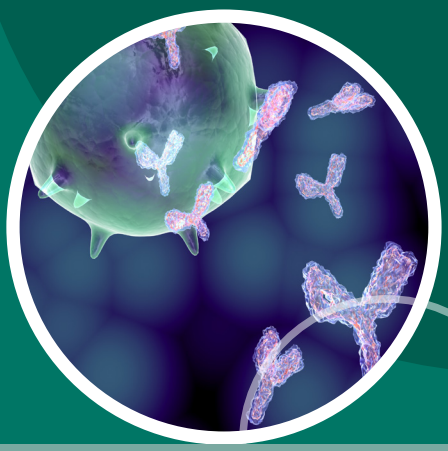

Biosimilars Conference 2015
A European View on Biosimilars with a Global Outlook

4-5 November 2015
London, UK

PROGRAMME 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

PROGRAMME COMMITTEE

Sabine Atzor
Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland

Suzette Kox
Senior Director International, European Biosimilars Group, European Generic and Biosimilar Medicines Association, Belgium

Elena Wolff-Holz
Paul-Ehrlich-Institute, Germany

PROGRAMME ADVISOR

Christian Schneider
Head of Licensing, Danish Health and Medicines Authority, Denmark and Chairman Biosimilar Medicinal Products Working Party (BMWP), EMA

OVERVIEW

This 2-day conference is the third of its kind. It will provide an update on the current status for biosimilars in EU and internationally with focus on both regulatory and scientific challenges as well as market access and experiences. Patients and physicians approach to use of biosimilars will be part of the conference scope including a discussion on biosimilars adoption into current treatment guidelines in EU. The conference will consist of plenary lectures followed by interactive panel discussions providing participants an opportunity to bring forward their own experience and share their thoughts and ideas with the experts.

KEY TOPICS

- Current regulatory status of biosimilars in the EU
- National policy developments on biosimilars
- International regulatory development regarding biosimilars
- Naming of biologicals including biosimilars
- Pharmacovigilance related to biopharmaceuticals, including biosimilars – EU and globally
- Market experience with biosimilars including market access and pricing
- Patients' and physicians' approach to use of biosimilars
- Immunogenicity

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 pros and cons of Biosimilars

FINAL PROGRAMME

DIA DEVELOP INNOVATE ADVANCE

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WEDNESDAY | 4 NOVEMBER 2015

08:00 REGISTRATION AND WELCOME COFFEE

09:00 WELCOME AND INTRODUCTION

09:15 SESSION 1

BIOSIMILARS AND NON-ORIGINATOR BIOLOGICS (NOBs) MARKET DEVELOPMENTS

Session Chair:
Steffen Thirstrup, Director and Advisory Board Member, NDA Advisory Services Ltd, UK

Biosimilar market is developing both in Europe and globally with an increasing demand for biotherapeutics. The first biosimilar was approved in the EU in 2006 and FDA approved the first in in the US in early March this year. The session looks into the trends in different regions over the past years and also discusses the market access and pricing.

Global Market Development of Biosimilars and of Non-Originator Biologics in Emerging Markets
Per Troein, Vice President Strategic Partners, IMS Health Inc, UK

Outcome of the October EC workshop on Access to and Uptake of Biosimilars
Hilda Juhasz, Policy Officer, European Commission, Directorate General For Enterprise and Industry, European Union

Panel Discussion on Biosimilar Market Developments

Panelists:

Per Troein, Vice President Strategic Partners, IMS Health Inc, UK

Hilda Juhasz, Policy Officer, European Commission, Directorate General For Enterprise and Industry, European Union

Pieter Dylst, Health Economics Officer, European Generic Medicines and Biosimilars Association, Belgium

Alexander Roediger, Director European Union Affairs, MSD Europe, Inc. (on behalf of EBE, the European Biopharmaceutical Enterprises, and EFPIA)

10:45 REFRESHMENT BREAK

CONTINUING EDUCATION

DIA meetings are generally approved by the SwAPP (Swiss Association of Pharmaceutical Professionals) Commission for Professional Development (CPD) and SGPM (Swiss Society of Pharmaceutical Medicine) and will be honoured with 12 credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

11:15 SESSION 2

EVOLVING REGULATORY LANDSCAPE IN THE EU, US AND REST OF THE WORLD

Session Chair:
Suzette Kox, Senior Director International, European Biosimilars Group, European Generic and Biosimilar Medicines Association, Belgium

Regulatory frameworks for biosimilars are being developed around the world. During this session, the experts will look into the regulatory developments in the EU but also in other highly regulated regions and globally. Topics, such as clinical data requirements, labelling, interchangeability, extrapolation and other topics related to regulatory will be discussed.

European Medicines Agency Update on Biosimilars
Peter Richardson, Head of Quality, Human Medicines Evaluation Division, European Medicines Agency, European Union

EMA Biosimilar Medicines Working Party Update on Recent Developments and Experiences in the Field of Biosimilars
Elena Wolff-Holz, Paul-Ehrlich-Institute, Germany

FDA Recent Developments and Experiences in the Field of Biosimilars
Presentation by Steven Koslowski, Director, Office of Biotechnology Products Office of Pharmaceutical Quality CDER, FDA, USA

WHO Update on Recent Developments and Experiences in the Field of Biosimilars and Non-Originator Products
Hye-Na Kang, Scientist, Technologies, Standards and Norms Team, Department of Essential Medicines and Health Products, World Health Organisation

13:15 LUNCH

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

14:15 SESSION 3

HOT TOPICS – PHARMACOVIGILANCE, IDENTIFICATION, TRACEABILITY, NAMING AND LABELING FOR BIOLOGICALS AND NEW APPROACHES TO BIOSIMILAR DEVELOPMENT

Session Chair:
Thijs Giezen, Hospital Pharmacist, Foundation Pharmacy for Hospitals in Haarlem, the Netherlands

Challenges associated with pharmacovigilance, traceability, global naming for biologicals as well as new approaches to biosimilar development will be shared and debated in this session.

Beyond Extrapolation: the Value of Pharmacology and Innovative Study Designs
Malte Peters, Global Head Clinical Development Biopharmaceuticals, Sandoz, Germany

Special Considerations for the Pharmacovigilance of Biologics
Xavier Kurz, PV Division European Medicines Agency, European Union

Identification and Traceability of Biologicals – Case Study from the Netherlands
Pieter Stolk, Project Manager, Escher - TI Pharma platform for regulatory innovation, the Netherlands

WHO Biologic Qualifier: an Opportunity to Advance Global Identification and Pharmacovigilance
Raffaella Giovanna Balocco Mattavelli, Group Lead, International Nonproprietary Name Programme, World Health Organization

15:45 REFRESHMENT BREAK

16:15 SESSION 3 CONTINUED

EuropaBio Survey of Physician Preferences for Information Sources and Contents of a Biosimilar Label (SmPC) in 7 EU Member States (2015)
Keith Watson, Director, AbbVie Ltd, UK (on behalf of Europabio)

Panel Discussion

All Session 3 speakers

Elke Grooten, Director Public Affairs, Sandoz Europe, Belgium
(on behalf of European Biosimilars Group)

17:15 WRAP UP OF DAY 1

17:30 NETWORKING RECEPTION

18:30 END OF DAY 1

THURSDAY | 5 NOVEMBER 2015

07:30 WELCOME COFFEE

08:30 SESSION 4

NATIONAL GUIDANCE/POLICY DEVELOPMENTS REGARDING BIOSIMILARS

Session Chair:
Sabine Atzor, Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland

2015 is marked by a number of position and policy developments regarding biosimilars in European countries. The session aims to provide details regarding these policies and guidelines touching upon real world evidence, market access, health technology assessment, prescription, interchangeability and guidelines for healthcare professionals and patients. This session will help to identify trends, communalities and differences.

The Netherlands: Medicines Evaluation Board (MEB) Updated Position on Prescription of Biosimilar Medicinal Products and National Switching
Dr Leon Van Aerts, Assessor, Medicines Evaluation Board, the Netherlands

Germany: Paul Ehrlich Institut (PEI) Position on Interchangeability of Biosimilars
Elena Wolff-Holz, Paul-Ehrlich-Institute, Germany

Finland: Position of Finnish Medicines Agency (FIMEA) on Interchangeability of Biosimilars
Pekka Kurki, Research Professor, Finnish Medicines Agency, Finland

Ireland: The Irish Health Products Regulatory Authority: Guide to Biosimilars for Healthcare Professionals and Patients
Sean Barry, Executive Pharmaceutical Assessor, Health Products Regulatory Authority, Ireland

10:30 REFRESHMENT BREAK

11:00 SESSION 5

USERS' EXPERIENCES AND PERSPECTIVES REGARDING BIOSIMILARS AND CONSIDERATIONS ON NATIONAL POLICY DEVELOPMENTS

Session Co-chairs:
Sabine Atzor, Head of EU Regulatory Policies, F. Hoffmann-La Roche Ltd, Switzerland; **Suzette Kox,** Senior Director International, European Biosimilars Group, European Generic and Biosimilar Medicines Association, Belgium

The session will continue by giving floor to healthcare professionals and patients and their points of view on the policy developments.

A Doctor's Experience and Perspective
Carl-Erik Flodmark, Professor, Medical Expert, The National Board of Health and Welfare, Sweden

Biosimilars in Clinical Practice: the Perspective of a Hospital Pharmacist
Thijs Giezen, Hospital Pharmacist, Foundation Pharmacy for Hospitals in Haarlem, the Netherlands

A Patient's Experience and Perspective
Marco Greco, Chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA), Belgium

A Payer's Experience and Perspective
Representative invited

13:00 LUNCH

14:00 PANEL DEBATE

WHAT WILL THE FUTURE LANDSCAPE OF BIOSIMILARS LOOK LIKE AND HOW SHOULD WE PREPARE FOR THAT?

Moderator:
Steffen Thirstrup, Director and Advisory Board Member, NDA Advisory Services Ltd, UK

Continuing from the previous sessions, the panel discussion will allow a stakeholder debate on status quo and discuss how the governance framework could facilitate better understanding and acceptance of biosimilars challenged by counter-arguments.

Setting the Scene:
Biosimilars - the Physicians' Learning Curve
Paul Cornes, Oncologist, Clinical Outcomes Group, Bristol Oncology Centre, Bristol, United Kingdom

Panelists:

Leon Van Aerts, Assessor, Medicines Evaluation Board, the Netherlands

Sean Barry, Executive Pharmaceutical Assessor, Health Products Regulatory Authority, Ireland

Thijs Giezen, Hospital Pharmacist, Foundation Pharmacy for Hospitals in Haarlem, the Netherlands

Marco Greco, Chairman of the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA), Belgium

Pekka Kurki, Research Professor, Finnish Medicines Agency, Finland

Malte Peters, Global Head Clinical Development Biopharmaceuticals, Sandoz, Germany *(on behalf of European Biosimilars Group)*

Alexander Roediger, Director European Union Affairs, MSD Europe, Inc., Belgium (on behalf of European Biopharmaceutical Enterprises, EFPIA)

15:45 CLOSING REMARKS

16:00 END OF CONFERENCE

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.surveymonkey.com/r/15115

PRESENTATION ACCESS

As a benefit of registration, presentations are available on the DIA website. Please sign in to DIA Website and choose "My Presentations" within "My account", 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 the Login Reminder.
After logging in to the website, you will see presentation PDFs from all the DIA offerings you have attended in the past 6 months. Simply choose the presentation you would like to view or download.

Please note that if a presentation is not available on the website, it is because:

- The presenter has not supplied us with a presentation file
- 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

CERTIFICATE OF ATTENDANCE

A Certificate of Attendance will be e-mailed to all attendees after they have filled in the evaluation. Please note certification requires full attendance to the event.

For more information please contact DIA EMEA Contact Center on EMEA@DIAglobal.org or call +41 61 225 51 51.