

SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON WEDNESDAY 10 JUNE 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.

Abridged Applications

The EAG considered and advised on

- A medicine for the treatment of asthma

Article 29 Referral

The EAG considered and advised on

- A medicine for the treatment of short stature in pubertal boys with growth hormone deficiency (GHD), in combination with exogenous growth hormone (GH).

Paediatric Investigation Plans

The EAG considered and advised on:

- A medicine for the treatment of patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency and/or urinary frequency in children from 6 years to 18 years of age.
- A medicine for the treatment of juvenile idiopathic arthritis (JIA)
- A liquid formulation for a medicine for the treatment of malignant glioma in children.

Follow Up Measures

The EAG considered and advised on

- A medicine for the treatment of children and adolescents aged 8 years and above suffering from moderate to severe major depressive episodes unresponsive to psychological therapy after 4-6 sessions.

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. The EAG also noted that Mrs Jane Houghton the nurse member had resigned due to pressure of work. It should be noted that the 12 May meeting was cancelled.

- 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 **Tuesday 07 July 2009 at 11 am**.

Useful website links

Title: Drug Safety Update: Volume 2 Issue 10, May 2009

You can find the section/document here:

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

Title: Drug Safety Update: Volume 2 Issue 9, April 2009

You can find the section/document here:

<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 Rosalind Smyth FMedSci

Brough Professor of Paediatric Medicine & Head of Division of Child Health, School of Reproductive & Developmental Medicine, University of Liverpool, Alder Hey Hospital, Liverpool.

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

Dr Paul Ewings BSc MSc PhD CStat FRSS

Head of Research & Development and Director of Peninsula and Taunton & Somerset R & D Units

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 Vas M Novelli FRACP FRCP FRCPCH

Consultant in Paediatric Infectious Diseases Unit, Great Ormond Street Hospital

Professor Michael Stevens MD FRCP FRCPCH FRCR (Vice Chair)

CLIC Professor of Paediatric Oncology, University of Bristol

Dr Jane Tizard MBBS, FRCP, FRCPCH

Consultant Paediatric Nephrologist, Bristol Royal Hospital for Children

Mrs Madeleine Wang

Patient Advocate

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

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

Invited Experts

Professor Peter J Helms MB BS PhD FRCP FRCPCH FFSEM

Professor of Child Health, University of Aberdeen and Consultant Paediatrician, Royal Aberdeen Children's Hospital **Chair of Respiratory & Allergy EAG**

***Professor Peter C Hindmarsh BSc MD FRCP FRCPCH**

Professor of Paediatric Endocrinology, Royal Free and University College Medical School. London

***Professor Ann Millar MBChB MD FRCP**

Professor in Respiratory Medicine, Bristol University & Honorary Consultant North Bristol NHS Trust **Member of Respiratory & Allergy EAG**

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

* via telephone