Innovation in Life Sciences
25 September 2008
Clifford Chance LLP, 10 Upper Bank Street, Canary Wharf, London E14 5JJ

Programme

09.00 – 09.30	Registration
09.30 - 09.35	Welcome by **Chair: Mr Justice Jackson**
09.35 - 10.00	**Professor Sir Alasdair Breckenridge, CBE, Chairman, MHRA:** *Key Note Speech* - on innovation, issues for regulators, society and industry and brief overview of conference topics.
10.00 - 10.30	**James Lawford-Davies & Alex Denoon, Clifford Chance**: *Advanced Therapy Products & Patents* - How IP protection and recent regulatory developments facilitate innovation.
10.30 - 11.00	**Professor Munir Pirmohamed, NHS Chair of Pharmacogenetics, Department of Pharmacology, University of Liverpool:** *The Regulatory Response to Innovation* - regulatory policy issues stemming from scientific innovation and how these differ from dealing with traditional drug-making.
11.00 – 11.15	Q&A Session
11.15 - 11.30	Tea & Coffee Break
11.30 - 12.00	**Professor Chris Mason, University College London**: *Innovation in Science - the view from the lab bench* - what innovative research is, how it is produced in universities, if and how scientists think about regulation or any end product in addition to the scientific pursuit.
12.00 - 12.30	**Pharmaceuticals : Investors and Industry** **Andrew Baum, Pharma Research Team, Morgan Stanley**: *The impact of financial factors on Innovation* **Helen Usmar Director EMEA, Deputy EU Qualified Person for Pharmacovigilance, Stiefel Laboratories**: *Industry and Innovation*
12.30 – 12.45	Q&A Session
12.45 - 14.00	Lunch

14.00 - 15.30	*Perspective of Medicines Regulators:* comparing institutional shifts necessary to regulate global innovation. **Chair: Professor Kent Woods, Chief Executive, MHRA** • **Dr Fabienne Bartoli, Deputy Director General, Agence française de sécurité sanitaire des produits de santé (Afssaps)** - the French regulator's approach to innovation. • **Jeffrey Bucholtz, Department of Justice, USA** - the FDA and lessons from off-label use. • **Nathalie Rampal Olmedo, European Medicines Agency -** the Advanced Therapies Regulation from the EMA's perspective.
15.30 - 15.45	Tea & Coffee Break
15.45 - 17.15	*Parallel Panel Sessions* **Panel 1: The Precautionary Principle and Challenges to Innovation by Civil Liability Claims** **Chair: Dr Peter Feldschreiber, MHRA/4 New Square** • **Roy Alder, formerly Director of Policy at MHRA -** The impact of the precautionary principle in regulatory decision-making in the approval of new medicines. • **David Body, Irwin Mitchell -** Challenges to innovation by product liability claims and vice versa. • **Dr Alexandra McConnell, Clifford Chance** - The precautionary principle as central to regulatory decision-making in uncertainty and innovation. • **Leigh Ann Mulcahy, 4 New Square** - Implications of its non- or mis-application. • **Alexandre Regniault, Simmons & Simmons -** Civil law perspective and the precautionary principle as a constitutional principle in France. **Panel 2: Regulation and Liability Interplay - Pre-emption** **Chair: Dr Duncan Fairgrieve, British Institute of International and Comparative Law & 1 Crown Office Row** • **Jeffrey Bucholtz, Department of Justice, USA -** US case law on pre-emption of state law claims by federal agency. • **Professor Mark Mildred, Nottingham Law School, Nottingham Trent University** - comparative US-EU analysis and the claimant lawyer perspective. • **Joseph Hetrick, Dechert -** defence lawyer perspective. • **Sara Gourley, Sidley Austin LLP -** defence lawyer perspective.

17.15 – 17.30	Closing remarks
17.30	Drinks and launch of "The Law & Regulation of Medicines", Dr Peter Feldschreiber (ed) in conjunction with Oxford University Press.
20.00 for 20.30	Dinner at the Travellers Club, 106 Pall Mall, London, SW1Y 5EP