



**8<sup>TH</sup> BIOSIMILAR MULTISTAKEHOLDER EVENT**  
**BRUSSELS, 5 DECEMBER 2024**  
**HYBRID**  
**9H00 – 16H45 CET**

**DRAFT AGENDA**

- 08.30 – 09.00**      **Registration and welcome**
- 09.00 – 09.15**      **Introductory note**
- Sandra Gallina, Director-General DG SANTE, European Commission (video message)
- 09.15– 09.30**      **Patient keynote speech**
- Board of the Portuguese League Against Rheumatic Diseases (*Liga Portuguesa Contra as Doenças Reumáticas*)
- 09.30 – 10.45**      **Ensuring biosimilar development and competition in Europe: where are we now?**
- Chair: National Scientific Advice Austrian Medicines & Medical Devices Agency (AGES), Chair of EMA Biosimilar Working Party
- The impact of biosimilar competition in Europe*
- IQVIA
- Regulatory perspective on the biosimilar pipeline and reflection on a tailored clinical approach to biosimilar development*
- Steffen Thirstrup, Chief Medical Officer, European Medicines Agency
- Update on biosimilar competition enforcement in the pharmaceutical sector (2018-2022)*
- DG COMP, European Commission
- Interactive Q&A discussion with the audience
- 10.45 – 11.00**      ***Coffee & networking break***
- 11.00 – 12.30**      **Promoting biosimilar uptake: current developments**
- Chair: HSE Medicines Management Programme (Ireland)

*Clinical perspective on biosimilar use in the rheumatology field*

- MD PhD Diakonhjemmet Hospital Oslo

*Updates on national biosimilar policies*

- Norway
- Belgium
- Portugal

Interactive Q&A discussion with the audience

**12.30 – 13.30**      ***Networking lunch***

**13.30 – 14.45**      **AUGMENT: an EU4Health biosimilar capacity-building project**

*Welcome and outline of the session*

- DG SANTE, GÖG

*Overview of the project and preliminary findings*

- AOTMIT, MUS, GÖG, NOVA

*Invited commenters on the design of the project and expectations*

- Drug Commission of German Doctors
- Ministry of Health, Cyprus
- Board of the Portuguese League Against Rheumatic Diseases (*Liga Portuguesa Contra as Doenças Reumáticas*)
- Medicines for Europe

**14.45 – 15.15**      ***Coffee & networking break***

**15.15 – 16.30**      **AUGMENT: an EU4Health biosimilar capacity-building project**

*Touchpoints for stakeholder involvement and launch of the EU Health Policy Platform Stakeholder Network*

- GÖG, AOTMIT

*Break-out sessions*

**16.30 - 16.45**      **Closing words**

- DG SANTE