Biosimilars Conference 2016

A European View on Biosimilar medicines with a Global Outlook

9-10 November 2016
Pullman Hotel Midi, Brussels, Belgium

PROGRAMME CHAIRS

Steffen Thirstrup
Director and Advisory Board Member, NDA Advisory Services Ltd, UK; Previous CHMP-member and Head of Licensing, Danish Health and Medicines Authority

PROGRAMME COMMITTEE

Thijs Giezen
Hospital Pharmacist; Member of the Biosimilar Medicines Working Party of the EMA
Foundation Pharmacy For Hospitals In Haarlem, The Netherlands

Julie Marechal-Jamil
Director Biosimilars Policy and Science Medicines for Europe, Biosimilar Medicines Group, Belgium

Aimad Torqui
Associate Director Global Regulatory Policy, MSD, The Netherlands
Member of the Biosimilars Working Group of the European Biopharmaceutical Enterprises (EBE, a specialized group of EFPIA)

PROGRAMME ADVISOR

Paul Cornes
Oncologist, Clinical Outcomes Group, Bristol Oncology Centre, United Kingdom

OVERVIEW

Biosimilar medicines' developments are maintaining their momentum and the 2016 Biosimilars Conference programme delves into strategic discussions regarding:

- **Market and regulatory developments** in the EU and globally, enlightened by the perspective of **healthcare professionals' and patients' experiences**
- National **policy developments** (e.g. pricing, reimbursement, incentives, government investments)

The impact of biosimilar medicines on the **competitive landscape** of biological products, in light of 10 years of market existence

As the 4th conference of its kind, the 2016 programme gives a complete **360-degree overview** of biosimilar medicines. Participants will leave the conference with a **wealth of new information** and an **expanded network** of contacts.

KEY TOPICS

- Current regulatory status of biosimilar medicines in the EU
- Learnings from the first US FDA approvals of biosimilar medicines
- Biological medicines in practice - experiences and views of patients, pharmacists, nurses, physicians and hospital managers/ payers (procurers)
- Key learnings from multi-stakeholder dialogue platforms on patients and healthcare professionals' information needs
- The balance of risk and benefits for biosimilars – where it stands after a decade of biosimilar use
- Interchangeability and switching of biosimilars
- Clinical experience and real world evidence for biosimilar medicines: what is the state of play in terms of clinical and economic value proposals

OBJECTIVES

- Deal with regulatory requirements, scientific and operational challenges
- Exchange experiences and discuss hot topics with experts
- Update the participant on the current knowledge including regulatory and scientific thinking
- Discuss the necessary conditions for optimal use

FINAL PROGRAMME

DIA

DAY ONE | 9 NOVEMBER 2016

08:00 REGISTRATION

09:00 WELCOME REMARKS

09:10 KEY NOTE

MARKET DEVELOPMENTS IN EUROPE AND GLOBALLY

Per Troein, VP Strategic Partners, IMS Health Inc, UK

09:30 SESSION 1

REGULATORY OUTLOOK FOR EUROPE

Session Chair:
Aimad Torqui, Associate Director Global Regulatory Policy, MSD, The Netherlands; Member of the Biosimilars Working Group of the European Biopharmaceutical Enterprises (EBE, a specialized group of EFPIA)

The session will discuss recent developments and future prospects in the EU regulatory landscape and their practical implications for development and approval of biosimilars.

Overview of the Immunogenicity Guideline
Venke Skibeli, Member of the Biosimilar Medicines Working Party of the EMA; Senior Scientist, Clinical assessor, Norwegian Medicines Agency, Norway

Practical Implementation of Immunogenicity Guidelines
Paul Chamberlain, NDA Group, UK

Other Guidelines Under Revision and Future Trends
Thijs Giezen, Hospital Pharmacist; Member of the Biosimilar Medicines Working Party of the EMA
Foundation Pharmacy For Hospitals In Haarlem, Haarlem, The Netherlands

Biosimilars for Rare Diseases
Richard Di Cicco, Harvest Moon Pharmaceuticals, USA

11:00 COFFEE BREAK

11:30 SESSION 2

REGULATORY OUTLOOK FOR OTHER REGIONS

Session Chair:
Julie Marechal-Jamil, Director Biosimilars Policy and Science, Medicines for Europe, Biosimilar Medicines Group, Belgium

The session will look into the recent regulatory and regulatory policy developments in the international regulatory landscape, focusing on those relating to biologic, including biosimilar, medicines. The WHO and IPRF will provide an outline of their respective activities and highlight how those can contribute to regulatory convergence initiatives in the field. In order to complement these regulators perspective, a description on how international regulatory developments impact global industry operators in the biosimilar sector will provide a pragmatic perspective on a desirable way forward.

WHO Activities in Support of Regulatory Convergence
Ivana Knezevic, Scientist, Technologies, Standards and Norms Team, Group Lead, WHO, Switzerland

Developments Within the International Pharmaceutical Regulators Forum
Peter Richardson, Head of Quality, Human Medicines Evaluation Division, European Medicines Agency, European Union

US Regulatory Landscape for Biosimilar Medicines
Hillel Cohen, Expert in Regulatory Policy, Regulatory Affairs & Scientific Strategy, Sandoz (Novartis), US

International Convergence: An Industry perspective
Cornelia Ulm, VP Regulatory Affairs Biosimilars, Merck Biosimilars, Biosimilar Medicines Group & EBE, Switzerland

13:00 LUNCH

14:00 SESSION 3

BIOSIMILAR MEDICINES IN CLINICAL USE – CASE STUDIES AND REAL-WORLD EVIDENCE

Session Chair:
Arnold Vulto, Professor of Hospital Pharmacy & Practical Therapeutics, Erasmus University, the Netherlands

This session will focus on the most recent experience related to clinical implementation of biosimilars.

Switching Between Reference and Biosimilar Medicines: Update on the Nor-Switch Study
Jorgen Jahnsen, Professor, University of Oslo, Norway

Real World Data About Biosimilars: Results from an Italian Distributed Network
Gianluca Trifiro, Assistant Professor, Department of Clinical and Experimental Medicine and Pharmacology, University of Messina, Italy

Hands-on Experiences on Practical Implementation of Biosimilar Outside of Switching Programme
Marieke Pereboom, Foundation Pharmacy For Hospitals In Haarlem, The Netherlands

Outcomes of Switching Therapy – Results from Danish Rheuma Biobank
Tina Kringelbach, Project Manager, Danish Rheuma Biobank, Denmark

15:30 COFFEE BREAK

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16:00 SESSION 4

COMMUNICATING TO HEALTHCARE PROFESSIONALS AND PATIENTS - STAKEHOLDER EDUCATION

Session Chair
Steffen Thirstrup, Director and Advisory Board Member, NDA Advisory Services Ltd, UK; Previous CHMP-member and Head of Licensing, Danish Health and Medicines Authority

The session will explore the developments on patient leaflet, guidelines on communicating to laypeople and healthcare professionals

European Commission Q&A for Patients on Biosimilar Medicines
Julie Marechal-Jamil, Director Biosimilars Policy and Science, Medicines for Europe, Biosimilar Medicines Group, Belgium

Irish Example on Stakeholder Education and Engagement
Joan O'Callaghan, Pharmaceutical Assessor, HPRA, Ireland

Choosing the Level of Language and Access to Information of Biologics and Biosimilars
Arnold Vulto, Professor of Hospital Pharmacy & Practical Therapeutics, Erasmus University, the Netherlands

17:30 | NETWORKING RECEPTION

DAY TWO | 10 NOVEMBER 2016

09:00 OPENING PRESENTATION

NUMERACY AND THE UNDERSTANDING OF CLINICAL TRIALS WITH BIOSIMILARS

Uwe Gudat, Head of Safety Biosimilars, Merck Serono Biosimilars, Switzerland

09:20 SESSION 5

PHARMACOVIGILANCE

Session Chair:
Thijs Giezen, Hospital Pharmacist; Member of the Biosimilar Medicines Working Party of the EMA; Foundation Pharmacy For Hospitals In Haarlem, The Netherlands

The session will address recent developments and experiences in the field of pharmacovigilance of biologics, including biosimilars. Topics covered include the Guidance on Good Vigilance Practice for biologics, experiences with post-authorization studies with biosimilars and traceability, including examples of hands-on-experiences in clinical practice.

GVP for Biologics and Eudravigilance Database – Update of New Processes and Impact on Biosimilars
Niels Vermeer, Detached National Expert, European Medicines Agency, European Union

Learnings from PASS - Practical View and Case Studies
Yun Gu, Director, Epidemiology, Worldwide Regulatory and Safety, USA

Good Practice with Registries for Biologics and Biosimilars
Michael Busch-Sørensen, Regional Epidemiology Director, European Registries, MSD, Denmark

11:15 COFFEE BREAK

11:45 SESSION 5

PHARMACOVIGILANCE CONTINUED

Practical Aspects and Intermediate Solutions - Hospital Experience on Traceability
Barbara Claus, Hospital Pharmacist, UZ Ghent, Belgium

Escher Study and Learnings Thereof – Pharmacovigilance of Biologics
Kevin Klein, Project Manager, Escher Project, Netherlands

Discussion and Q&A

13:00 LUNCH

14:00 SESSION 6

CONVERGENCE OF REGULATORY SCIENCE AND MEDICAL PRACTICE: ARE WE ON TRACK? – ROUND TABLE DISCUSSION

Session Chair: Steinar Madsen, Medical Director, Norwegian Medicines Agency

The session will be a round table discussion with short presentations from each speaker.

Norwegian View
Steinar Madsen, Medical Director, Norwegian Medicines Agency

Perspective from Healthcare Professionals
Arnold Vulto, Professor of Hospital Pharmacy & Practical Therapeutics, Erasmus University, the Netherlands

Perspective from the Regulators
Thijs Giezen, Hospital Pharmacist; Member of the Biosimilar Medicines Working Party of the EMA
Foundation Pharmacy For Hospitals In Haarlem,
The Netherlands

Perspective from the Payers
Lonneke Timmers, Menzis, the Netherlands

Views from Health Care Professionals and Patients
Neil Betteridge, the European League Against Rheumatism, UK

16:30 END OF CONFERENCE

VENUE

Pullman Hotel Midi
Place Victor Horta 1
1060 Brussels

CONTINUING EDUCATION

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EVALUATION

We value your feedback on the content and organisation of this conference. The electronic survey will be sent to you after the conference and can also be accessed through the following link: https://www.research.net/r/CF_Operational_Excellence

PRESENTATION ACCESS INFORMATION

As a benefit of registration, presentations will be made available on the DIA website. Login to My DIA and choose My Presentation Downloads, where you will be able to download all presentations that have been submitted by speakers.

Note: You will need to enter your DIA User ID and password to verify your status. If you have forgotten your DIA User ID and password, use our Login Reminder.

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- There was no slide presentation planned by the speaker
- The speaker did not agree to share it with other participants
- You have not yet paid the registration fee