European Commission
Multi-stakeholder Workshop
Biosimilar Medicinal Products
5 May 2017

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2010-2013: Process on Corporate Responsibility Working Group Access to and Uptake of Biosimilars

- **Objectives**
  - Exchange between the EU member states and the stakeholders (patients, doctors, etc.) about the current experience with biosimilars
  - Overview on availability of biosimilar medicinal products in European national markets
  - Definition of the necessary conditions for an informed uptake and adequate patient access to biosimilar medicinal products

- **Approach**
  - Understanding amongst all stakeholders that there is a need for a partnership between patients, doctors and other healthcare professionals, regulators, payers, insurers and policy makers and the commercial operators
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- Final deliverables
  - Overview of information on reimbursement status of biosimilar medicinal products in EEA countries
  - IMS study on *Biosimilar accessible market: Size and biosimilar penetration*
  - *What you need to know about Biosimilar Medicinal Products*. A consensus information document with a specific Q&A for patients, physicians and payers
Follow-up activities

- Translations of consensus information paper (available now in DE, EN, ES, FR, IT, PL, PT)
- IMS Health / EC yearly report on biosimilars competition and market uptake
- Multi-stakeholder Workshops:
  - 6 October 2015: Follow-up discussions from patients', doctors', payers' perspective
  - 20 June 2016: patients in the focus
  - 5 May 2017: healthcare professionals in the focus
- Update Q&A on biosimilars for patients
"Interestingly, the European biosimilars guide — which emphasizes that it has been created "by and for patients," together with input from the EMA and EC — highlights that what’s being done across the pond isn’t the same as the approach taken in the fledgling U.S. market — where nearly seven in 10 consumers don’t know what a biosimilar is, according a survey by PriceWaterhouseCoopers."
EC Workshop's general objectives

- Providing a regular opportunity for gathering all relevant parties to facilitate an exchange between all stakeholders
- Particularly to give a floor for patients and doctors, pharmacists, nurses to express their views
- To present a regular update on uptake and market evolution
Issues discussed

- Patients' and healthcare professionals' perspective:
  - Informed decision taking - access to unbiased, reliable and adequate information (in their native tongue)
  - Concerns around safety and efficacy, post-marketing surveillance and pharmacovigilance
  - Clinical experience with switching and interchangeability

- Payers' / Insurers' perspective:
  - Increased patient access to high quality treatments while taking into account the scarce financial resources
  - Sustainability of healthcare systems AND the industrial base
Next event: 5 May 2017

- IMS Health Report 2017: The impact of biosimilar competition
- Session 1: Biological Medicines Access Mechanisms: Balancing Access and Freedom of Prescription
- Launch of the new information document for healthcare professionals
- Session 2: Collaborative Approach in the Use of Biosimilar Medicines
- Session 3: Building stakeholder confidence in biosimilar medicines through evidence-based information sharing
Thank you!


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