European Commission Multi-stakeholder Workshop

Biosimilar Medicinal Products

5 May 2017

Hilda Juhász
European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

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

Objectives

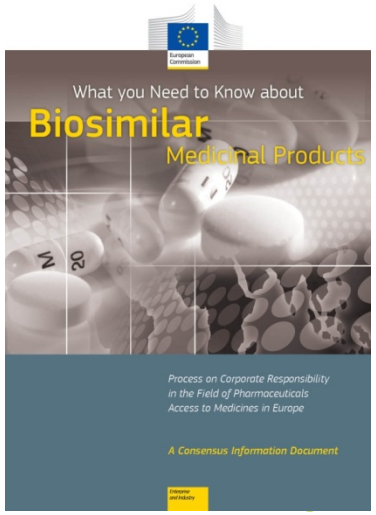
- Exchange between the EU member states and the stakeholders (patients, doctors, etc.) about the current experience with biosimilars
- Overview on availability of biosimilar medicinal products in European national markets
- Definition of the necessary conditions for an informed uptake and adequate patient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

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

- **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

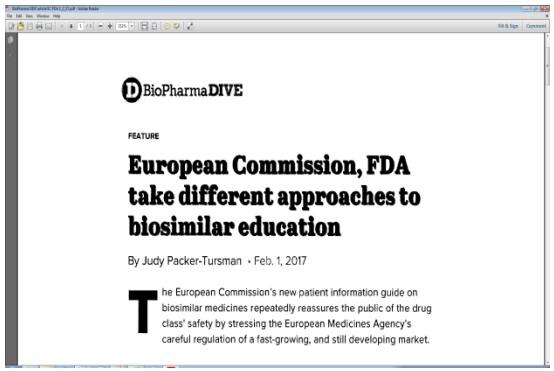
- Translations of consensus information paper (available now in DE, EN,ES, FR, IT, PL, PT)
- IMS Health / EC yearly report on biosimilars competition and market uptake
- Multi-stakeholder Workshops:
  - 6 October 2015: Follow-up discussions from patients', doctors', payers' perspective
  - 20 June 2016: patients in the focus
  - **5 May 2017: healthcare professionals in the focus**
- Update Q&A on biosimilars for patients

Q&A on Biosimilars for Patients

- Published in 7 languages in January 2017 (available now in DE, EN,ES, FR, IT, PL, PT)

http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=9066&lang=en

"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."



BioPharmaDIVE

FEATURE

European Commission, FDA take different approaches to biosimilar education

By Judy Packer-Tursman • Feb. 1, 2017

The European Commission's new patient information guide on biosimilar medicines repeatedly reassures the public of the drug class' safety by stressing the European Medicines Agency's careful regulation of a fast-growing, and still developing market.

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!

http://ec.europa.eu/growth/sectors/healthcare/competitiveness/index_en.htm

hilda.juhasz@ec.europa.eu