

# **SUMMARY OF THE COMMITTEE ON SAFETY OF MEDICINES MEETING HELD ON THURSDAY 12 OCTOBER 2005**

## **LICENSING**

### **Product Specific**

#### **New Products**

- The Committee considered and advised on a vaccine
- The Committee considered and advised on a medicine for use in the adjunctive treatment of *patients experiencing, or at risk of, methotrexate toxicity.*

The Committee considered and advised on a medicine for *the treatment of a genetic biochemical disorder that can cause mental retardation and skeletal problems.*

- **Hearing**
- The Committee heard a company's oral presentation for a medicine to be used in the *treatment of excessive sleepiness*. The Committee was not reassured by the company's oral presentation as to the safety and efficacy of this product and advised the Licensing authority accordingly not to grant a marketing authorisation for wider indications.

### **Pre Hearings**

- The Committee considered a company's written data in response to its letter of 10 May 2004 for a medicine to be used for the *prevention of osteoporosis in postmenopausal women*. The Committee was not reassured by the data and agreed that the company should present their case at an oral hearing. .
- The Committee considered a company's written data in response to its letter of 17 October 2003 for a *thrombolytic medicine*. The Committee was not reassured by the data and agreed that the company should present their case at an oral hearing..

### **Variation**

- The Committee considered and advised on a medicine already licensed for the treatment of breast cancer. The new indication requested is for the "*adjuvant treatment of post menopausal women with hormone receptor positive early breast cancer*".

### **PHARMACOVIGILANCE**

- The Committee considered issues relating to long acting beta -2 adrenoceptor agonists
- The Committee noted and discussed the Pharmacovigilance statistics for the month of September.

### **Other items**

- The Committee considered and advised on issues relating to a device used in the delivery of a medicine for respiratory conditions.
- The Committee noted the international reclassification of Brazil and Chile with respect to ruminant derived materials used in the manufacture of medicines.

***Information that could identify the companies and the names of the products is being withheld on the grounds that this advice remains confidential at the date of this summary and publication would be premature while regulatory action continues. The advice will be published in due course. Section 22 of the Freedom of Information Act 2000 applies.***

### **Procedural Items**

- i. In addition, the Committee completed its usual procedural business including the need to observe the confidentiality of the meeting, and to declare interests. Apologies, announcements, approval of minutes and updates following the July CHMP meeting

were discussed. Professors Chipman, Darbyshire, Smyth, Weller, Drs Donaghy, Forfar and Leonard declared interests in one or more agenda items.

- ii. A list of Members who attended the meeting is at **Annex A**.
- iii. Medicines Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.
- iv. The meeting started at 10am and finished at 3.50pm.

The next meeting of the Committee is scheduled for **Wednesday 27 October 2005 at 10.00am**

### **Useful website links**

#### ***Current problems in Pharmacovigilance:***

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=433&within=Yes&keywords=current+problems+in+pharmacovigilance](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=current+problems+in+pharmacovigilance)

#### ***Member's declaration of interests:***

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=433&within=Yes&keywords=member%27s+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 Evaluation Agency updates:***

<http://www.emea.eu.int/whatsnewp.htm>

#### ***MHRA Website:***

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=5](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.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=yellow+card+website)

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

### **MEMBERS ATTENDING**

#### **Professor Gordon W Duff MA BM BCh PhD FRCP, FRCPE, FMedSci**

Professor of Molecular Medicine & Director of Division of Genomic Medicine,  
Sheffield University: **CHAIRMAN**

#### **Dr Barbara A Bannister MSC FRCP**

*Consultant in Infectious and Tropical Diseases & Clinical Head of Service Infection & Immunity, Royal Free Hospital*

#### **Dr Timothy L Chambers JP MBBS FRCP FRCPE FRCPI FRCPCH**

*Consultant Paediatrician, Southmead Hospital, Bristol and Senior Clinical Lecturer in Child Health, Bristol University*

#### **Professor James K Chipman BSc PhD F I Biol FRCPATH**

*Professor of Cell Toxicology, Birmingham University*

**Professor Janet H Darbyshire OBE MB ChB FRCP**

*Professor of Epidemiology and Director of the MRC Clinical Trials Unit, Royal Free and University College London Medical School, University College, London*

**Dr Michael J Donaghy D. Phil(Oxon) FRCP co-vice Chairman**

*Reader in Clinical Neurology, Oxford University & Consultant Neurologist, Radcliffe Infirmary, Oxford.*

**Dr J Colin Forfar BSc (Hons) MD PhD FRCPE FRCP**

*Consultant Cardiologist, John Radcliffe Hospital, Oxford, Senior Lecturer in Medicine, University of Oxford, Director of Cardiac Medicine and Clinical Centre Chair, Oxford Regional Heart Centre*

**Professor Jennifer Hunt Han.D.Sci, M. Phil BA (Hons) RGN FRCN**

*Research Consultant*

**Professor Michael J S Langman BSc MD FMedSci FRCP**

*Professor of Medicine, Birmingham University Medical School*

**Dr Rosemary Leonard MBE MA MB, BChir MRCGP DRCOG**

*Principal in General Practice, London*

**Dr Ann B Millar MB chB MD FRCP**

*Consultant Senior Lecturer in Respiratory Medicine, Bristol University*

**Professor B Kevin Park BSc PhD Hon MRCP**

*Professor of Pharmacology, Liverpool University.*

**Professor Munir Pirmohamed MC ChB PhD FRCP**

*Professor of Clinical Pharmacology, Liverpool University*

**Professor John F Smyth MD FRCS(Ed) FRCP (L&E)**

*Professor of Medical Oncology and Head of Division of Molecular and Clinical Medicine, University of Edinburgh*

**Professor Ian V D Weller MD FRCP - co vice chairman**

*Professor of Genitourinary Medicine, University College London Medical School.*

**Dr Patricia Wilkie PhD**

*Lay Representative*

**GUEST MEMBERS**

**Professor Kevin Morgan PhD**

*Department of Human Sciences and Sleep Research Centre, Loughborough University*

**Professor Anthony N Nicholson OBE MB ChB FRCP FFOM FRACS FRCPPath**

*Medical Director Academic Clinic for Disorders of Sleep and Wakefulness, MRC School of Biomedical & Molecular Sciences, Surrey University*