biosimilar medicines
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# EPF – Medicines for Europe Seminar

## *Biosimilar Medicines – How to deliver on patient information needs?*

26 April - Brussels

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# Is information for patients satisfactory?

- We have an opportunity to work together to improve **accessibility** and **suitability** of information on biologics and biosimilars
- Overall understanding of biologic, including biosimilar, medicines remains in general rather low
- Surveys (e.g. EFCCA, etc.) show patients call for more information for on biosimilar medicines and don't believe existing information is easy enough to access
  - Can the information be easily found?
  - Can the information be easily understood?

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# Currently available information sources

- *EMA Q&A on biosimilar medicines of 2007 – revised in 2012* *(EMA Biosimilar medicines – Q&A on biosimilar medicines – September 2012)*
- *Multi-stakeholder consensus document "What you need to know about biosimilars"* *(EC DG GROW – Corporate Social Responsibility – Market Access for Biosimilars – 2013-2017)*
- *EC Q&A documents tailored for*
  - *Patients (EC DG GROW – Q&A for patients – Biosimilar medicines explained – 2016)*
  - *Physicians (EC DG GROW – Q&A for physicians – 2017 – under development)*
- *International Alliance of Patients Organisations (IAPO) biosimilars toolkit*
  - *Briefing paper, guide and factsheets available in English, Spanish and Portuguese*
- *Several scientific publications by EU regulators [5] have been designed to address clinicians specifically*

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# Further open questions for discussion

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# Open questions

- What are your experiences as patient organizations?
- What additional information sources exist?
- What additional information should be made available?
- Are the focus areas of the Medicines for Europe Q&A correct?
- Are the current questions the right ones?

# Biosimilar “hot topics” Q&A – Example Biologics Variability

- Can biologics be exactly copied or replicated?
- Can biologics variability be controlled?
- What do people call “(clinical) drift” and “quality drift” in the context of biologic medicines?
- How can one be sure that the biosimilar medicine remains comparable to its reference product throughout its life-cycle?
- What variability can be tolerated between the reference and the biosimilar medicine?

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# Next Steps

Proposal for a Joint-taskforce on biosimilar medicines

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# The creation of a joint taskforce

- *Objective:*
  - *Stimulate dissemination and easy access to authoritative information*
- *Focus:*
  - *"What": content of the information*
  - *"How": methods of dissemination*
- *Call for nomination of members by end-May*

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# Thank you