EU Regulatory Essentials, Pharmaceuticals and Biologics

Monday, 1 October 2018

8:00 am	**Registration and Continental Breakfast**
9:00 am	**Welcome** • Outline of the planned sessions • Participants' background and expectations • Suggestion of topics not yet on the agenda **Patricia Anderson, MSc**, **RAC, FRAPS,** vice president, regulatory affairs, RedHill Biopharma Ltd.
9:15 am	**Understanding the EU Environment** • Legal instruments • EU legislation for pharmaceuticals • Role of national agencies versus EMA • Consequences of Brexit This session will provide the background of the EU, how European pharmaceutical legislation is put into place and its relationship to national laws. An overview of EMA will be provided, as well as a discussion of the role and responsibilities of EMA versus the national competent authorities and a brief comparison to FDA. Potential changes of the EU regulatory system in consequence of the Brexit will be addressed. **Bettina Ziegele, MA,** head, Innovation Office, Paul-Ehrlich-Institute, Germany
9:45 am	**Development Considerations and Scientific Advice** • Understanding your product • Interacting with EU health authorities during development • EMA and national scientific advice • PRIME and adaptive pathways The focus of this session will be on development considerations, the positioning of a drug (small molecule, biologic, advanced product, etc.) and its regulatory implications. Opportunities for approaching EMA and national health authorities during development, such as scientific advice, will be discussed. In addition, new initiatives of European regulators to foster timely access of patients to medically needed drugs will be presented. **Andrea Laslop, MD,** head, Scientific Office, Federal Office for Safety in Health Care, Austria

10:15 am	**Pediatrics** • Pediatric regulation • Points to consider in pediatric development • Integrative development strategies In this session an overview of the paediatric legislation relevant for drug development and approval in Europe will be given. Specific pitfalls and strategies to overcome any potential hurdles will be addressed regarding the paediatric requirements for both intended paediatric indications as well as for validation of licensing applications in adult indications. **Karl-Heinz Huemer, PhD, MD,** Scientific Office, Federal Office for Safety in Health Care, Austria
10:45 am	**Refreshment Break**
11:00 am	**Orphan Drugs** • Orphan procedure • Important differences US/EU • Major issues identified by COMP **Patricia Anderson, RAC, FRAPS,** vice president, regulatory affairs, RedHill Biopharma Ltd.
11:30 am	**New Clinical Trials Regulation** • Clinical trials legislation • Clinical trial applications • Obligations during conduct of clinical trials • Implementation challenges A comparative overview of conducting clinical trials in the EU with current EU directive and the new EU trial regulation will be addressed in this session along with the implementation schedule and challenges. Procedural-related topics, such as the submission of a clinical trial application, ethics committee submission, the reporting of adverse events, privacy rules that impact the collection of clinical data and the importation and release of investigational drugs within the EU will be discussed. **Isabelle Lefebvre, MSc RA, RAC EU and US,** Vice President Regulatory Affairs, Branded & Generic Prescription Drugs, Consumer Product, Valeant Pharmaceuticals North America, LLC.
12:00 pm	**Marketing Applications: Different Formats and Different Timelines** This session will present the objective of the European pharmaceutical legislation and describe the four types of marketing applications: the centralized procedure, mutual recognition procedure, decentralized procedure and national procedure. The session will also highlight regulations and websites to remember and, at a high level, describe the format of the marketing authorization application and the CTD dossier. **Matthias Dormeyer, PhD,** MDC RegAffairs GmbH

12:30 pm	**Lunch**
1:30 pm	**Postmarketing Procedures and Lifecycle Management** This session will give an overview of the various types of marketing authorization (MA) maintenance and post-authorization procedures. Lifecycle management procedures such as variations and extension applications will be discussed, as well as renewals, specific obligations and other conditions that need to be fulfilled following the successful marketing authorization of a medicinal product in the EU. **Beate Schmidt, MSc, MDRA, RAC,** benefits regulatory consulting, RAPS European Liaison
2:00 pm	**Pharmacovigilance** This session will give a general overview of the current pharmacovigilance requirements during the postauthorization phase of a medicinal product in the EU. An overview of the EU pharmacovigilance landscape, which changed significantly in 2012, will be provided. The session will include an overview of the good pharmacovigilance practices, which are critical for a successful quality pharmacovigilance system. **Piet Vervaet, MD,** vice president of drug safety and pharmacovigilance, Halozyme Therapeutics
2:30 pm	**Refreshment Break**
3:00 pm	**Roundtable Sessions—Introductions** In this part of the workshop, participants will break out into smaller groups and get a chance to discuss any questions with the session leaders directly. In addition to the four core topics below, this interactive forum will also address topics suggested by participants that have not been covered in the agenda. • Industry members talk about their EU experiences — **Patricia Anderson and Piet Vervaet** • The Paediatric Committee (PDCO) — **Beate Schmidt and Karl-Heinz Huemer** • The Committee for Medicinal Products for Human Use (CHMP) — **Andrea Laslop and Matthias Dormeyer** • Clinical trials in Europe — **Bettina Ziegele and Isabelle Lefebvre**
3:10 pm	**Roundtable Rotation 1**
3:30 pm	**Roundtable Rotation 2**
3:50 pm	**Roundtable Rotation 3**
4:10 pm	**Roundtable Rotation 4**
4:30 pm	**Wrap-up** • Sharing highlights from roundtable discussions (open forum)
5:00 pm	**Adjourn**