PROGRAMME

Maximising Value in Health with Biosimilar Policies

Day 1 – Thursday 18 April 2024

8.00 am	Registration and welcome coffee
9.00 am	**Conference opening speech - Isabell Remus**, Chair of the European Biosimilar Medicines Group & Head Biopharma and Specialty Business, Sandoz
9.10 am	**Conference keynote speech - Michael Soldan,** Senior Adviser
9.30 am	**Session 1 - Building a unified and robust health bioeconomy in Europe – In need of a biosimilar strategy**
	The Biosimilar medicines concept was born in Europe along with R&D, biotechnological and biomanufacturing know-how. The regulatory, clinical and market experience to date has led to the transformation of health outcome opportunities through competition, delivering affordability and access, as well as enhancing supply security. In this session, panellists will discuss how to maintain and further grow a strong EU biosimilar industry in the global biotech ecosystem, looking at various EU policy initiatives and developments and their impact on market competition and industry competitiveness.
	Moderator: **Adrian van den Hoven**, Director General, Medicines for Europe Keynote speaker: **Ferenc Marofka**, Policy Officer, Health Industrial Ecosystem, DG GROW, European Commission Speakers: • **Saskia van der Erf**, Partner, Strategies in Regulated Markets (SiRM), The Netherlands • **Erik Bogsch**, Biosimilar Business Unit Director, Gedeon Richter, Hungary • **Margaret Kyle**, Centre for Industrial Economics (CERNA), France • **Julia Pike**, Global Head of IP, Sandoz, Germany Q&A with audience
10.45 am	**Spotlight 1 – Measuring the impact of biosimilar policy beyond treatment affordability**
	Experience with biosimilar medicines in Europe has delivered variable health outcomes in the various therapeutic areas and geographies where they are available, owing to the respective health and pharmaceutical policy frameworks. Beyond the direct benefits of biosimilar competition, such as a reduction of biologic therapeutic costs, there are a number of indirect benefits which are not always monitored, measured or documented. In this spotlight session, a health economic perspective on the value of biosimilar medicines will be provided.
	Moderator: **Alexandra Moulson**, Chief Development Officer and Managing Director, Polpharma Biologics Speaker: **Marius Geanta**, Association Centre for Innovation in Medicine (Ino-Med), Romania

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11.05 am	Coffee break
11.35 am	**Session 2 – Building bridges between all actors of biosimilar policy implementation**
	Recent reports show disparity and disconnect between the biosimilar approvals (opportunity) and their use in different countries and set up. There have been numerous endeavours to enhance information availability, provide training and education, as well as engage in multistakeholder policy initiatives. In this panel, the latest initiatives and aspirations will be shared along with good practice recommendations.
	Moderator: **Kati Sarnola**, Kela Social Insurance Institution, Finland Speakers: • **Peter Schneider**, Health Economist at the Austrian National Public Health Institute (GeOG), Austria • **Esa Heinonen**, Chair of the HMA Biosimilar Working Group and Senior Adviser to the Finnish Medicines Agency (FIMEA) • **Sanja Matić**, Head of Department for Utilisation and Prices of Medicines, Agency for Medicines (Halmed), Croatia • **Julie Maréchal-Jamil**, Director Biosimilar Policy & Science, Medicines for Europe Q&A with audience
1.00 pm	Buffet lunch
2.00 pm	**Session 3 – Future proofing the access roadmap to the next wave of cancer medicines**
	The Beating Cancer Plan highlighted the benefit of comprehensive cancer control strategies to reverse the tide and reduce the overall burden of cancer diseases in Europe. Among the 4 pillars of the plan, biosimilar medicine policies contribute directly to "diagnosis and treatment", enhancing affordability and accessibility, but also indirectly to other pillars across the disease journey. Over the next 10 years, nearly 1/3rd of biologic Loss of Exclusivities will be oncology biologics, however current pipeline information indicates a significant downward trend in the number of biosimilar candidates being developed (from 4 to 1 per reference molecule). In this session, stakeholders will explore the reasons behind this trend and discuss solutions to nurture biosimilar competition and foster re-investment of savings into high impact intervention.
	Moderator**: Kate O'Regan**, Head of Communications and Stakeholder Relations, Medicines for Europe Speakers: • **Aurelio Arias**, Director, Thought Leadership, IQVIA • **Rosa Giuliani**, Medical Oncologist, United Kingdom • **Chiara Brouns**, Policy Advisor, Dutch Healthcare Insurers, The Netherlands • **Zorana Maravic**, Chief Executive Officer, Digestive Cancers Europe (DiCE) Q&A with audience

3.25 pm	Coffee break and **NEW this year: presentations in our speaker corner** 3.40 - 3.50 pm New methods of biotherapeutics production in transgenic goat milk, enabling wider patient access, **Xavier Frapaise**, Chief Medical Officer Bio-Sourcing
4.00 pm	**Session 4 – Consolidating European Biosimilar Regulatory Science**
	The European Medicines Agency has pioneered the advent of the 1st biosimilar medicines regulatory pathway. The current EU pharmaceutical legislative reform and sustained activities from the regulatory network towards the EU network strategy 2025 goals are leading to a renewed fitness check of existing processes and requirements, as well as a preparedness evaluation of the next generation of biological medicines opening up to biosimilar competition. This session will allow the presentation of the latest data from recently authorised biosimilar medicines, emerging questions from scientific advice and highlights of the workplans from the EMA BMWP.
	Moderator: **Elena Guillén**, Clinical Pharmacologist, Hospital Clínic de Barcelona, Spain Speakers: • **René Anour**, Chair of EMA Biosimilar Medicines Working Party and Austrian Medicines Agency (AGES), Austria • **Nils Jost,** Assessor, Paul Ehrlich Institute (PEI), Germany • **Niklas Ekman,** Vice-Chair of EMA Biosimilar Medicines Working Party, BWP Member, Head of Biological Section, Senior Researcher at Finnish Medicines Agency (FIMEA) • **Andrea Laslop**, Head of Scientific Office, Principal Expert Austrian Medicines Agency (AGES), Austria • **Martin Schiestl**, Global Head Regulatory Affairs Policy, Sandoz Q&A with audience
5.30 pm	**Day 1 wrap up - Mina Grguri**, Biosimilar Policy & Science Officer, Medicines for Europe
5.40 pm **7.00 pm**	Networking cocktail

Day 2 – Friday 19 April 2024

8.30 am	Morning coffee
9.00 am	**Day 2 Opening speech - Ivana Knezevic**, Scientist, Team Leader, Norms and Standards for Biologicals, World Health Organization (WHO)

9.15 am	**Spotlight 2 - Tackling inequity: effectively translating biosimilar savings into patient access**
	Biosimilar medicines contribute to meaningful savings for healthcare systems in Europe. Despite this, disparities in access to biologics remain illustrating the need for effective policies to allow efficient and targeted recycling of the budget headroom. In this session, we will hear about recent research findings which put in perspective possible levers for European policy development in support of access to medicines, a critical priority for the EU health agenda.
	Moderator: **Eveline Schurink**, MD MPH, VP Clinical Development, Patient's Safety and Medical Affairs, Alvotech Speaker: **Jorge Mestre-Ferrandiz**, Independent (Health) Economics Researcher and Consultant
9.35 am	**Session 5 – Reforming EU and national market policies**
	This conference session will focus on sharing insight and experience. We aim to dissect national market dynamics that significantly impact biosimilar competition and the sustainable uptake of biological medicines. We will examine the potential for collective action at EU level, as well as possible national plans, to enhance market competitiveness and find the right balance between affordability and sustainability.
	Moderator: **Maja Graf**, Associate Director, Policy & Market Access, Medicines for Europe Speakers: • **Magnus Bodin**, Chair of the Biosimilar Market Access Committee, Medicines for Europe and Head of International Access & Policy, Biogen • **Pål Rydstrøm**, Senior Project Manager, Sykehusinnkjøp (SHI), Norway • **Mark Samuels**, British Generic Medicines Association (BGMA), United Kingdom • **Jorge Mestre-Ferrandiz**, Independent (Health) Economics Researcher and Consultant Q&A with audience
10.50 am	Coffee break
11.20 am	**Spotlight 3 – Towards a national biosimilar strategy: addressing within-country disparities in use and adoption**
	Promoting competition in off-patent markets has greatly contributed to health system efficiency, through increasing penetration of biosimilar medicines. Healthcare financing and national policy frameworks can explain some differences among EU member states in how they are able to seize the biosimilar opportunity. When it comes to discrepancies in within-country performance, other determinants impact the adoption and diffusion of biosimilars in the healthcare system. This session will look at the specific situation observed in Portugal and recommend how it can be addressed.
	Moderator: **Julie Maréchal-Jamil**, Director Biosimilar Policy & Science, Medicines for Europe Speaker: **Julian Perelman**, National School of Public Health of the Nova University of Lisbon, Portugal

11.40 am	**Session 6 – ASK THE REGULATORS: International regulators' panel**
	Regulators around the globe are actively discussing and evolving 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? What emphasis will be put on cooperation, convergence, reliance going forward? **Do not miss the chance to ask your question(s) to the regulators!** **Please send your QUESTION(S) to info@medicinesforeurope.com with the reference 'BIOS24', latest by 25 March 2024**
	Moderator: **Gillian Woollett**, VP, Head Regulatory Strategy and Policy, Samsung Bioepis and Biosimilars Committee Chair, IGBA Speakers: • **Steffen Thirstrup,** Chief Medical Officer, EMA • **Fabricio Carneiro de Oliveira,** General Manager of Biological Products, ANVISA, Brazil • **Rana Malkawi,** Drug Directorate Director/Regulatory Affairs Consultant, JFDA, Jordan • **Stacey Ricci,** Director, Scientific Review Staff, Office of Therapeutic Biologics and Biosimilars, CDER, FDA, USA • **Anne Cook,** Biologicals Quality Assessor, MHRA, UK • **Ivana Knezevic**, Scientist, Team Leader, Norms and Standards for Biologicals, World Health Organization (WHO) Q&A with audience
1.10 pm	**Conference closing remarks – Fabrice Romanet**, Vice-chair, Biosimilar Medicines Group, Medicines for Europe and Managing Director Fresenius Kabi SwissBiosim
1.20 pm 2.30 pm	End-of-conference buffet lunch

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