

## **SUMMARY MINUTES OF THE BIOLOGICALS & VACCINES EXPERT ADVISORY GROUP HELD ON MONDAY 12TH 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 Biologicals and Vaccines 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.*

The Biologicals and Vaccines Expert Advisory Group (BVEAG) considered and made recommendations to the Commission on Human Medicines (CHM) on the following applications:

**ABRIDGED** (*Applications for new licences for known drug substances which rely in part on previously submitted data or on data submitted by other licence holders*)

- a product for active immunisation against tetanus, diphtheria and pertussis in persons aged 4 years and over as a booster

### **PAPERS/ OTHER ITEMS**

- a medicine indicated for imaging in the treatment of breast cancer
- an update on the Human Papillomavirus (HPV) vaccine

### **Procedural Items**

In addition, the EAG completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements, approval of minutes and European updates. Professor Read declared interests in one or more agenda items.

- i. A list of EAG members and invited experts 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.
- iii. The meeting started at 10.30am on Monday 12<sup>th</sup> October 2009 and finished at 1pm.

The next meeting will take place on **9<sup>th</sup> November 2009**.

## **SUMMARY MINUTES OF THE BIOLOGICALS & VACCINES EXPERT ADVISORY GROUP HELD ON MONDAY 12TH OCTOBER 2009**

Useful website links

***Drug Safety Update:***

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

***Members' declaration of interests:***

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=433&within=Yes&keywords=member%27s+declaration+of+interests](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=member%27s+declaration+of+interests)

***European Medicines Evaluation Agency updates:***

<http://www.ema.europa.eu/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/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=433&within=Yes&keywords=yellow+card+website](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=yellow+card+website)

<http://www.yellowcard.gov.uk>

**SUMMARY MINUTES OF THE BIOLOGICALS & VACCINES EXPERT  
ADVISORY GROUP HELD ON MONDAY 12TH OCTOBER 2009**

**ANNEX A**

**MEMBERS ATTENDING:**

**Dr Angela E Thomas MB BS PhD FRCPE FRCPATH FRCPCH (Chair)**

Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh

**Professor Christopher Bucke BSc PhD F.I.I. Biotech**

Professor of Biotechnology, Westminster University

**Dr Stephen C Inglis BSc PhD**

Director, National Institute for Biological Standards and Control (NIBSC)

**Dr Helen J Lachmann BA BChir (Cantab) MA MB (Cantab) MRCP MD CCST**

Senior Lecturer/Honorary Consultant Nephrologist, National Amyloidosis Centre,  
Department of Medicine, Royal Free and University College Medical School (RFUCMS)

**Professor Elizabeth Miller OBE, BSc, MB.BS, FRCPATH, FFPHM**

Consultant Epidemiologist, Immunisation Department, Centre for Infections, Health  
Protection Agency

**Professor Robert C Read MBChB, BMedSci, MRCP, M.D, FRCP**

Professor of Infectious Diseases, University of Sheffield and Hon. Consultant  
Physician Central Sheffield Teaching Hospitals Trust, Royal Hallamshire Hospital

**Carolyn, Lady Roberts RGN RHV MSc**

Chair, The Ethox Foundation-Oxford Centre for Ethics and Communication in  
Healthcare Practice. Health visitor - Lay representative

**Dr Robin Thorpe BSc, PhD, FRCPATH**

Head, Division of Biotherapeutics, National Institute for Biological Standards and Control  
(NIBSC)