BIOSIMILAR MEDICINES

Virtual Summit 2021

BIOSIMILARS: INVESTMENT IN HEALTH THAT MATTERS

22 April 2021
6 May 2021
20 May 2021
15:00-16:30 (CEST)

LIVE SESSION SERIES
ONLINE CONTENT PLATFORM

biosimilar medicines
a medicines for europe sector group

The 2021 Biosimilar Medicines Virtual Summit will explore the latest developments in biosimilar medicines policies and look at future opportunities and challenges in this field. In a novel online format, each live session will be complemented by resources such as recorded interviews and presentations, infographics, and reports.
Registration for this summit will be free and will grant access to a website containing all the related material.

ONLINE CONTENT PLATFORM

All registered participants will receive a password that enables access to the Biosimilar Medicines Virtual Summit online content platform. On this website, each participant can explore a wide range of resources associated with the live sessions, including pre-recorded interviews, infographics and reports. New contents will be released ahead of each live session, and the website is accessible at any time. This innovative format allows users to focus on the resources that are most relevant to them and tailor their participation in the Virtual Summit to their schedule.

CHECK OUR ONLINE PLATFORM FOR ADDITIONAL CONTENT

SESSION 1 - **EU barometer for resilient access to biologics**

EU Member States have deployed a diverse range of biosimilar medicines strategies that create win-win-win policies:

- payers and insurers benefit from the increased cost-efficiency of biosimilar medicines,
- patients and healthcare professionals benefit from alternative biological treatment options and,
- the sustainability of the biosimilar marketplace is ensured to guarantee that these benefits are enjoyed by stakeholders in the long-term.

In this session, panellists will discuss how they plan to achieve biosimilar market sustainability, giving examples of successful measures and actions, including their strategies to redeploy benefits from biosimilar use and enhance healthcare.

VIEW RECORDED INTERVIEW SPEAKERS ON ONLINE PLATFORM

Live panel discussion - 22 April 2021, 15:00 - 16:30 (CEST)

Opening remarks

- **Isabell Remus -** Chair of the Biosimilar Medicines sector group, Medicines for Europe and Head Biosimilars & Specialty Business, Sandoz Europe

Moderator

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

SPEAKERS	Live panel discussion	Recorded interview speakers
Tomas Tesar - Associate Professor, Faculty of Pharmacy, Comenius University, Slovakia	✓	
Philippe Van Wilder - Professor, Université Libre de Bruxelles School of Public Health, Belgium	✓	
Dorthe Bartels - Senior Strategic Advisor, Amgros I/S	✓	

Bernard Duggan - Chief II Pharmacist, HSE-Medicines Management Programme, Trinity Centre for Health Sciences, St James's Hospital	✓	
Marcin Czech - Professor and Head of the Department of Pharmacoeconomics, Institute of Mother and Child Warsaw, Poland		
Luca Degli Esposti - CEO, CliCon, Italy		

SESSION 2 – **Translating experience into regulation**

Beyond marketing authorisation processes, regulators can support earlier and broader access, as well as contribute to future access, by evolving regulatory requirements. This can be achieved through

- improving efficiency in the development and registration process and
- sharing and learning from experience to date

In this session, the panel will discuss the current regulatory tools and particularly their fitness-for-purpose.
The exchange will aim to assess whether further efficiency in biosimilar development (e.g. clinical streamlining) can be achieved in a coherent and timely manner as a result of international regulatory dialogue.

VIEW RECORDED INTERVIEW SPEAKERS ON ONLINE PLATFORM

Live panel discussion - 6 May 2021, 15:00 - 16:30 (CEST)

Opening remarks

- **Isabell Remus -** Chair of the Biosimilar Medicines sector group, Medicines for Europe and Head Biosimilars & Specialty Business, Sandoz Europe

Moderator

- **Keith Watson** - Vice President, Regulatory Policy and Strategy, Celltrion

SPEAKERS	Live panel discussion	Recorded presentations
Elena Wolff-Holz - Chair of Biosimilar Medicinal Products Working Party (BMWP) of CHMP, European Medicines Agency	✓	
Ana Hidalgo-Simon - Head of Advanced Therapies, European Medicines Agency	✓	
Sarah Yim - Director, Office of Therapeutic Biologics and Biosimilars, U.S. Food and Drug Administration (FDA)	✓	
Hye Na Kang - Scientist in the Norms and Standards for Biological Products (NSB) team of the department of Health Products Policy and Standards (HPS), WHO	✓	
Anne Cook - Expert Quality Assessor, Medicines and Healthcare products Regulatory Agency (MHRA), UK	✓	
Martin Schiestl - Global Head Regulatory Affairs Policy, Sandoz Biopharmaceuticals	✓	

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Celia Lourenco - Director General, Biologic and Radiopharmaceutical Drugs Directorate (BRDD) of the Health Products and Food Branch, Health Canada		
Guido Pantè - Technical Officer, Prequalification Unit, Department of Regulation and Prequalification (RPQ), WHO		

SESSION 3 - **From disruption to care for cancer patients**

The use of biosimilar oncology medicines (first line and supportive care) can actively contribute to the success of the EU Beating Cancer plan. Biosimilar medicines can be instrumental in tackling inequalities in cancer care, making biological standards of care more affordable and, more importantly, allowing the redeployment of resources, freed up by the use of biosimilar medicines, into areas of cancer care where great needs have been identified, such as prevention, diagnostics and quality of life.
The panellists will share perspectives on how best to ensure that the benefits of the use of biosimilar medicines form an integral part of the strategy as well as discuss the areas of greatest need along the cancer care continuum for better patient care.

VIEW RECORDED INTERVIEW SPEAKERS ON ONLINE PLATFORM

Live panel discussion - 20 May 2021, 15:00 - 16:30 (CEST)

Opening remarks (recorded)

- **Stella Kyriakides -** Commissioner for Health and Food Safety, European Commission

Moderator

- **Laura Shields** - Managing Director, Red Thread EU

SPEAKERS	Live panel discussion	Recorded interview speakers
Stella Kyriakides - Commissioner for Health and Food Safety, European Commission		
Rosa Giuliani - Director of Public Policy, European Society for Medical Oncology (ESMO)	✓	
Johan De Munter - Assistant Nurse Manager Cancer Center, University Hospital Ghent & President, European Oncology Nursing Society	✓	
Zorana Maravic - Acting CEO, Digestive Cancers Europe (DiCE)	✓	
Matti Aapro - President, European Cancer Organisation	✓	
Maja Sercic - Policy & Science Manager, Medicines for Europe	✓	
Antonella Cardone - Director, European Cancer Patient Coalition (ECPC)		

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