



**Biosimilar Medicinal Products:
From Marketing Approval to Commercial Reality**
Tuesday 5 December 2006
Central London

- 09:00 - 09:25 **Registration**
- 09:25 - 09:30 **Welcome and Introduction**
Dr Lincoln Tsang, Chairman BIA Regulatory Advisory Committee , Arnold & Porter

Regulation of biosimilar products

- 09:30 – 10:10 **Overview of current regulatory policy and scientific developments**
Dr Gopalan Narayanan, Unit Manager, Biotechnology and Biologics, Medicines and Healthcare products Regulatory Agency (MHRA)
- 10:10 – 10:40 **Coffee break**
- 10:40 – 11:20 **Innovative Industry Viewpoint**
Mr Alan Morrison, Senior Director Regulatory Affairs, Amgen, UK
- 11:20 - 12:00 **Generic Industry Viewpoint**
Dr Tim Oldham, VP Strategic Partnerships, Mayne Pharma, UK
- 12:00 – 12:30 **Panel Discussion and Q&A**
- 12:30 – 13:30 **Lunch**

Issues from safety and naming to implications for end users, including the financing perspective into commercialisation

- 13:30 – 14:10 **Safety assessment**
Dr James Green, Senior VP, Preclinical and Clinical Development Sciences, Biogen Idec, USA
- 14:10 – 14:40 **Financing perspective: Future of biosimilars – is it worth the investment?**
Ms Frances Cloud, Director, Research, Nomura Code Securities, UK
- 14:40 – 15:10 **Coffee break**
- 15:10 – 15:50 **Naming elements – Application of INN to biological products**
Professor Derek Calam OBE, Chairman INN Expert Committee, WHO
- 15:50 – 16:20 **Patient perspective**
Mr Rod Mitchell, Board Member, International Alliance of Patients' Organizations
- 16:20 – 16:50 **Panel Discussion and Q&A**
- 16:50 – 17:30 **Tea/coffee and Networking**