

SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON THURSDAY 03 DECEMBER 2009

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 Paediatric Medicines Expert Advisory Group 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.

Papers

The EAG noted:

- A presentation introducing the Paediatric Regulation

Paediatric Investigation Plans

The EAG considered and advised on

- A medicine for the treatment of anaemia associated with chronic renal failure.
- A medicine for the treatment of overactive bladder syndrome.
- A medicine for the treatment of Major Depressive Episodes, Generalised Anxiety Disorder and chronic low back pain.

Article 45 Procedures

The EAG considered and advised on

- A medicine for used as an anaesthetic and analgesic agent in neonates and children.

Procedural Items

In addition, the EAG completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, agree its minutes, apologies and announcements. No interests were declared.

- i. A list of Members who attended the meeting is at **Annex A**.
- ii. Medicines and Healthcare products Regulatory Agency staff may be present for all or part of the meetings or for specific items.

The meeting started at 11 am and closed at 2:30 pm.

The next meeting is scheduled for **Tuesday 5 January 2010 at 11 am**.

Useful website links

EMA – MEDICINES FOR CHILDREN

<http://www.emea.europa.eu/htms/human/paediatrics/studies.htm>

Drug Safety Update: Volume 2 Issue 10, May 2009

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON046451>

Drug Safety Update: Volume 2 Issue 9, April 2009

<http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/CON043809>

Drug Safety Update:

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

Member's declaration of interests:

<http://www.mhra.gov.uk/home/groups/l-ctu/documents/websiteresources/con2022959.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

Yellow Card Website:

<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Medicines/index.htm>

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

MEMBERS ATTENDING

Chair

Professor Michael Stevens MD FRCP FRCPCH FRCR (Vice Chair)

CLIC Professor of Paediatric Oncology, University of Bristol

Members

Dr Eileen M Baildam MB ChB DRCOG DCH RCP FRCP FRCPCH

Consultant Paediatric Rheumatologist, Alder Hey Children's NHS Foundation Trust

Dr Steven Cunningham PhD FRCPCH FRCP

Consultant Respiratory Paediatrician, Royal Hospital for Sick Children, Edinburgh

Professor Ruth Gilbert MB ChB MSc MD FRCPCH

Professor of Epidemiology, Institute of Child Health & UCL

Dr Rebecca Mann BMBS FRCPCH

Consultant Paediatrician, Taunton and Somerset Hospital

Professor Anthony Nunn BPharm FRPharmS Hon FRCPCH

Clinical Director of Pharmacy, Alder Hey Children's NHS Foundation Trust & Associate Director, NIHR Medicines for Children Research Network, University of Liverpool; Industry Professor, School of Pharmacy and Biomedical Sciences, Liverpool John Moores University

Dr Shirley Price MSc, PhD, FBTS, ERT, FHEA

Director of Postgraduate Taught Studies, Division of Biochemical Sciences, Faculty of Health and Medical Sciences, University of Surrey,

Dr Jane Tizard MBBS, FRCP, FRCPCH

Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

Dr Heather Wallace PhD FRCPath FBTS ERT

Senior Lecturer, Department of Medicines and Therapeutics, University of Aberdeen

Dr William P Whitehouse BSc MB BS DCH FRCP FRCPCH

Clinical Senior Lecturer in Paediatric Neurology, Dept of Child Health, Queen's Medical Centre, Nottingham

Dr Geoffrey Wong MA MD(Res) MBBS MRCP FHEA

GP Principal and Walport Clinical Lecturer in Primary Care, UCL

Dr Edward Wozniak BSc MB BS FRCP FRCPCH

Professional Adviser in Paediatrics, Department of Health