Biosimilar Breakout Session :

HMA-EMA Multi-stakeholder workshop on shortages

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Objectives of session on biosimilars

HMA-EMA multi-stakeholder workshop on shortages

- **Understand stakeholders' experience on shortages** of biological medicines, including biosimilars and gather views on **whether availability of biosimilars could** be a good way to **prevent shortages** of biologicals
- Provide an **overview** of the work **of HMA working group on biosimilars** and explain the **EU scientific position on interchangeability**
- Understand how the work undertaken by the **European Medicines Agencies Network** could **prevent potential shortages of biologicals** and **increase the uptake of biosimilars**

Outcome of pre-meeting survey

- Survey run pre-meeting to understand stakeholders' experiences
- Responses from all stakeholder groups low response rate (26%, n=26)
- Some relevant **observations:**
  - **Need for increasing information on biosimilars** over 50% (13 out of 25)
  - **Experience of shortage of a biological or a biosimilar medicine** 50% (13 out of 26)
  - **Most respondents trust interchangeability** 84% (21 out of 25)
  - **Various reasons for lack of trust on interchangeability** (16%, 4 out of 25) including lack of comparative studies, resource implications when training patients to use another device after switching and potential loss of efficacy due to immunogenicity
  - Perception of **biosimilars as useful alternatives to prevent shortages** of biological medicines (62%, 16 out of 26)

Breakout session on Biosimilars

- **Extensive scientific and clinical experience** with biosimilars, including on safety and prescriber-led switching
- Need for **more timely communication** on the regulatory science underpinning biosimilars to **foster trust**
- **Consistent messaging needed** across all the different players of the healthcare system, while adapting to the needs of different therapeutic areas
- **Need to address concerns on interchangeability**, such as off label use and the importance of patient consent
- **Varied reasons for lack of availability** (e.g., procurement, market forces, patent issues, etc.)
- **Different speed of access to biosimilars across EU** – need for MSs to prepare and engage early with tenderers
- Need to address **sustainability of biosimilar development** as pipeline forecast predicts lack of biosimilars for some products
- **HTA and payers support biosimilarity** but identified hurdles on implementation of interchangeability

  (e.g., switching studies for devices to prove compatibility)
- Biosimilars are different from generic medicines, but **implementation has to follow a similar approach**
- **Biosimilars can prevent shortages** of biological medicines

Thank you for listening

Further information

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https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union