

**SUMMARY OF THE ONCOLOGY & HAEMATOLOGY EXPERT  
ADVISORY GROUP MEETING HELD ON THURSDAY 1<sup>ST</sup> FEBRUARY 2007**

*Information that could identify the companies and the names of the products is being withheld on the grounds that this advice remains confidential at the date of this summary and publication would be premature while regulatory action continues. The advice will be published in due course. Section 22 of the Freedom of Information Act 2000 applies.*

**LICENSING**

**Product Specific**

**New Products**           *(not previously licensed in the United Kingdom)*

- The EAG considered and advised on a medicine to be used in the characterisation of lymph nodes in the evaluation of tumour spread in pelvic cancers.
- The EAG considered and advised on a medicine to be used for maintenance of remission in adult patients with acute leukaemia in first remission to prolong the duration.
- The EAG considered and advised on a medicine to be used for the treatment of advanced renal cell carcinoma.
- The EAG considered and advised on a medicine to be used in patients with advanced breast cancer whose tumours overexpress and who have not received prior therapy.
- The EAG considered and advised on a medicine to be used for the treatment of chronic myeloid leukaemia in chronic or accelerated phase.

**Reclassifications**

- The EAG considered and advised on a medicine to be used for the reduction of heavy menstrual bleeding in women with regular (21-35 day) cycles.

**Other Items**

- European Scientific Advice procedure - –medicine to be used in the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC) in combination with chemotherapy

## **Procedural Items**

As this was the 1<sup>st</sup> meeting of the EAG, the Chairman welcomed members who introduced themselves. There followed an induction programme which included giving the background to the work of the Medicines Healthcare products Regulatory Agency as it related to the licensing of medicines and pharmacovigilance, the interactions with Europe and the advisory body system. The Chairman also gave a background introduction on the code of practice and interests in the pharmaceutical industry and the importance of being vigilant.

In addition, the EAG completed procedural business including the need to observe the confidentiality of the meeting, to declare interests, apologies, announcements and minutes. Professors Hancock, Lederman, Linch and Smyth declared interests in one or more agenda items

- i. A list of members who attended the meeting is at **Annex B**.
- 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 2pm and finished at 4.30pm

## **Useful website links**

*Current problems in Pharmacovigilance:*

[http://www.mhra.gov.uk/home/idcplg?IdcService=SS\\_GET\\_PAGE&nodeId=433&within=Yes&keywords=current+problems+in+pharmacovigilance](http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=433&within=Yes&keywords=current+problems+in+pharmacovigilance)

*Member's 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.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/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>

## **MEMBERS ATTENDING**

### **Professor John F Smyth MD FRCP FRCS FRCR FRS**

*Professor of Medical Oncology & Director of the CR UK Cancer Research Centre,  
University of Edinburgh: Chair*

### **Professor J Cassidy MBChB MD MSc FRCP (G&E)**

*Professor of Oncology & Head of Dept of Cancer Research UK Dept of Medical  
Oncology, University of Glasgow*

### **Professor B W Hancock DCH MD FRCP FRCR**

*Professor of Clinical Oncology, University of Sheffield*

### **Dr Alison Jones, MB ChB, JCHMT, MD, FRCP**

*Medical Oncology, Department of Oncology, Royal Free Hospital,*

### **Professor Jonathan A Ledermann BSc MB BS MD FRCP**

*Professor of Medical Oncology Royal Free and University College Medical School,  
UCL & Hon Consultant in Medical Oncology, UCL Hospitals NHS Foundation Trust.*

### **Professor David C Linch MA BChir FRCP FRCPath FMedSci**

*Professor of Haematology, Royal Free & University College Medical School*

### **Emeritus Professor E C Gordon Smith MA MSc FRCPath FRCP FRCPE FMedSci**

*Professor of Haematology, St George's Hospital, University of London*

### **Professor Michael C G Stevens MD FRCP FRCPCH FRCR**

*CLIC Professor of Paediatric Oncology, University of Bristol*