

# **SUMMARY OF THE COMMITTEE ON SAFETY OF MEDICINES MEETING HELD ON THURSDAY 29 SEPTEMBER 2005**

## **LICENSING**

### **Product Specific**

#### **Abridged**

- The Committee advised on a medicine to be used in the treatment of intracocular hypertension and chronic open – angle glaucoma and concluded that therapeutic equivalence with the brand leader had not been established.
- The Committee advised on a medicine (a nasal spray) to be used for seasonal allergic (including hayfever) and perennial rhinitis and concluded that therapeutic equivalence with the brand leader had not been established.
- The Committee advised on a medicine (a cream and an ointment) to be used in the treatment of severe inflammatory skin disorders and concluded that therapeutic equivalence with the brand leader had not been established.
- The Committee advised on a medicine to be used in the treatment of acne vulgaris and concluded that therapeutic equivalence with the brand leader had not been established. In addition the Committee felt that the side effects profile should be further examined.
- The Committee advised on an antibiotic and concluded that therapeutic equivalence with the brand leader had not been established.

#### **New Product**

- The Committee considered and advised on a medicine to be used in the treatment of diabetes.

#### **Variations**

- The Committee advised on a medicine already licensed for psychotic conditions to add an indication to include the treatment of conditions associated with autism in children and adolescents. The Committee agreed that the variation should be granted provided the product particulars were amended.
- The Committee advised on medicines already licensed in the treatment of low dose hormone replacement therapy to add an indication for the treatment of the prevention of osteoporosis. The Committee were not satisfied that safety and efficacy had been proven.

## **PHARMACOVIGILANCE**

- The Committee considered and advised on matters relating to a medicine used in the treatment of attention deficit hyperactivity disorder in children and adolescents aged 6 years and over.
- The Committee received the report of the Patient Adverse Drug Reaction Reporting Working Group and noted that the yellow card for patients would be launched towards the end of October.

- The Committee noted the Pharmacovigilance statistics for the month of August.

## **OTHER ITEMS**

- The Committee noted the consultation document ARM 33 – a proposal to reclassify fluconazole 150mg capsules from P to GSL.

*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 Buckton, Darbyshire, Dargie, Jeffries, Nutt, Weller, Woodhouse and Dr Donaghy 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 12 October 2005 at 10.00am**

## **Useful website links**

Current problems in Pharmacovigilance:

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=368](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=368)

Member's declaration of interests:

<http://www.mhra.gov.uk/home/groups/es-cb/documents/committeedocument/con2015703.pdf>

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=286](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=286)

<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**

**Professor Deborah Ashby BSc MSc PhD CStat Hon. MFPHM Hon. MRCR**  
Professor of Medical Statistics, London University.

**Ms Helen K Barnett BPharm MSc LicAc MBAC**  
Lay Representative

**Professor Graham Buckton BPharm PhD DSc FRPharmS FRSC**  
Professor of Pharmaceutics, School of Pharmacy, University of London:

**Professor John Caldwell BPharm PhD DSc CBiol FIBiol Hon. MRCP**  
Professor of Biochemical Toxicology and Dean, Faculty of Medicine, Liverpool  
University

**Dr Robert T Calvert BSc PhD FRPharmS**  
Former Consultant in Medicines Management, North & East Yorkshire & North Lincs  
Health Authority(retired)

**Professor Henry J Dargie MB ChB FRCP FESC**  
Consultant Cardiologist & Co-Director of CRI in Heart Failure, Glasgow University

**Dr Michael John Donaghy D. Phil(Oxon) FRCP co-vice Chairman**  
Reader in Clinical Neurology, Oxford University & Consultant Neurologist, Radcliffe  
Infirmary, Oxford.

**Professor Jennifer Mary Hunt Hon.D.Sci, M. Phil BA (Hons) RGN FRCN**  
Research Consultant Professor Donald J Jeffries BSc MBBS FRCP FRCPPath  
Professor of Virology, St. Bartholomew's Hospital, London

**Professor Martin John Kendall MB ChB MD FRCP**  
Professor of Clinical Pharmacology, Birmingham University Medical School.

**Dr Terence A Maguire BSc PhD MCPP**  
Pharmacy Contractor, Northern Ireland

**Professor Klim McPherson BA MA PhD FFPHM FMedSci**  
Visiting Professor of Public Health Epidemiology, Churchill Hospital, Oxford

**Professor David Nutt DM FRCP FRCPsych FMedsci**  
Professor of Psychopharmacology, Bristol University

**Professor Stuart Hamilton Ralston MD, FRCP, FMedSci, FRSE**  
Professor of Medicine and Bone Metabolism, Rheumatic Diseases Unit, Western General  
Hospital

**Professor Robert Read MD FRCP**

Professor of Infectious Disease Division of Genomic Medicine & Biomedical Science,  
Sheffield

**Dr Ross Jenkins Taylor MB ChB MD FRCP (Edin) FRCGP DCH**

Senior Lecturer in General Practice, University of Aberdeen & General Medical  
Practitioner Principal, Grampian Health Board.

**Dr Angela E Thomas MB BS PhD FRCP(E) FRCPath FRCPCH**

Consultant Paediatric Haematologist, Royal Hospital for Sick Children, 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

**Professor Kenneth W Woodhouse MD FRCP ILTM**

Professor of Geriatric Medicine & Pro Vice Chancellor, University of Wales College of  
Medicine, Cardiff.

**Guest Members**

**Professor Eric Taylor MA MB FRCP FRCPsych FMedSci**

Professor of Child & Adolescent Psychiatry, Institute of Psychiatry, King's College,  
London and

**Mr Richard Mills**

Director of Research, National Autistic Society

**Observers**

**Mrs Madeline Wang**

Lay **and** the Patient ADR Reporting WG

**Mrs Barbara Wood MA (CantB)**

Barrister **and** the Patient ADR Reporting WG .