

SUMMARY MINUTES OF THE BIOLOGICALS SUB-COMMITTEE HELD ON MONDAY 10th OCTOBER 2005

1. Drug Related

The Sub-committee considered the following:

Licensing – New Products

- The Sub-committee considered an incoming mutual recognition procedure indicated for the immunisation of children against tick-borne encephalitis.
- The Sub-committee considered a centralised procedure for use in the adjunctive treatment of patients experiencing or at risk of methotrexate toxicity.

Licensing – Pre-Hearing

- The Sub-committee considered the viral safety of a national application for a thrombolytic product.

Other Issues

- The Sub-committee discussed three papers on:
 - i. batch release of a vaccine.
 - ii. risk assessment of UK medicinal products Following the GBR reclassification of Brazil and Chile
 - iii. an update on Prion in Human Urine

Information which 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.

2. **Procedural Issues**

In addition, the Sub-committee completed its usual procedural business including the need to observe the confidentiality of the meeting, to declare interest, apologies, announcements and approval of minutes. Dr Inglis declared non-personal non-specific interest in one or more items.

A list of Members who attended the meeting is at **Annex A**.

Medicines Healthcare and products Regulatory Agency staff may be present for all or part of the meeting or for specific items.

The meeting commenced at 10:30am.

Useful website links

MHRA Website:

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=5

MEMBERSHIP OF THE BIOLOGICALS SUB-COMMITTEE

Professor Donald J Jeffries BSc MBBS FRCP FRCPath – (Chairman)

Professor of Virology, St Bartholomew's Hospital, London

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

Professor of Biotechnology, Westminster University

Professor Derek H Calam OBE MA DPhil CChem FRSC Hon MRPharmS

Chair of the British Pharmacopoeia Commission and European Directorate for the Quality of Medicines Certification Steering Committee. Visiting Professor, Strathclyde University.

Dr Stephen C Inglis BSc PhD

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

Emeritus Professor Nicholas A Mitchison BA D.Phil FRS

Professor of Immunology, University College London Medical School

**Emeritus Professor Geoffrey C Schild CBE BSc PhD FIBiol FRCPath Hon. MRCP
FRCP (Ed)**

Emeritus Professor of Vaccines, Imperial College School of Medicines, University of London

Dr Angela Thomas MB BS PhD FRCP(E) FRCPath FRCPCH (Vice Chair)

Consultant Paediatric Haematologist, Royal Hospital for Sick Children, Edinburgh and Regional Adviser in Paediatrics