATIONS *(Any change to the information registered in a marketing authorisation (MA) is referred to as a variation to the MA. MA holders must apply to the Licensing authority for approval of such changes. Variations may range from the addition of a significant new indication to changes in the manufacturing process or straightforward changes in company names)*

The Commission considered and advised on a diagnostic product used to detect blood clots in lung vessels.

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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 for the symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over.

RECLASSIFICATION (*Applications to change the legal status of medicines from use under medical supervision as a Prescription Only Medicine (POM) to a Pharmacy Medicine (P) available under the supervision of a pharmacist (POM to P); or from P legal status to General Sale List (GSL) availability from a wider range of retail outlets (P to GSL).*)

The Commission considered and advised on the following:

- POM to P reclassification of a topical medicine for the symptomatic relief of pain and inflammation
- P to GSL reclassification of a topical medicine for the treatment of rheumatic pains, muscular aches, sprains, strains and sports injuries

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

The Commission was informed that over recent months some postal Yellow Cards have been "returned to sender". Following an investigation by Royal Mail, it was discovered that the redirection instructions had failed and reports have not been delivered to the MHRA as a result.

The Commission was informed of the actions that had been taken by the MHRA to:

- advise stakeholders
- retrieve the missing reports
- expedite analysis of any reports that had been delayed
- ensure the delivery of post had been fully resolved

The Commission noted the actions that had been taken and endorsed the plans for retrieval of Yellow Cards and asked the MHRA to consider the following:

- to ensure that no signals have been missed as a result of this issue
- to ensure that confidence in the reporting of ADRs is restored for both healthcare professionals and members of the public

PAPERS/ OTHER ITEMS

The Commission considered and discussed papers and presentations on the following:

- advice on combined oral contraceptives and missed pills
- the risk of breast cancer in pre- and post-menopausal women using the Mirena intra-uterine system (IUS)

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- a referral procedure for a medicine indicated for growth hormone deficiency in children and adults
- a therapeutic review of a product designed to aid smoking cessation
- the training programme for Principal Investigators for Investigational New Medicines by the Faculty of Pharmaceutical Medicine
- the discontinuation of a medicine indicated for the treatment of symptomatic anaemia associated with chronic renal failure

Proposals to Enable the Sale, Supply and Administration of Medicines by Dental Hygienists and Dental Therapists Under a Patient Group Direction (PGD)

1. The Chairman welcomed a representative from the Department of Health (DH) Dental and Eye Care Services.
2. MHRA introduced the proposals explaining that Commissioners would recall that PGDs are written instructions for the sale, supply or administration of a medicine in an identified clinical situation. There is a legal framework underpinning the development of PGDs and only certain statutorily regulated health professionals are able to use them. The proposals before the Commission recommend that PGDs are extended to Dental Hygienists and Dental Therapists. Both are regulated under the Dentists Act 1984 and registered with the General Dental Council.
3. MHRA went on to say that if recommended by the Commission, the proposals would allow Dental Hygienists and Therapists to sell, supply or administer fluoride supplements and toothpastes. As there are significant regional oral health inequalities across the UK, the proposals would benefit priority groups by enabling preventive treatments to be available to patients without the need to refer the patient back to a dentist.
4. The proposals would also enable Dental Hygienists and Therapists to administer local anaesthesia licensed for dental use. This specifically relates to local infiltration and inferior dental block anaesthesia. The dentist remains responsible for inducing and maintaining anaesthesia by inhalation or intra-venous routes. In response to a question from the Chairman, DH clarified that inferior dental block anaesthesia related to the anaesthesia to the lower jaw This produces anaesthesia of the Inferior Dental Nerve a branch of the Mandibular nerve (the third branch of the Trigeminal nerve). This produces anaesthesia over a large number of teeth (typically all the teeth on the side of the injection). The anaesthetic solution is deposited near the trunk of the nerve. This is in contrast to local infiltration anaesthesia used in the upper jaw, where the anaesthetic solution is deposited at the nerve terminals and produces anaesthesia of a small number (1-3) of teeth.
5. The Commission noted that the British Dental Association had some concern about Dental Hygienists and Therapists administering local anaesthetics for dental use without consulting a doctor and that additional training might be required on the selection and use of alternative anaesthetics for patients. DH confirmed that under existing training Dental Hygienists and Therapists would be required to be competent in the use of the medicines.

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6. Commissioners had several comments and questions around the use of local anaesthetics containing adrenaline. DH advised the Commission that the incidence of adverse incidents involving adrenaline was very low. In response to some concern expressed about its administration to patients with underlying medical conditions, DH explained that Dental Hygienists and Therapists were already trained to undertake this task. They administer medicines in accordance with the dentist's prescription and the treatment plan for the patient (which is also prepared by the dentist). The dentist is accountable for the treatment plan and would be expected to take account of underlying conditions, for example, hypertension. This would not change if the proposals are accepted as similar directions were required under a PGD. However, the PGD proposals would avoid potential delay in treatment by allowing a Hygienist or Therapist to, for example, alter the dose for a patient without the need to obtain another prescription from the dentist. In response to a Commissioner's question, DH confirmed that she considered that Dental Hygienists and Therapists' training was sufficient to allow an element of professional judgement in these circumstances.

7. DH advised Commissioners that Dental Hygienists and Therapists were trained in cardiopulmonary resuscitation (CPR) and continuing professional development was compulsory to maintain their professional registration. Commissioners were reassured to learn that the level of emergency care provided by Hygienists and Therapists would be on a par with that of a dentist.

8. In summarising the Commission's views, the Chairman said that they would endorse the proposals. In reaching that recommendation, to address some residual concerns, the Commission would encourage the DH to explore with the General Dental Council the possibility of the Council offering guidance to the dental profession on the circumstances when adrenaline should or should not be used in practice. The Commission also recommended that the Council might wish to review the current training of Dental Therapists and Hygienists prior to the introduction of PGDs and that the sale, supply or administration of the relevant medicines under a PGD should be based on an accurate and up to date medical history of the patient.

Professional Appointments to Expert Advisory Groups

The following appointments were made to the Commission's Expert Advisory Groups:

- i) **Neurology, Pain & Psychiatry Expert Advisory Group**
Professor Richard S G Knight BA (Oxon) BM BCh FRCP
Professor of Clinical Neurology, Director, National CJD Surveillance Unit,
Western General Hospital, Edinburgh
- ii) **Dr Anthony L Johnson BSc PhD FIS FSS CStat.**
Senior Medical Statistician, MRC Biostatistics Unit, Cambridge and MRC
Clinical Trials Unit, London

- iii) **Biologicals & Vaccines Expert Advisory Group**
Professor Marc L Turner BMBS FRCP FRCPE FRCPATH,
Associate Director, Edinburgh Blood Transfusion Centre

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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, Thomas and Weller 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.
- iii. On Thursday 12th February, the meeting started at 10.10am and finished at 4.30pm. On Friday 12th February, the meeting started at 9.30am and finished at 12.30pm.

The next meeting will take place on **Thursday 11th & Friday 12th March 2010**.

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Useful website links

Drug Safety Update:

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm>

Members' declaration of interests:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=member%27s+declaration+of+interests

European Medicines Agency updates:

<http://www.ema.europa.eu/whatsnewp.htm>

MHRA Website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=5

Yellow Card Website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=yellow+card+website

<http://www.yellowcard.gov.uk>

ANNEX A

Commissioners 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 **Thursday Only**

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 Chairman**)

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

Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

Ms Amanda Hoey

Director, Consumer Health Consulting Ltd - Lay representative

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 FRCP

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

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Dr Rosalind Ranson MB BS MA MRCGP

General Practitioner, London

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 FRCP

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, Public Health 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 Chairman**)

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 Infection/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

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INVITED EXPERTS

Dr Ailsa Gebbie MB ChB FRCOG

Consultant in Community Gynaecology, Family Planning & Well Woman Services,
NHS Lothian, Edinburgh (Vice Chair of Medicines for Women's Health Expert
Advisory Group)

Professor Peter C Hindmarsh BSc MD FRCP FRCPCH

Consultant Paediatric Endocrinologist, Royal Free and, University College Medical School.&
Member of the Paediatric Medicines Expert Advisory Group

OBSERVER

Dr Vanessa A L Graham BA BM BCh FRCP

Consultant Chest Physician, Central Middlesex Hospital and Willesden Chest Clinic
& Member of the Cardiovascular, Diabetes, Renal, Respiratory & Allergy Expert
Advisory Group