SUMMARY OF THE COMMISSION ON HUMAN MEDICINES MEETING HELD ON THURSDAY 7TH SEPTEMBER 2017

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.gov.uk) and will be considered in accordance with the FOI Act.

LICENSING

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 to treat men with an enlarged prostate (benign prostatic hyperplasia (BPH)) - a non-cancerous enlargement of the prostate gland
- three medicines indicated for the treatment of bacterial infections
- a medicine indicated for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD).

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 indicated for the use in patients aged 1 year and older with asthma who remain symptomatic on treatments that include an inhaled corticosteroid
- an application to update the terms of a marketing authorisation for a cardiovascular medicine.

CLINICAL TRIAL APPLICATIONS (Applications to conduct clinical trials in the United Kingdom where external advice is required)

The Commission considered and advised on a clinical trial application for a medicine for the treatment of blood cancer.
PHARMACOVIGILANCE (The process of identifying and responding to drug safety concerns arising with marketed medicines)

The Commission noted that there was an 7% increase in the total number of spontaneous reports received up until the end of July 2017 compared to the same period in 2016. The Commission was made aware that in the year to date, 50% of reports were from healthcare professionals, 33% from industry and 17% from patients, parents and carers.

PAPERS/ OTHER ITEMS

The Commission considered and discussed feedback from the ad hoc group on proposals for Independent Prescribing for Paramedics and Diagnostic Radiographers. In conclusion, the Commission endorsed the ad-hoc group’s recommendations to support independent prescribing for paramedics. They also endorsed the recommendation that independent prescribing for diagnostic radiographers should not be supported at this time.

The Commission was given an update on progress on the review of the CHM Expert Working Group on Hormone Pregnancy Tests (HPTs).

Appointments and Reappointments to Expert Advisory Groups (EAGs)

The Commission approved the re-appointment of the following member to the Paediatric Medicines EAG for a period of three years:

Professor Steven Cunningham MBChB PhD FRCPCH (Vice Chair)
Consultant and Honorary Professor in Paediatric Respiratory Medicine, NHS Lothian Royal Hospital for Sick Children and University of Edinburgh

The Commission approved the re-appointment of the following member to the Infection EAG for a period of three years:

Dr Hermione Lyall BSc Hons MB ChB Hons MD FRCPCH
Consultant in Paediatric Infectious Diseases, St Mary’s Hospital, Imperial College Healthcare NHS Trust, London

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 Friedland, Gore, Macleod, Ralston, Taylor, Weir, Professor Sir Munir Pirmohamed and Dr Gilson declared interests in one or more agenda items and the appropriate action was taken.
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. The meeting started at 10:04 on Thursday 7th September and finished at 15:28.

The next meeting will take place on Thursday 5th October 2017 at 10:00 & Friday 6th October 2017 at 09:30.
Useful website links

Drug Safety Update:
https://www.gov.uk/drug-safety-update

Members’ declaration of interests:

European Medicines Agency updates:

MHRA Website:

Yellow Card Website:
http://yellowcard.mhra.gov.uk/
MEMBERSHIP OF THE COMMISSION ON HUMAN MEDICINES

Chair

Professor Stuart Ralston  MB ChB MD FRCP FMedSci FRSE FFPM (Hon)
Arthritis Research UK Professor of Rheumatology, University of Edinburgh, Western General Hospital, Edinburgh

Members

Dr J Colin Forfar  BSc (Hons) MBChB PhD MD MA FRCP FRCP (Edin)
Retired Consultant Physician and Cardiologist, John Radcliffe Hospital, Oxford

Dr Jamie Fraser  BSc MB ChB MRCGP
GP Partner, Southside Surgery, Inverness

Professor Jonathan S Friedland  MA PhD FRCP FRCPE FRCPI FMedSci
Hammersmith Campus Director & Head of Section of Infectious Diseases & Immunity, Imperial College London; Hon Consultant in Infectious Diseases ICHT

Dr Richard J C Gilson  MD FRCP
Reader in Sexual Health and HIV and Honorary Consultant Physician
Director, UCL Centre for Sexual Health and HIV Research Head, Research Department of Infection and Population Health University College London

Professor Martin Gore  CBE MBBS PhD FRCP
Consultant Medical Oncologist, The Royal Marsden NHS Foundation Trust and Professor of Cancer Medicine, Institute of Cancer Research

Professor Malcolm R Macleod  BSc MBChB MRCP PhD FRCP (Edin)
Professor of Neurology and Translational Neurosciences, University of Edinburgh and Honorary Consultant Neurologist, NHS Forth Valley

Dr Rebecca Mann  BMBS FRCPCH
Consultant Paediatrician, Taunton and Somerset NHS Foundation Trust

Dr Siraj Misbah  MBBS (Hons) MSc FRCP FRCPath
Consultant Clinical Immunologist, Lead for Clinical Immunology, Oxford University Hospitals

Professor David G C Owens  MD (Hons) FRCP FRCPsych
Professor of Clinical Psychiatry, Edinburgh University
Professor Sir Munir Pirmohamed MB ChB (Hons) PhD FRCP FRCP (Edin) FBPhS FMedSci
David Weatherall Chair of Medicine, University of Liverpool, NHS Chair of Pharmacogenetics, Associate Executive Pro Vice Chancellor, Director of the Wolfson Centre for Personalised Medicine, Director of the MRC Centre for Drug Safety Science

Professor Kevin M G Taylor BPharm PhD FRPharmS
Chair of the British Pharmacopoeia Commission and Professor of Clinical Pharmaceutics, UCL School of Pharmacy, London

Professor Angela E Thomas MB BS PhD FRCPE FRCPath FRCPCH (Vice-Chair)
Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

Professor Helen M Ward MSc BSc (Hons) RGN RCN Nurse Practitioner PGCEA PG Cert NMP
Associate Professor, Non-Medical Prescribing, London South Bank University

Professor Christopher Weir BSc (Hons) PhD MSc FRSS C.Stat C. Sci
Personal Chair in Medical Statistics and Clinical Trials, Usher Institute of Population Health Sciences and Informatics, University of Edinburgh

Dr Martin Wilson MB ChB, MPhil (Glasgow), FRCP(Edin)
Consultant Physician in Care of the Elderly, Raigmore Hospital, Inverness

Invited Expert

Mrs Madeleine Wang BA (Hons)
Lay Representative. Patient Advocate