

## **SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON THURSDAY 23 APRIL 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.

### **European Work Sharing Procedures**

The EAG considered and advised on:

- Skeletal muscle relaxants
- Medicines affecting bone metabolism

### **Paediatric Investigation Plans**

The EAG considered and advised on:

- A medicine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).
- A medicine for the treatment of Major Depressive disorder (MDD).
- A medicine for the treatment of breakthrough pain in children.

### **Papers**

The EAG considered and advised on

- A therapeutic review of medicines used in the treatment of paediatric patients under 12 years of age with asthma.

### **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 Professor Diana Gibb had been appointed to the EAG. The EAG also welcomed an observer from the CHMP Paediatric Committee.

- 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 12 May 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](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 (Chair)**

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

**Professor Richard Cooke MD FRCP DCH**

Professor of Neonatal Medicine, Liverpool Women's Hospital

**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

**Dr George Rylance MB ChB FRCPCH**

Consultant Paediatrician & Paediatric Clinical Pharmacology, Royal Victoria Infirmary, Newcastle

**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 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