

## **SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON MONDAY 5 OCTOBER 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](mailto:info@mhra.gsi.gov.uk)) and will be considered in accordance with the FOI Act.

### **Papers**

The EAG noted:

- A presentation about Patient Information - the public face of the medicine

The EAG considered and advised on:

- Review of UK Paediatric Strategy on Medicines for Children

### **Paediatric Investigation Plans**

The EAG considered and advised on

- A medicine for the treatment of insomnia

### **Article 45 Procedures**

The EAG considered and advised on

- A medicine for which no paediatric formulation existed and which is currently licensed for the treatment of postmenopausal osteoporosis, for steroid-induced osteoporosis in postmenopausal women and for Paget's disease 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. 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 **Thursday 03 December 2009 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](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

**Dr Paul Ewings BSc MSc PhD CStat FRSS**

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

**Professor Diana Gibb MBChB MD MRCP MSc**

Professor in Epidemiology, Medical Research Council Clinical Trials Unit, London  
Honorary Consultant Paediatrician, Great Ormond Street Hospital for Children NHS Trust and  
Honorary Senior Lecturer, Institute of Child Health, London

**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 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

**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 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