Day 1 - Thursday 25 May 2023		
	08.00	**Registration and Welcome Coffee**
	09.00	**Conference Opening - Adrian van den Hoven,** Medicines for Europe
	09.10	**Keynote Speech - Harald Mische,** European Commission DG Santé
	09.30	**Session 1 - EU regulatory reform and biosimilar leadership**
		The EMA is undergoing a transformation of its ways of working while, at the same time, the regulatory experience with biosimilar medicines applications points to a need for a natural evolution. How can the proposed revised pharmaceutical legislation (Directive, regulation) support this evolution in a timely fashion? How can we adapt requirements and overcome known feasibility challenges? (scientific advice procedure, guideline revision, streamlining clinical development)
		Moderator: **Christian K. Schneider,** Biopharma Excellence Speakers • **Martin Schiestl**, Sandoz • **Peter Richardson**, EMA • **Niklas Ekman**, FIMEA and EMA Biosimilar Medicines Working Party
	11.00	**Spotlight 1 - Early prevention of the inflammatory cascade – how biosimilar availability shifted the treatment paradigm for paediatric IBD patients** **Moderator: Julie Maréchal-Jamil**, Medicines for Europe **Lissy de Ridder**, Associate Professor in Paediatric Gastroenterology, Erasmus MC-Sophia Children's Hospital, Rotterdam
		Q&A with the audience
	11.20	**Networking Coffee Break**
	11.50	**Presentation - Perspective on European trends, Future biologic LoE landscape and its changing health economics outlook** **Aurelio Arias,** IQVIA
		Q&A with the audience
	12.20	**Spotlight 2 - Understanding the Patient Journey in a Rare Disease Condition** **Moderator: Kate O Regan**, Medicines for Europe **Tanya Collin-Histed**, International Gaucher Alliance
	12.40	**Presentation - USA: Biosimilar market Trends, Issues and Outlook** **Marta Wosinska,** The Brookings Institution, USA
		Q&A with the audience
	13.10	**Networking Buffet Lunch**

	14.10	**Session 2 - Collaborative & Worksharing Initiatives: Fast Lane to regulatory convergence?**
		International collaborative schemes (IPRP biosimilars WG and ACCESS Consortium) have an ability to drive convergence, via aligned positions, training opportunities or materials etc. They can also serve to pre-empt future harmonisation needs (i.e. when divergence is ALREADY present), and instead foster upfront international alignment. This becomes highly relevant considering future pipelines and off-patent versions of combination therapeutics, orphan, cell & gene and RNA therapeutics as the next biosimilar regulatory and science challenge to resolve (e.g. comparability approaches, product vs platform regulation).
		Moderator: **Fabrice Romanet**, Vice Chair of the Biosimilar Medicines Sector Group, Medicines for Europe and Fresenius Kabi SwissBioSim GmbH Speakers • **Michael Rosu-Myles**, Health Canada, Canada • **Stacey Ricci**, US FDA, USA • **Yasuhiro Kishioka**, PMDA, Japan • **Steffen Thirstrup**, EMA, EU
	15.30	**Networking Coffee Break**
	16.00	**Session 3 - Competition: Foundation to deliver the value of Biosimilar medicines**
		Biosimilar medicines have been of instrumental value to the healthcare systems by bringing competition to the space of biologicals, where expenditure is rising at an escalated rate. Biosimilar medicines are an attractive target for optimising procurement policies, as the recent EU study on the public procurement practices points out, providing an important tool towards better use of resources. However, there are several elements to the policy framework, that will only together result in instilling healthy competition. In this session we will look at the current state of play and how to ensure long-term healthy competition in the field of biologics.
		Moderator: **Magnus Bodin**, BMAC Vice Chair and Biogen Speakers • **Laure Geslin**, DG Sante, European Commission • **Neil Grubert**, Independent Global Market Access Consultant, UK • **Despoina Makridaki**, EAHP - European Association of Hospital Pharmacists
	17.30	**Reflections from day one on how biosimilar policies have provided for better health in Europe**
	17.45	**Networking Cocktail**

Day 2 - Friday 26 May 2023		
	08.30	**Start of the day Coffee**
	09.00	**Spotlight 3 - Focus on Madrid and its local initiative in support of the use of Biosimilar medicines in healthcare practice** **Moderator: Julie Maréchal-Jamil**, Medicines for Europe **Ainhoa Aranguren**, Madrid Regional Department of Pharmacy and Medical Devices, Madrid Health Service SERMAS, Spain
		Q&A with the audience
	09.30	**Session 4 - Early effective treatment with biological medicines - unlocking the potential of biosimilar medicines for healthcare and public health improvement**
		Biological medicines have revolutionised the treatment of chronic inflammatory immunological and ophthalmological diseases such as rheumatoid arthritis (RA), plaque psoriasis, inflammatory bowel disease (IBD) and neovascular age-related macular degeneration (nAMD). However, the high cost of biological therapies has often resulted in treatment inequalities. The integration of biosimilar medicines into treatment algorithms has led to a reduction of biological treatment costs. It is now the responsibility of regulatory bodies, clinical societies, guideline- and formulary-committees to revisit guidance so that patients eligible for biological treatments obtain timely access. This session will look at recent examples of optimised disease management initiatives and how guideline revisions can lead to an improved patient journey thanks to evolving clinical practice.
		Moderator: **Fernando de Mora**, University of Barcelona, Spain Speakers • **Milan Lukáš**, IBD Clinical and Research Centre ISCARE and 1st Medical Faculty, Charles University, Czech Republic • **Peter Taylor**, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, UK • **Mourad Farouk Rezk**, Biogen Biosimilars • **Liese Barbier**, Postdoctoral Researcher Pharmaceutical Sciences, KU Leuven, Belgium
	11.00	**Networking Coffee Break**

	11.30	**Session 5 – Global biosimilar business leaders – Roundtable**
		The biopharmaceutical industry has been heavily impacted in recent years by the pandemic and surges in energy costs and inflation. Yet, the biologic loss of exclusivities for the next decade represents an unprecedented opportunity for biosimilar medicines developers and patients with Non-Communicable Diseases. In this session, we will hear from business leaders on their vision for the future.
		Moderator: **Adrian van den Hoven,** Medicines for Europe Speakers • **Dan Cohen**, Biogen • **Xavier Mesrobian**, Vice-Chair, BMAC and Accord Healthcare • **Harshika Sarbajna**, Alvotech • **Kyung-Ah Kim**, Samsung Bioepis • **Darius Panaligan**, Fresenius Kabi Biosim • **Peter Stenico**, Sandoz
	12.45	**Conference Closing Speech - Pekka Kurki**, Adjunct Professor, University of Helsinki, Finland
	13.00	**Conference Conclusion - Julie Maréchal-Jamil**, Medicines for Europe
	13.10	**Conference Buffet Lunch**
	14.30	**End of Conference**

PLATINUM SPONSORS

accord We make it better

FRESENIUS KABI caring for life

SANDOZ A Novartis Division

SILVER SPONSOR

SAMSUNG BIOEPIS

CONFERENCE SPONSOR

polpharma biologics

MEDIA PARTNER

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

Follow the event on twitter #BIOS23

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