

SUMMARY OF THE PAEDIATRIC MEDICINES EXPERT ADVISORY GROUP MEETING HELD ON TUESDAY 7 JULY 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.

Paediatric Investigation Plans

The EAG considered and advised on:

- A medicine for the treatment of patients with locally advanced or metastatic NSCLC after failure of at least one prior chemotherapy regimen.

Paper

- The EAG considered and advised on a renewed UK strategy on medicines for children.

Article 45 Procedures

The EAG considered and advised on:

- Two medicines used for the symptomatic relief of mild to moderate osteoarthritis of the knee.

Abridged Applications – Pre Hearings

The EAG considered and advised on:

- a medicine for the potential to treat children with chronic kidney disease associated with hypertension, proteinuria or both.
- A medicine for potential use in the management of hypertension.

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 congratulated Dr Chambers on the receipt of his OBE for services to medicines. No interests were declared. The minutes were amended to show that Professor Nunn was present for the meeting.

- 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 2:15 pm.

The next meeting is scheduled for **Monday 7 September 2009 at 11 am.**

Useful website links

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

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.

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

Dr Rebecca Mann BMBS FRCPCH

Consultant Paediatrician, Taunton and Somerset Hospital

Dr Vas Novelli FRACP FRCP FRCPCH

Consultant in Paediatric Infectious Diseases Unit, Great Ormond Street 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 George Rylance MB ChB FRCPH

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

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

Professor Andrew Wolf MB B Chir FFA RCS Eng

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

Dr Heather Wallace PhD FRCPATH FBTS ERT

Senior Lecturer, Department of Medicines and Therapeutics, University of Aberdeen

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

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