

SUMMARY OF THE CHEMISTRY, PHARMACY & STANDARDS HELD ON WEDNESDAY 16th FEBRUARY 2005

1. Drug Related

The Sub committee considered:

Licensing - Pre- Hearing

- the company's response data for a drug indicated for the relief of post-operative pain for up to 48 hours. The Sub committee considered the pharmaceutical issues and were reassured on quality and agreed to advise the Committee on Safety of Medicines accordingly.
- the company's response data for a drug indicated for the reduction of intraocular pressure (IOP) in patients with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers. The Sub committee considered the pharmaceutical issues and were reassured on quality and agreed to advise the Committee on Safety of Medicines accordingly.

Licensing - New Products

- a centralised application indicated for the treatment of complicated skin and soft tissue infections (cSSTI) suspected or known to be caused by Gram positive bacteria. The Sub committee considered the pharmaceutical issues and were reassured on quality and agreed to advise the Committee on Safety of Medicines accordingly.

Licensing - Abridged

- a national application indicated in the regular treatment of asthma where use of a combination is appropriate and symptomatic treatment of patients with severe COPD and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators. The Sub committee considered the pharmaceutical issues and were not reassured on quality and agreed to advise the Committee on Safety of Medicines accordingly.
- a mutual recognition procedure indicated for the long-term treatment of persisting, moderate to severe bronchial asthma in patients requiring bronchodilator therapy in combination with long-term anti-inflammatory therapy. The Sub committee considered the pharmaceutical issues and were not reassured on quality and agreed to advise the Committee on Safety of Medicines accordingly.

Other Issues

The Sub committee noted a paper on Nanoscience and nanotechnologies for information and were asked to send in comments.

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. Procedures

In addition, the Sub Committee completed its usual procedural issues such the need to declare interests, apologies, announcements, approval of minutes and updates. Professors Buckton, Clark, Denyer, Griffin, Marriott, Meredith and Dr Eccleston declared interests in one or more agenda items.

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

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

The meeting commenced at 10:30am.

- 3.** The next meeting of the Sub Committee is scheduled for 16th March 2005 at 10.30am.

**MEMBERSHIP OF THE CHEMISTRY, PHARMACY
AND STANDARDS SUB-COMMITTEE (CPS)**

(1 April 2002 to 31 March 2005)

Professor Graham Buckton BPharm PhD DSc FRPharmS FRSC
Professor of Pharmaceutics, School of Pharmacy, University of London:
(Chairman)

Professor Michael E. Aulton BPharm, PhD MRPharmS
Professor of Pharmaceutical Technology and Head of Graduate School, De
Montfort University

Professor Brian J Clark MSc PhD CChem FRSC
Professor of Pharmaceutical and Biomedical Analysis, Bradford University

Professor Stephen Denyer FPharm PhD MRPharmS
Head of School of Pharmacy, Cardiff University

Dr Gillian M Eccleston BSc PhD MRPharmS
Reader in Pharmaceutics, Strathclyde University

Professor Roger J Griffin MRPharmS
Professor of Anticancer Drug Discovery and Development, University of Newcastle

Professor Christopher Marriott BPharm PhD DSc FRPharmS CChem FRSC
Professor of Pharmaceutics, King's College, London

Dr Peter A Meredith BSc PhD
Reader in Medicines and Therapeutics, University of Glasgow