

BIOSIMILAR MEDICINES CONFERENCE

HILTON AMSTERDAM AIRPORT SCHIPHOL

3 - 4 APRIL 2025

  #BIOS25


better access. better health.

Fuelled by the past, gearing up for the future – Day 1

08.30 am	Registration and welcome coffee
09.00 am	Conference opening remarks – Isabell Remus , Chair, Biosimilar Medicines Group & Sandoz
09.10 am	Keynote speech Rainer Becker , Director D “Medical Products and Innovation”, European Commission, DG SANTE
09.30 am	Session 1 – More than ‘affordable access’: the biosimilar industry as a key player of the European biotech ecosystem
	A flagship sector of the European pharmaceutical industry, the biosimilar medicines industry plays a significant role for European citizens, firstly as a pillar of healthcare systems and access, and then as an active contributor to the expansion of the European biotech and biomanufacturing footprint. At the crossroads between European Policy agenda priorities for Health and Competitiveness, and an upcoming decade of unprecedented biologics Loss of Exclusivities, this panel will discuss how European and national biosimilar strategies can constitute stepping stones for a bright European future.
	Moderator: Adrian van den Hoven , Medicines for Europe Panellists: <ul style="list-style-type: none">• Rainer Becker, European Commission, DG SANTE• Representative, European Commission, DG GROW (inv)• Representative, National Ministry of Health, Spain (inv)• Representative, Ministry of the Economy, Slovenia (inv)• Antonella Cardone, Cancer Patient Europe• Isabell Remus, Chair, Biosimilar medicines Group & Sandoz
10.30 am	Spotlight 1 – Evaluating patient impact – Focusing on health policy improvement that matters
	The question ‘what’s in it for me?’ has long driven the conversation on biosimilar medicines with the patient/patient organisations community. More specifically, this question has conditioned utilisation, acceptance, as well as the perception and realisation of individual and collective benefits. This session will explore the key factors to consider in evaluating how biosimilar policy frameworks impact patients, and how these can guide future improvements.
11:00 am	Coffee break
11.45 am	Session 2 – More than ‘affordable’: high impact healthcare intervention – The case of biosimilar use in rheumatoid arthritis and asthma
	Smart investment in healthcare interventions is a foundation of effective and efficient public health. Beyond treatment cost reduction, the availability of biosimilar competition offers an opportunity for healthcare providers to lift cost-containment restrictions to access, revisiting access pathways to considerably impact health outcomes and overall disease burden. In this session, panelists will

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	discuss various approaches to evaluating the impact of health interventions on society and explore opportunities for biosimilar access policies to contribute to enhancing patients' quality of life.
	Moderator: Fernando de Mora , UAB – Autonomous University of Barcelona, Spain Panellists: <ul style="list-style-type: none">• Job van Boven, University Medical Center Groningen, Netherlands• Malina Müller, WifOR Institute, Germany• Elsa Mateus, Portuguese League Against Rheumatic Diseases, Portugal• Mourad Rezk, Biogen
01.00 pm	Buffet lunch
02.30 pm	Session 3 – More than 'uptake': Shaping a dynamic biologics market competition framework
	This session will explore the evolving dynamics of biologics market competition, focusing on creating a sustainable and competitive framework for biosimilars, with particular emphasis on pricing, procurement practices, and sustainability. Key factors shaping biologics market competition beyond uptake will be identified, with an examination of how various countries and regions are fostering sustainable biologics competition. Policymakers and industry stakeholders will discuss collaborative strategies to promote both competition and access to biological treatments.
03.30 pm	Spotlight 2 – Next generation biosimilar medicines: early shaping of regulatory science, competition and access for Cell & Gene Therapies
	Cell and Gene Therapies (CGT) are advanced therapies which provide for new and sometimes curative treatment options for patients, mainly in cancer (60%). The European budget impact is expected to grow 6-fold (2023-2029) and reach nearly 14bio€. With the first CGT products approaching loss of exclusivity, the panel will look into the current challenges and discuss recommendations for biosimilar stakeholders to actively start building the required follow-on framework.
	Panellists: <ul style="list-style-type: none">• Arti Rai, Duke-Margolis, USA• Elena Guillen, Leiden University Medical Center, The Netherlands
04.00 pm	Coffee break
04.45 pm	Session 4 – Strengthening global biosimilar regulatory science: Aligning regulatory expectations
	2025 is a pivotal year for global biosimilar streamlining, with several regions and organisations engaging publicly in discussions on creating a more efficient regulatory framework for biosimilar development. This session will offer the latest updates, unveiling the opportunities for convergence, and in the discussion, the drafting of a future roadmap that has global implementation and regulatory acceptance of streamlining as the finish line.

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	Panellists: <ul style="list-style-type: none">• Sarah Yim, FDA, USA• Ryosuke Kuribayashi, PMDA, Japan• Ali Alhomaïdan, SFDA, Saudi Arabia• René Anour, EMA BMWP and AGES, Austria• Niklas Ekmann, FIMEA, Finland• Steffen Thirstrup, EMA• Martin Schiestl, Sandoz
06.00 pm	Day 1 wrap up
	Networking cocktail

Fuelled by the past, gearing up for the future – Day 2

09.00 am	Day 2 - Opening speech
09.20 am	Session 5 – International regulatory developments: global regulators’ panel
	In the session, regulatory experts from around the globe will provide insight on biosimilar-relevant regulatory developments. Among the key topics, the panel will discuss existing opportunities for regulatory convergence and how to make the most of them, while simultaneously weighing in on overcoming obstacles, further enabling reliance procedures between jurisdictions.
	Moderator: Mina Grguri , Medicines for Europe Speakers: <ul style="list-style-type: none">• Alex Juma, African Union Development Agency (AUDA NEPAD), African Medicines Regulatory Harmonisation (AMRH)• Radhouane Cherif, EMA• Gaston Moran, ANMAT, Argentina (inv)• Mesil Aksoy, TITCK, Turkiye (inv)• Ivana Knezevic, WHO (inv)
10.45 am	Spotlight 3 – Advent of biosimilar medicines in ophthalmology
	The first biosimilar versions of biological medicines used in ophthalmology have been approved for use in the EU and have been available for clinicians to use in various indications (notably to treat Macular Degeneration). In this discussion, we will learn where the medical community stands on biosimilar adoption and what it could mean for patients and the treatment paradigm.
	Speaker: Reinier Schlingemann , Professor of ophthalmology, Amsterdam Medical Center & Euretina, Netherlands
11:15 am	Coffee break

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12:00 pm	Session 6 – Turning potential into action – Biosimilar repurposing and combination therapies reshape accessibility and transform outcomes
	Tremendous progress has been made in cancer therapy and patient outcomes over the last decade. Besides due emphasis on prevention, evidence points to the fact that treating cancer effectively often involves targeting multiple pathways simultaneously – by way of triple or quaternary combination therapy. Tight control over access to biotherapeutics not only results in delay to accessing combination strategies but also hidden potential in known agents. In this session, speakers will explore how biosimilar medicines availability for today's standards of care could provide the necessary space to advance clinical research in support of innovation in care pathways.
	Moderator: Alexandra Moulson , Polpharma Biologics Panellists: <ul style="list-style-type: none">• Paul Cornes, Oncologist, UK – Closing the Care Gap in Oncology• Elena Elez, Medical Oncology Department Vall d'Hebron Institute of Oncology (VHIO), Spain – Biosimilars: a window of opportunity to gain treatment options in metastatic colorectal cancer• Zorana Maravic, Digestive Cancers Europe• Susana Millan, mAbxience (inv)
01.15 pm	Conference closing remarks – Joe Dunford , Vice-Chair, Biosimilar Access Committee, Biosimilar medicines group & Accord Healthcare
01.30 pm	Buffet lunch
02.30 pm	Conference adjourns

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