

SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON MONDAY 7 SEPTEMBER 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 considered and advised on

- Future Pharmacovigilance for Children's Medicines.

The EAG noted:

- A EU guideline on the investigation of medicinal products in term and pre-term neonate.

Paediatric Investigation Plans

The EAG considered and advised on

- A medicine for the treatment of symptomatic anaemia associated with chronic kidney disease in patients aged 2 to 18 years.

Article 46 Procedures

The EAG considered and advised on

- A medicine for the treatment of children and adolescents with ADHD and comorbid conditions, including oppositional defiant disorder (ODD) and reading disorder.

Abridged Application

The EAG considered and advised on

- A medicine proposed for use as an adjunct to diet when response to other treatments is inadequate.

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 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 **Monday 05 October 2009 at 11 am.**

Useful website links

EMEA – 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

Mrs Alison Bowser

Independent lay representative Royal College of GPs, Cornwall and Isles of Scilly PCT, NICE medicines concordance guidelines development group & Member of Pharmacovigilance, Patient Information and Dermatology EAGs

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

DR GEORGE RYLANCE MB CHB FRCPCH

Consultant Paediatrician & Paediatric Clinical Pharmacology, School of Clinical Medical Sciences (Child Health), University of Newcastle upon Tyne

Dr Jane Tizard MBBS, FRCP, FRCPCH

Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

Mrs Madeleine Wang

Patient Advocate

Professor Andrew Wolf MB B Chir FFA RCS Eng

Paediatric Anaesthesiology, Intensive Care and Pain Management, Bristol Royal Infirmary

Dr Geoffrey Wong MA MD(Res) MBBS MRCGP FHEA

GP Principal and Walport Clinical Lecturer in Primary Care, UCL

Dr Edward Wozniak BSc MB BS FRCP FRCPCH

Consultant Paediatrician and Trust Associate Medical Director, Portsmouth Hospitals NHS Trust, (CMO representative)

Dr Morris Zwi MB BCh FRCPsych

Consultant Child & Adolescent Psychiatrist Richmond Royal Hospital

Commission Observer

Professor Anthony Nunn BPharm FRPharmS Hon FRCPCH

Clinical Director of Pharmacy, Royal Liverpool Children's NHS Trust & Associate Director
Medicines for Children Research Network, University of Liverpool, Industrial Professor, School of
Pharmacy and Chemistry, Liverpool John Moores University