

SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON MONDAY 29 JANUARY 2010

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 and discussed:

- A paper on the progress of the EAG in 2009.
- A draft European guideline relating to the treatment of attention deficit hyperactivity
- Issues surrounding the study and use of dopamine agonists in children with a diagnosis of restless legs syndrome
- Issues relating to a medicine indicated for the symptomatic treatment of anaemia associated with renal disease and myeloid malignancies.

Paediatric Investigation Plans

The EAG considered and discussed:

- A medicine for the treatment of moderate to severe pelvic pain in post menarcheal girls with refractory endometriosis.
- A solution for the supportive antiseptic treatment of wounds.

Article 45 Procedures

The EAG considered and advised on:

- A medicine which has unique anti-inflammatory and anti-proliferative effects with applications for the treatment of rheumatic and non rheumatic diseases.
- A medicine currently licensed for the treatment of episodes of major depression in adults.

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 and welcomed to two new members, Ms Lyn Hagger and Professor Peter Hindmarsh to membership. 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 11:00 am and closed at 1:30 pm.

The next meeting is scheduled for **Thursday 02 March 2010 at 11:00 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/websitesresources/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

Ms Lynn E Hagger MA LL.B

Lay representative

Professor Peter C Hindmarsh BSc MD FRCP FRCPCH

Consultant Paediatric Endocrinologist, Royal Free and, University College Medical School.

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 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

Professor of 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 Morris Zwi MB BCh FRCPsych

Consultant Child & Adolescent Psychiatrist, Richmond Royal Hospital