

SUMMARY OF THE COMMISSION ON HUMAN MEDICINES MEETING HELD ON THURSDAY 12 JANUARY 2012 and FRIDAY 13 JANUARY 2012

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 biological medicine for the repair of cartilage defects
- a medicine indicated for the treatment of pseudobular affect¹
- a medicine for the treatment of symptomatic vitreomacular adhesion (VMA)²
- a medicine for the treatment of venous thromboembolism
- a medicine for the treatment of moderate to severe active rheumatoid arthritis
- a medicine to make breathing easier for patients who have breathing difficulties due to a lung disease called chronic obstructive pulmonary disease (COPD)
- a medicine to lower high blood phosphorous levels in patients undergoing dialysis due to poor kidney function
- a medicine for the treatment and prevention of bleeding in patients with haemophilia B³

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 the treatment of mild to moderate pain and for use as an antipyretic. To be used in many conditions including headache, toothache, earache, teething, sore throats, colds, influenza, aches, pains and post immunisation fever.
- the treatment of acne
- a medicine used in liver disease
- a medicine for use in the treatment of hypothyroidism
- a medicine for the treatment of erectile dysfunction

¹ A medical condition that causes involuntary, sudden and frequent episodes of laughing and/or crying

² As a person gets older, the vitreous (jelly-like material in the centre of the eye) shrinks and separates from the retina (the light-sensitive layer in the back of the eye). VMA occurs when the vitreous remains attached to the central part of the retina.

³ A condition in which patients are deficient in coagulation Factor IX

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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 medicine for the treatment of polyarticular juvenile idiopathic arthritis⁴ in children aged 4-17 years

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

The Commission noted a 7% increase in the total number of spontaneous reports received in the time period of January to end of December 2011 compared to the same time period in 2010. In the year to date, 49% of reports were from pharmaceutical industry, 44% from the healthcare profession and 7% from members of the public.

The Commission:

- advised on the safety review of hypotonic saline
- noted information relating to a medicine indicated for use in treating type 2 diabetes

Antifibrinolytics: re-assessment of risks and benefits

Antifibrinolytic medicines are used to prevent excessive bleeding which might occur, for instance, during surgery. The antifibrinolytic agent aprotinin has been suspended from the UK market since 2007.⁵ The suspension followed the 'BART' study⁶ which showed that aprotinin was associated with an increased risk of death compared with two other antifibrinolytics, tranexamic acid and aminocaproic acid (the latter of which is currently not licensed for use in the UK).

The Commission recalled its meetings in September 2010, November 2010, June 2011 and October 2011, where assessments on the risks and benefits of aprotinin, tranexamic acid and aminocaproic acid were discussed.

At its current meeting, the Commission considered the latest advice from its Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group⁷ on the issue, and made further recommendations, including the need to collect additional safety data. The Commission's recommendations were taken forward for further discussion within Europe.

⁴ An inflammatory disease, affecting one or more joints, with diagnosis typically occurring in children under the age of 16 years

⁵ <http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON2033201>

⁶ <http://www.ncbi.nlm.nih.gov/pubmed/18480196>

⁷ <http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommissiononHumanMedicines/ExpertAdvisoryGroups/CardiovascularDiabetesRenalRespiratoryandAllergy/index.htm>

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PAPERS/ OTHER ITEMS

The Commission considered and discussed the following:

- issues relating to a licensed antibiotic
- a European reflection paper on data requirements for parenteral liposomal products
- the Department of Transport advisory working group on medicines and driving

Procedural Items

The Chairman welcomed Professor Kevin Taylor to membership of the Commission. 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, Park, Pirmohamed, Smyth, Thomas, Weller and Williams declared interests in one or more agenda items but this did not debar them from taking part in the proceedings.

A list of Commissioners and Invited Experts who attended the meeting is at **Annex A**.

- i. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.
- ii. The meeting started at 10 am on Thursday 12 January and finished at 4.35pm. On Friday 13 January the meeting started at 9.30am and finished at 1.30pm.

The next meeting will take place on 9th and 10th February 2012.

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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=GET_FILE&dDocName=CON091081&RevisionSelectionMethod=Latest

European Medicines Agency updates:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/landing/news_and_events.jsp&url=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac0580022519

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>

COMMISSIONERS ATTENDING:

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

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

Professor Deborah Ashby OBE BSc MSc PhD CStat Hon. MFPHM Hon. MRCR

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

Patient and Public Involvement Officer, Research Design Service, Southampton University

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

Visiting Professor of Pharmaceutical Sciences at the University of Strathclyde

Professor Janet H Darbyshire CBE MB ChB FMedSci FRCP FFPH FRSS (Hon)

Emeritus Professor of Epidemiology, University College London

****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 FRCP (Hon) FBTS

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

+Professor Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP(E)

Professor of Clinical Pharmacology, University of Liverpool, NHS Chair of Pharmacogenetics and Director of the Wolfson Centre for Personalised Medicine

++Professor Stuart Ralston MB ChB MD FRCP (Glas & Edin) FMedSci FRSE

Head of the School of Molecular and Clinical Medicine & Arthritis Research UK Professor of Rheumatology, Molecular Medicine Centre, Western General Hospital, Edinburgh

Dr Rosalind Ranson MB BS MA MRCP

Private General Practitioner, Chelsea Consulting Rooms, London

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&Professor Rosalind L Smyth MA MBBS MD FRCPCH FFPM (Hon) FMedSci
Brough Professor of Paediatric Medicine, Director of NIHR Medicines for Children Research Network, Director of Clinical Research, University of Liverpool Alder Hey Children's NHS Foundation Trust Liverpool

Professor Kevin M G Taylor BPharm PhD MRPharmS
Professor of Clinical Pharmaceutics, UCL School of Pharmacy

=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
Professor of Clinical Pharmacology and Therapeutics at Newcastle University, and Consultant Physician, Newcastle Hospitals NHS Foundation Trust

Professor Ian V D Weller BSc MB BS MD FRCP
Emeritus Professor of Sexually Transmitted Diseases, Research Department of Infection and Population Health, University College London

Invited Expert

Professor Faith M Williams MA PhD FBTS
Professor of Toxicology, Medical Toxicology Centre and Institute of Cellular Medicine, Newcastle University

* 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 Cardiovascular/Diabetes/Renal/Respiratory & Allergy Expert Advisory Group

++ Chair of the Gastroenterology, Rheumatology, Immunology & Dermatology Expert Advisory Group