SMi presents Europe’s leading 7th annual conference

Biosimilars Europe

Holiday Inn Kensington Forum, London, UK

The latest updates on regulation, market access strategies and improvement of commercialisation

WORKSHOPS: 28TH
CONFERENCE: 29TH - 30TH
SEPT 2016

Chair:
• Dr Virginia Acha, Executive Director – Research, Medical & Innovation, ABPI

2016 Featured Speakers:
• Huiguo Hu, General Manager of International Business, Shanghai CP Guojian Pharmaceutical Co. Ltd
• Dr Niraj Chhaya, Risk Management, Boehringer Ingelheim GmbH
• Alanas Dimitrov, Head of Strategy & Portfolio Management, Biosimilars, Merck Group
• Alan Sheppard, Principal, Global Generics and Biosimilars, IMS Health
• Dr Alok Sharma, Head, Bio-Analytical Development, Lupin Ltd
• Dr Andrea Laslop, Head of Scientific Office, Austrian Agency for Health and Food Safety
• Joan O’Callaghan, Research Scientist for Regulatory Science Ireland, Health Products Regulatory Authority, Ireland

Exclusive Highlights in 2016:
• Hear how the evolving regulatory landscape and guidelines will impact on biosimilars
• Overcome market access and commercialisation barriers
• Assess market trends and align your business strategy on emerging markets
• Technical updates on protein characterisation and analytical comparability to speed up data collection

TWO INTERACTIVE PRE-CONFERENCE HALF-DAY WORKSHOPS
Wednesday 28th September 2016, Holiday Inn Kensington Forum, London, UK

Biosimilars: Maximisation of IP regulatory rights
8.30am - 12.30pm
Workshop Leaders:
Marie Manley, Partner and Head of the Regulatory Department, Bristows LLP
and Libby Amos, Associate, Regulatory Department, Bristows LLP

How is the payer environment for biosimilars evolving?
1.30pm - 5.30pm
Workshop Leader:
Dr Ad Rietveld, Director, RJW & partners Ltd

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ACADEMIC & GROUP DISCOUNTS AVAILABLE
9.00 Chairman’s Opening Remarks
Dr Virginia Acha, Executive Director – Research, Medical & Innovation, ABPI

9.10 The effects of biosimilar competition across Europe
Dr Ad Rietveld, Director, RJW & partners Ltd

9.50 Biosimilars: The next decade!
Dr Duncan Emerton, Senior Director, Syndicated Insights

10.30 Morning Coffee

11.00 The importance of early immunogenicity and product quality assessment (PQA) in biosimilar development
Laura Perry, Director of Scientific Affairs, Cell Line Development, Abzena

11.40 Strategies to enter the emerging markets
Huiguo Hu, General Manager of International Business, Shanghai CP Guojian Pharmaceutical Co. Ltd

11.40 TECH TALK BY SPONSOR
Abzena offers a suite of complementary services and technologies. Its range of technologies include immunogenicity assessment, antibody drug conjugation, protein engineering, PEGylation, cell line development, GMP manufacturing and a range of bespoke assays to enables the development of better biopharmaceuticals which will have a greater chance of reaching the market. www.abzena.com

12.20 Networking Lunch

1.30 Biosimilars – the second translational gap
Dr Virginia Acha, Executive Director – Research, Medical & Innovation, ABPI

2.10 CASE STUDY: The emerging biosimilars asset class – strategy & portfolio management in a VUCA (Volatile, Uncertain, Complex & Ambiguous) world
Atanas Dimitrov, Head of Strategy & Portfolio Management, Biosimilars, Merck Group

2.50 Afternoon Tea

3.20 Biologics and biosimilars: Trends and challenges

4.00 Analytical strategies in biosimilar development

4.40 Chairman’s Closing Remarks and Close of Day One
8.30 Registration & Coffee

9.00 Chairman’s Opening Remarks
Dr Virginia Acha, Executive Director – Research, Medical & Innovation, ABPI

REGULATORY AND LITIGATION UPDATES ON BIOSIMILARS IN EUROPE

OPENING ADDRESS
9.10 European regulatory update for biosimilars
• Latest revisions of biosimilar guidelines
• How much clinical evidence do we need
• Lessons learned from recent approvals in Europe
Dr Andrea Laslop, Head of Scientific Office, Austrian Agency for Health and Food Safety

9.50 Regulatory Science Ireland: Biosimilars research project
• Prescriber attitudes and behaviours towards biosimilar medicines
• Reducing the information gap
• Comparison of international models for providing safe and effective supply of biosimilar medicines
Joan O’Callaghan, Research Scientist for Regulatory Science Ireland (RSI), Health Products Regulatory Authority, Ireland

10.30 Morning Coffee

11.00 KEYNOTE ADDRESS
From biosimilars to biogenerics?
• Uptake of biosimilars in clinical practice
• The importance of switching
• Switching - clinical trials and practical experiences
Dr Steinar Madsen, Medical Director, Norwegian Medicines Agency

11.40 Litigation update: Europe and the US
• A look at the latest biosimilar litigation cases from the UK and the US
• Assessing the drivers, strategy and outcomes
• Looking ahead to future disputes and a new European landscape: the Unified Patent Court
Dr Dominic Adair, Partner, Bristows LLP

12.20 Networking Lunch

1.30 Robust Pharmacovigilance: A key to successful biosimilars
• Guidelines for biosimilar pharmacovigilance in the EU and USA
• Key considerations: Immunogenicity, interchangeability, traceability
• Risk management plans for biosimilars
Dr Niraj Chhaya, Risk Management, Boehringer Ingelheim GmbH

TECHNOLOGICAL DEVELOPMENTS

2.10 Looking for fingerprints
• Bioanalytical characterisation - developing a robust and comparative structural and functional study between innovator and originator
• From physical to chemical: What are the parameters and how to showcase similarities?
• Technology breakthrough: Yielding 3D structure of monoclonal antibodies at atomic-level
• Reliability and repeatability for regulators’ approvals

2.50 Afternoon Tea

3.20 The increasing importance of medical devices for regulatory and commercial success of biosimilars
• Biosimilars offer very few opportunities for differentiation
• Autoinjectors and other medical device components are the only area, where biosimilars can offer additional value and differentiate
• Originators and biosimilar developers are facing an “arms race” with medical devices to secure
Dr Dirk Kreder, CEO, Anteris medical GmbH

4.00 Chairman’s Closing Remarks and Close of Day Two

9th Annual Biosimilars Europe
Day Two | Friday 29th September 2016

Want to know how you can get involved? Interested in promoting your services to this market?
Contact Teri Anli, SMi Marketing on +44 (0) 207 827 6162 or email: tarri@smi-online.co.uk

Register online at: www.biosimilars-europe.com
Alternatively fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711
Overview of workshop:
A full workshop covering all aspects of pharmaceutical regulation applicable to biosimilars. The workshop will begin with an explanation of the interplay between the various IP regulatory rights in the EU and then look at each in detail. The workshop will also reflect on the interaction between regulatory and competition law before finishing. An interactive case study will be run throughout the topics of the workshop to test the knowledge gained.

Why should you attend this workshop:
To gain knowledge of:
• Regulatory Data Protection
• Market exclusivity for orphan medicinal products
• Supplementary protection certificates
• Paediatric rewards

Programme:
8.30 Registration
9.00 Opening remarks and introductions
9.10 Session 1: Regulatory Data Protection (RDP)
• What RDP rights are available in the EU?
• RDP and marketing protection in a nutshell
• Case study: Calculating the period of RDP
• Hot issues and grey areas specific to biosimilars
• Circumvention of RDP
9.50 Session 2: Orphan medicinal products
• Orphan market exclusivity
• Case study: Duration of market exclusivity
• Derogations to market exclusivity
• Strategic issues and practical implications
10.30 Coffee
11.00 Session 3: Supplementary Protection Certificates (SPCs)
• What is an SPC and why do we need them?
• Scope of the SPC regulation
• Conditions for obtaining an SPC
• Duration of the SPC
• Case study: Calculating the SPC
• Particular considerations for a biotechnological molecule
11.40 Session 4: The Paediatric Regulation and summary of workshops
• Interaction with the SPC regulation
• Rewards under the paediatric regulation
• Life Cycle Management – an overview of IP rights
• Interaction between regulatory and competition
12.20 Closing remarks
12.30 End of workshop

About the Workshop Leaders:
Marie Manley is a Partner and head of the IP Regulatory Department at Bristows LLP (London). She advises on both contentious and non-contentious matters, focusing on regulatory and competition law in the bio-pharma, medical devices, cosmetic and food sectors; including life cycle management issues, advertising and product liability. Marie is Chairperson of the Legal Affairs Community for DIA. Marie is considered as a leading practitioner for regulatory law and is described by clients as a “regulatory superstar”. She is recommended in Legal 500, Chambers and Partners; also London Top 100 & London Top 50 Women and EU Law & Super Lawyers UK (2013).

Libby Amos is an associate in the IP Regulatory department advising clients on both contentious and non-contentious EU and UK regulatory matters. Libby is currently advising a leading pharmaceutical company on an appeal against a Commission Decision alleging violations of Articles 101 and 102 TFEU. Libby has recently co-authored chapters on authorisation and advertising of medicinal products for the newly published textbook Navigating European Pharmaceutical Law.

About the Bristows:
Bristows is a full service London law firm serving innovative companies and industry leaders around the world. Bristows has a true cross-disciplinary Life science team of over 60 lawyers in this space encompassing our renowned IP practice, regulatory, competition, commercial, transactional and IT/data protection teams. The strength of each individual practice complements the others to provide a fully integrated service.

Many of Bristows life sciences specialists have backgrounds in chemistry, biochemistry, biotechnology, physics and engineering.
Overview of Workshop:
The regulatory barriers for the launch of biosimilars seem to have been overcome with a growing number of products coming to the market, in particular in the EU. Although in principle welcoming the introduction of biosimilars and thus more competition, payers are still contemplating how to make use of biosimilars to drive cost of biologicals down. At the same time, manufacturers are still seeking ways of positioning biosimilars to compete effectively with the originator biologicals.

The workshop will examine the current state of affairs and take a look into what the future may bring with a focus on the changing payer environment.

Why should you attend this workshop:
• Gain insight from highly experienced professionals and colleagues
• Understand the payer environment for biosimilars in different markets
• Be able to make founded predictions for the future payer environment
• Enrich your ideas on how to launch biosimilars successfully or defend your originator product successfully against biosimilar competition.

Programme:
1.30 Registration and Coffee
2.00 Opening remarks and introductions
2.10 Session 1: Biosimilars: why is regulatory approval still not enough to achieve sales?
• Biosimilars vs generics – a similar level of success?
• Outline of the pricing, reimbursement and formulary access process
• The real hurdles to biosimilar sales
2.50 Session 2: The payer perspective: biosimilars are what we’ve been waiting for!
• Growing demand and rising expenditure
• Specialty care products are the biggest cost area
• The impact of geography – Europe vs US
• Payer attitudes to biosimilars
• Payer developments with respect to biosimilars
3.30 Afternoon Tea
4.00 Session 3: How to ensure that evidence for biosimilars is relevant to the payer
• Expectations of evidence in support of pricing and access
• Are biosimilars a special case when it comes to evidence?
• How payers look at value – it’s not all about cost-effectiveness
• Getting over the last hurdle to ensure prescriber buy-in
4.40 Session 4: Case studies
• Selection of case studies on biosimilar introductions
5.20 Closing remarks
5.30 End of workshop

About the Workshop Leader:
Ad Rietveld is a former GP with marketing experience in the industry (Solvay) and extensive consulting experience in pricing and market access (Cambridge/IMS).
Ad was a former national payer in the Dutch Ministry of Health and has been a Consultant to World Bank, EU and WHO, advising countries on how to build their pricing and reimbursement systems. In 2008, Ad co-founded RJW & partners Ltd, a consultancy that provides pricing and market access services to pharmaceutical and medical device companies.

About the Organisation:
RJW & partners Ltd is a UK-based Consultancy with presence in Europe, US and Australia. RJW & partners provide strategic pricing and market access advice to pharmaceutical and medical device companies of all sizes. RJW & partners services cover all geographies and therapy areas.
Terms and Conditions of Booking

Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be recorded and payment taken before entry to the event. Bookings within 7 days of the event require payment on booking. Access to the Document Portal will not be given until payment has been received.

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