
| Fuelled by the past, gearing up for the future – Day 1 | |
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| **08.00 – 09.00** | Registration and welcome coffee |
| **09.00** | **Conference opening remarks - Isabell Remus**, Biosimilar Medicines Group, Medicines for Europe & Sandoz |
| **09.10** | **Session 1 – 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, panellists will 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<br>Panellists<br>• **Elsa Frazão Mateus,** Portuguese League Against Rheumatic Diseases, Portugal<br>• **Job van Boven,** University Medical Center Groningen, The Netherlands<br>• **Malina Müller,** WifOR Institute, Germany<br>• **Mourad Rezk**, Biogen-World Wide Medical Affairs<br>**Q&A** |
| **10.40** | **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. |
| | Moderator: **Kate O'Regan**, Medicines for Europe<br>Speaker: **Luisa Avedano,** European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) (remote)<br>**Q&A** |
| **11:10** | Coffee break |
| **11.40** | **Keynote speech**<br>**Rainer Becker**, European Commission, DG SANTE |
| **12.00** | **Session 2 – More than 'affordable access': the biosimilar industry as a key player of the European biotech ecosystem** |

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| | 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<br>Panellists<br>• **Rainer Becker**, DG SANTE, European Commission<br>• **Giulia Del Brenna**, DG GROW, European Commission (remote)<br>• **Karolina Nowak**, Medical Research Agency, Poland<br>• **Antonella Cardone,** Cancer Patients Europe<br>• **Isabell Remus**, Biosimilar Medicines Group, Medicines for Europe & Sandoz<br>**Q&A** |
| **13.00** | Buffet lunch |
| **14.15** | **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. |
| | Moderator: **Maja Graf**, Medicines for Europe<br>Panellists<br>• **Aurelio Arias**, IQVIA<br>• **Robert Sauermann,** Austrian Social Insurance, Austria<br>• **Adam Anderson**, NHS England, UK<br>• **Magnus Bodin**, Biosimilar market access committee, Medicines for Europe & Biogen<br>**Q&A** |
| **15.30** | **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. |

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| | Moderator: **Julie Maréchal-Jamil**, Medicines for Europe<br>Panellists<br>• **Elena Guillen Benitez**, Leiden University Medical Center, The Netherlands<br>• **Arti Rai,** Duke-Margolis, USA (remote)<br>**Q&A** |
| **16.10** | Coffee break |
| **16.40** | **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. |
| | Moderator: **Nivedita Roy**, Alvotech<br>Panellists<br>• **Steffen Thirstrup**, EMA<br>• **Sarah Yim**, FDA, USA (remote)<br>• **Ryosuke Kuribayashi**, PMDA, Japan<br>• **Ali Alhomaidan**, SFDA, Saudi Arabia (remote)<br>• **René Anour**, EMA Biosimilar Medicines Working Party and AGES, Austria<br>• **Niklas Ekman**, EMA Biosimilar Medicines Working Party and FIMEA, Finland<br>• **Martin Schiestl**, Sandoz<br>**Q&A** |
| **18.00** | **Day 1 Wrap up** |
| **18.00 - 19.30** | Networking cocktail in the Hilton hotel lobby |

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

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| **08.30 - 9.00** | Networking coffee |
| **9.00** | **Day 2 Welcome** |
| **9.00** | **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. |

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| | Moderator: **Mina Grguri**, Medicines for Europe<br>Speakers<br>• **Imen Ben Mansour**, National Agency of Medicines and Health Products (ANMPS), Tunisia<br>• **Gastón Morán**, ANMAT, Argentina<br>• **Radhouane Cherif**, EMA<br>• **Alex Juma Ismail**, African Union Development Agency - New Partnership for Africa's Development (remote)<br>**Q&A** |
| **10.30** | **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. |
| | Moderator: **Julie Maréchal-Jamil**, Medicines for Europe<br>Speaker: **Reinier Schlingemann**, Professor of Ophthalmology, Amsterdam Medical Center & Euretina, The Netherlands<br>**Q&A** |
| **11:00** | Coffee break |
| **11:30** | **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<br>Panellists<br>• **Paul Cornes**, Oncologist, UK<br>**--> Closing the care gap in oncology**<br>• **Elena Elez,** Medical Oncology Department Vall d'Hebron Institute of Oncology (VHIO), Spain<br>**--> Biosimilars: a window of opportunity to gain treatment options in metastatic colorectal cancer**<br>• **Zorana Maravic**, Digestive Cancers Europe<br>• **Susana Millán Ruiz**, mAbxience |

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| | **Q&A** |
| **13.00** | **Conference closing remarks - Joseph Dunford**, Biosimilar Access Committee, Medicines for Europe & Accord Healthcare |
| **13.10** | Buffet lunch |
| **14.30** | Conference adjourns |

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