Life Sciences College

Agenda

Wednesday, 17 April 2013

10:00	**Welcoming Remarks** *Alexander Natz* **Secretary General, EUCOPE AISBL** *Maarten Meulenbelt* **Partner, Sidley Austin LLP**
10:00 – 10:30	**Recent Developments in Clinical Trials** • Overview of the Proposed Clinical Trials Regulation • Practical Implementation Issues from the Perspective of the Pharmaceutical Industry • Considerations Regarding the Publication of Raw Clinical Trial Data *Olivier Goarnisson* **Senior Legal Advisor, Celgene International**
10:30 – 11:30	**Proposed EU Data Protection Regulation, Pseudonymized Data and Secondary Use of Samples** • Update on the Proposed EU Data Protection Regulation and its Impact on the Life Sciences Industry • Use of Pseudonymized Data in Clinical Research • Data Protection Concerns Regarding the Secondary Use of Samples *Uwe Fiedler* **Global Privacy Officer, Parexel International** *William Long* **Partner, Sidley Austin LLP**
11:30 – 12:00	**Coffee Break**
12:00 – 12:30	**Update on Social Media** • Challenges Related to Social Media from the Perspective of an Industry Self-Regulated Body *Helen Roberts* **Industry Representative, UK Prescription Medicines Code of Practice Appeal Board (PMCPA)**

12:30 – 13:00	**Overview of Emerging Pricing and Reimbursement Practices** • Smart Policy Making – A Balance Between Innovation, Access and Sustainability • Update on the Transparency Directive • Access to Medicines vs. Pricing and Reimbursement Practices (External Reference Pricing and Therapeutic Tendering) ***Alexander Roediger*** **Director European Union Affairs, Merck Sharp & Dohme (Europe), Inc.**
13:00 – 14:00	**Lunch**
14:00 – 14:30	**Pharmacovigilance and the Role of the Pharmacovigilance Risk Assessment Committee (PRAC)** • Role of the PRAC • Overview of Tasks and Responsibilities • Practical Considerations and Challenges from the PRAC's Perspective ***Jean-Michel Dogné*** **Belgian Member of the PRAC and Head of the Department of Pharmacy, Namur Thrombosis and Hemostasis Center (NTHC)-Narilis, University of Namur**
14:30 – 15:30	**Regulatory Agencies – Panel Discussion** • Implementation of Pharmacovigilance Legislation • New transparency rules in the EU • Challenges of a Globalized World • Future changes to the Clinical Trials Directive • Revision of Swiss Act on Therapeutic Products • Ratification of the Council of Europe Medicrime Convention ***Andreas Balsiger Betts*** **Head of Legal Affairs, Swissmedic, Swiss Agency for Therapeutic Products (Switzerland)** ***Andrea Laslop*** **Head of Scientific Office, Austrian Agency for Health and Food Safety – AGES (Austria)** **Moderator:** ***Vincenzo Salvatore*** **Senior Counsel, Sidley Austin LLP**
15:30 – 16:00	**Coffee break**

16:00 – 16:30	**Recent Developments in EU Pharmaceutical Law** • Overview of Recent Case-Law concerning Borderline Products • Impact on the Life Sciences Industry ***Markéta Šimerdová*** **Legal Service, European Commission**
16:30 – 17:00	**Differential Pricing of Medicines for Unmet Medical Needs** • A question of Solidarity • Voluntary Code of Conduct: Soft Law Approach for Access to Innovative Drugs • Transparent Market Entry Plan ***Johan Van Calster*** **Administrator, Policy and Government Affairs Office for Medicinal Products, Clivan bvba**
17:00 – 17:30	**Patient Safety** • Use of Unlicensed Medicines • Reused Devices, Pharmacovigilance etc. ***Mike Isles*** **Executive Director, European Alliance for Access to Safe Medicines (EAASM)**
17:30	**Closing Remarks**

Life Sciences College

Thursday, 18 April 2013

8:30	**Welcoming Remarks** ***Alexander Natz*** **Secretary General, EUCOPE AISBL** ***Maarten Meulenbelt*** **Partner, Sidley Austin LLP**
8:30 – 9:00	**Patient Support Programmes and Social Media** • Social Media as a Value-Add for Patient Support Programmes • Regulatory Challenges Presented in Managing Social Media Tools • Strategies in Meeting Challenges Ahead ***Dirk Lenz*** **Director of Group Legal and Regulatory, Atlantis Healthcare**
9:00 – 9:30	**Trademarks and Latest Regulatory Developments** • Recent Developments in Compulsory International Non-proprietary Name Prescribing in the EU • Overview of the EMA Guideline on Invented Names ***Stefano Marino*** **General Counsel, Sigma-Tau and Chairman of Trademark Committee, European Federation of Pharmaceutical Industries and Associations (EFPIA)**
9:30 – 10:30	**Competition Aspects of Pharmaceutical Law – Panel Discussion** ***Satish Sule*** **Case Handler, Pharma and Health Services, DG Competition, European Commission** ***Jacob Westin*** **Assistant General Counsel, GlaxoSmithKline** ***Angela Staunton*** **Global Antitrust Counsel, Bayer Healthcare** **Moderator: *Kristina Nordlander* Partner, Sidley Austin LLP**
10:30 – 11:00	**Coffee Break**
11:00 – 11:30	**The Proposal for a Regulation on Clinical Trials: Legal and Ethical Issues** • Overview of the Ethical Aspects of the Proposed Clinical Trials Regulation • Impact of New Rules on Pediatric Research • EU network of Global Research in Pediatrics (“GRIP”) – FP7 Founded Project ***Annagrazia Altavilla*** **Associate Senior Lecturer, Espace Ethique Méditerranéen, Aix-Marseille University (France)**

11:30 – 12:00	**New Rules on Active Pharmaceutical Ingredients (API) Imports from Third Countries – Latest Developments** • Overview of the Legal Framework • Update on Third Countries List and Written Confirmation Requirement • Temporary Suspension of the New rules – Viable Option? ***Oliver Sude*** **Legal Counsel, EUCOPE AISBL**
12:00 – 12:30	**A Paediatrics Update** • Challenges of Obtaining Deferrals and Waivers • The Role of Pediatric Networks • Pediatric-Use Marketing Authorizations: a Critical Reflection ***Adriana Ceci*** **Associate Professor of Paediatrics, Aldo Moro University and Member of the European Medicines Agency's Paediatric Committee (PEDCO)**
12:30 – 13:30	**Lunch**
13:30 – 14:00	**Practical Considerations on Classification of Borderline Products** • Definition of Borderline Products Under EU law • Scientific, Regulatory and Legal Issues • Practical Tips for Classifying Borderline Product (including case studies) ***Shayesteh Fürst-Ladani*** **Managing Director, SFL Regulatory Affairs & Scientific Communication Ltd.**
14:00 – 15:00	**Perspective of In-House Lawyers – Panel Discussion** ***Antoon Loomans*** **Senior Vice President and General Counsel, GlaxoSmithKline Biologicals** ***Nakisa Serry*** **Vice President Legal, Celgene International** ***Victoria Kitcatt*** **Assistant General Counsel, Pfizer** ***Yuung Yuung Yap*** **Senior Legal Counsel, Johnson & Johnson**
15:00 – 15:30	**Coffee Break**

15:30 – 16:00	**Legal Aspects of Good Manufacturing Practice** • Enforcement Trends and Regulatory Environment • Company Action Plan in Connection with Recalls, Field Quality Issues and Counterfeit Product ***William McConagha*** **Partner, Sidley Austin LLP**
16:00 – 16:30	**Pharmaceutical Law and EU Data Protection** • Discussion and Analysis of Selected Aspects of the Proposed EU Data Protection Regulation from the Perspective of the European Data Protection Supervisor (EDPS) • Snapshot of the Legislative Procedure ***Per Johansson*** **Legal Officer in Policy and Consultation Unit, European Data Protection Supervisor**
16:30	**Closing Remarks**