18th Biosimilar Medicines Conference

THON HOTEL EU, BRUSSELS, 6 - 7 OCTOBER 2022

biosimilar medicines

a medicines for europe sector group

Translating the Pharmaceutical Legislation into Access & Affordability

The 2022 Biosimilar Medicines in-person conference will take place in Brussels on the 6th and 7th October 2022. During this event, speakers and panellists will explore how biosimilar medicines can not only enable access to all important therapies, but also unlock more advanced integrated care for patients. Throughout the conference, stakeholders will analyse and discuss the existing challenges and future opportunities to make biosimilar medicines an efficient resource, in light of the implementation of the Pharmaceutical Strategy for Europe and the ongoing revision of the Pharmaceutical Legislation.

DAY 1 Thursday 6 October 2022 - 08:00 - 19:00 CEST

08:00 – 09:00 **REGISTRATION & WELCOME COFFEE**

09:00 – 09:10 **OPENING SPEECH**
Isabell Remus – Chair of the Biosimilar medicines group, Medicines for Europe and Head Biosimilars & Specialty Business, Sandoz Europe

09:10 – 09:30 **KEYNOTE OPENING ADDRESS**
Andrzej Ryś – Director for Health systems, medical products and innovation, DG SANTE, European Commission

09:30 – 10:45 **SESSION 1**
OPENING PANEL DISCUSSION - Delivering for patients - Towards an ambitious implementation of the pharmaceutical strategy for Europe

What are the changes in the European legislation, as well as outside legislation, which would help the biosimilar medicines promise on access, competition, efficiency, and affordability come to life?
In a multi-stakeholder panel, we will hear perspectives from those working on reforming the EU framework as well as from those actively involved in operating it.

Moderator

- **Adrian van den Hoven** – Director General, Medicines for Europe

Speakers

- **Kaisa Immonen** – Director of Policy, European Patients' Forum
- **Yannis Natsis** – Director, European Social Insurance Platform
- **Esa Heinonen** – Senior Adviser, Fimea and Chair of the HMA Biosimilar Working Group
- **Isabell Remus** – Chair of the Biosimilar medicines group, Medicines for Europe and Head Biosimilars & Specialty Business, Sandoz Europe

10:45 – 11:15 **NETWORKING COFFEE BREAK**

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com

18th Biosimilar Medicines Conference

THON HOTEL EU, BRUSSELS, 6 - 7 OCTOBER 2022

biosimilar medicines

a medicines for europe sector group

11:15
12:25

SESSION 2
THE 'NO-ACTION' SCENARIO – Taking a close look at the landscape of European access to biological medicines

Biosimilar medicines use continues to vary greatly across European countries and therapy areas. A number of ambitious initiatives endeavour to tackle the burden of cancer and NCDs. Today, these disparities in use lead to inefficiencies and waste for healthcare systems, conflicting with the proven track record of successful biosimilar use. This question becomes even more pressing as healthcare systems move into recovery from the pandemic. What are we saying yes to, if nothing changes or if change is (too) slow?

Moderator

- **Julie Maréchal-Jamil** – Director Biosimilars Policy & Science, Medicines for Europe

Speakers

- **Joao Vasco Santos** – President, Public Health Economics section, EUPHA
- **Luca Degli Esposti** – Chief Executive Officer, Clicon, Italy
- **Leszek Stabrawa** – HTA Expert, Alphamed
- **Michele Uda** – Director General, Egualia, Italy

12:25
12:45

PRESENTATION
Sustainability of the European biosimilar market and competition – trends and trajectory
Max Newton – Engagement Manager, Global Supplier & Association Relations, IQVIA

12:45
13:45

NETWORKING LUNCH

13:45
15:15

SESSION 3
PROVIDING A FLEXIBLE EUROPEAN REGULATORY FRAMEWORK FOR THE FUTURE: opportunities to advance biosimilar regulation

What are the key emerging biologic regulatory science issues? How can regulatory science and biosimilar development strategies progress alongside to promote early exchanges between manufacturers and regulators? How can this impact the development of biosimilar medicines?

Moderator

- **Fabrice Romanet** – Vice Chair of the Biosimilar Medicines Sector Group, Medicines for Europe and SVP, Head of Program Leadership, Regulatory and Governmental Affairs – Biosimilars, Fresenius Kabi

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com

18th Biosimilar Medicines Conference

THON HOTEL EU, BRUSSELS, 6 - 7 OCTOBER 2022

biosimilar medicines

a medicines for europe sector group

Speakers

- **Elena Wolff-Holz** – Chair of Biosimilar Medicinal Products Working Party (BMWP) of CHMP, European Medicines Agency
- **Martin Schiestl** – Global Head Regulatory Affairs Policy, Sandoz
- **Andrea Laslop** – EMA Scientific Advice Working Party, EMA Committee for Medicinal Products for Human Use
- **Sol Ruiz** – Chair of the EMA Biologics Working Party

15:15 – 15:45 **NETWORKING COFFEE BREAK**

15:45 – 17:15

SESSION 4

ENSURING ACCESS TO AFFORDABLE MEDICINES: How can adapting purchasing and procurement policies contribute to meet evolving health needs?

Buying processes are a centrepiece to medicines accessibility, availability and affordability. A number of reforms have seen the light at national level in different European member states. How can national learnings be shared to allow progress in other countries?

As the portfolio of biosimilar medicines evolves, how can the European institutions contribute to building a robust and resilient framework?

Moderator

- **Sarah Garner** – Senior Policy Advisor, WHO EURO

Speakers

- **Stephanie Kohl** – Policy & Advocacy Officer, European Association of Hospital Pharmacists (EAHP)
- **Nina Uldal** – Director - Negotiations, Tenders and Supply Chain, AMGROS, Denmark
- **Jean-Michel Descoutures** – Coordinator for Procurement of Medicines, Réseau des Acheteurs Hospitaliers (RESAH), France
- **Magnus Bodin** – Head of Biosimilars Market Access, Biogen

17:15 – 17:30 **DAY 1 CLOSING REMARKS**

Marta Baldrighi – Policy and Science Officer, Medicines for Europe

17:30 – 19:00 **NETWORKING COCKTAIL**

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com

18th Biosimilar Medicines Conference

THON HOTEL EU, BRUSSELS, 6 - 7 OCTOBER 2022

biosimilar medicines

a medicines for europe sector group

DAY 2 Friday 7 October 2022 - 08:30 - 14:00 CEST

08:30 – 09:00 **WELCOME COFFEE**

09:00 – 09:20 **OPENING ADDRESS**

Applied resilience and efficiency at the heart of European rebuilding efforts

Sarah Garner – Senior Policy Advisor, WHO EURO

09:20 – 10:45 **SESSION 5**

ENABLING INNOVATION IN HEALTHCARE PRACTICES: How can biosimilar policies contribute to advancing integrated care services?

Integrated care appears as a number one solution for efficient healthcare provision and a better outcome. Its implementation highlights a number of 'structural' challenges and, in particular, siloed information, operations and budgets. Programmes for the introduction of Biosimilar medicines have shone a light on how pockets of reforms can significantly impact access but also care pathways and patient outcomes. How can benefit-sharing schemes be scaled up?
[For more: 1) Teresa Barcina Lacosta et al. (link) – 2) Bernard Duggan et al. (link)]

Moderator

- **Arnold G. Vulto** – Hospital Pharmacist, Honorary Professor of Hospital Pharmacy & Practical Therapeutics, Erasmus University Medical Center Rotterdam and Honorary Professor of Pharmaceutical Sciences at the Dept. of Pharmaceutical Sciences KU Leuven, Belgium

Speakers

- **Teresa Barcina Lacosta** – PhD Researcher in Pharmaceutical Sciences, KU Leuven, Belgium
- **Bernard Duggan** – Chief I Pharmacist, HSE-Medicines Management Programme, Trinity Centre for Health Sciences, Saint James's Hospital, Dublin, Ireland
- **Sonia Trope** – Director, ANDAR (Association Nationale de Défense contre l'Arthrite Rhumatoïde), France
- **Rosa Giuliani** – Oncologist, Clatterbridge Cancer Centre, Liverpool, UK

10:45 – 11:15 **NETWORKING COFFEE BREAK**

11:15
12:40

SESSION 6

INTERNATIONAL REGULATORS' PANEL - Advancing biologic regulatory science: How to converge efforts for an efficient and responsive global regulatory framework?

Beyond the lively European biosimilar arena, regulators around the globe are actively discussing or shaping biosimilar frameworks. This session will provide a platform for international regulators to share the latest developments in their respective jurisdictions. What is the cumulated experience to date? How have scientific advances been incorporated? What are the foreseeable changes coming? What emphasis will be put on cooperation, convergence, reliance going forward?

Moderator

- **Gillian Woollett** – VP, Head of Regulatory Strategy and Policy, Samsung Bioepis

Speakers

- **Ana Hidalgo-Simon** – Head of Advanced Therapies, EMA Human Medicines Division
- **Niklas Ekman** – Head of Biological Section, Finnish Medicines Agency (FIMEA)
- **Denis Arsenault** – Health Canada Biologic and Radiopharmaceutical Drugs Directorate
- **Stacey Ricci** – Director of the Scientific Review Staff, Office of Therapeutic Biologics and Biosimilars, FDA's Center for Drug Evaluation and Research

12:40
12:50

CONFERENCE CLOSING REMARKS

Julie Maréchal-Jamil – Director Biosimilars Policy & Science, Medicines for Europe

12:50
14:00

NETWORKING END-OF-CONFERENCE BUFFET LUNCH

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com

18th Biosimilar Medicines Conference

THON HOTEL EU, BRUSSELS, 6 - 7 OCTOBER 2022

biosimilar medicines

a medicines for europe sector group

PLATINUM SPONSOR

SANDOZ A Novartis Division

SILVER SPONSORS

Biogen

FRESENIUS KABI caring for life

SAMSUNG BIOEPIS

CONFERENCE SPONSOR

polpharma biologics

MEDIA AND SUPPORTING PARTNERS

BIOSIMILAR DEVELOPMENT

GaBi GENERICS AND BIOSIMILARS INITIATIVE *Building trust in cost-effective treatments*

IQVIA

Follow the event on twitter #BIOS22

For further information and to register Biosimilar Medicines Conference | Medicines for Europe

Medicines for Europe AISBL
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- E : info@medicinesforeurope.com
www.medicinesforeurope.com