European Commission

Stakeholder Event on Biosimilar Medicinal Products

Brussels, 5 May 2017

(Conference Center Albert Borschette, rue Froissart 36, 1040 Brussels – Room 0D)

DRAFT AGENDA

10.30 Introductory note

10.40 IMS Health Report 2017: The impact of biosimilar competition
Per Troein, Vice President Global Strategic Planning, IMS Health

11:00-12:30 Session 1

Biological Medicines Access Mechanisms: Balancing Access and Freedom of Prescription

Biological medicines access mechanisms vary among EU Member States. An increasing number of Member States use public tendering under the EU Public Procurement rules (Directive 2014/24/EU) to purchase biological medicines. These rules should guarantee access to biologic treatments for patients, while allowing freedom of choice for physicians by ensuring that treatment options are not limited and the prescribing decision remains with the treating physician. Certain Member States have implemented “Gainshare” approaches to align stakeholders in the use of biologic medicines.

Using concrete case studies, this session will explore how the new EU public procurement and tendering rules as well as novel “Gainshare” agreements foster greater access and what they mean for the freedom of prescription of treating physicians and the sustainability of the biologics market. Furthermore, the session will bring perspectives from different stakeholders related to these access mechanisms.

Chair:

Arnold Vulto, Professor of Hospital Pharmacy & Practical Therapeutics, Erasmus University Medical Center, NL

Panel:

- **An Baeyens**, Legal and Policy Officer, Directorate General Internal Market, Industry, Entrepreneurship and SMEs, European Commission
- **Paolo Bonaretti,** Economic Advisor, Cabinet Office, Ministry of Economic Development, Italy
- **Stanislav Primozic**, Head of Sector for Pharmacoeconomics, Pharmacovigilance and HTA – JAZMP
- **Márk Péter Molnár**, Research Leader, Corvinus University of Budapest, former Head of Reimbursement National Health Insurance Fund, Hungary
- **Maggie Dolan**, Specialist Procurement Pharmacist, National Health Service Commercial Solutions, UK

12.30 – 13.30 **Networking Lunch**

13:30- 13:45 **Launch of the new information document for healthcare professionals**

Juan Garcia Burgos, Head of Public Engagement, European Medicines Agency

13.45 – 14:45 **Session 2**

Collaborative Approach in the Use of Biosimilar Medicines

An inclusive participation is crucial to ensuring appropriate and efficient use of biosimilar medicines at an individual and societal level, including the involvement of patients, healthcare professionals, and payers or insurers. This session will explore best practices in ensuring commitment and involvement of all stakeholders to appropriate use and sustainable uptake of biosimilar medicines. Representatives of patients, physicians, nurses, pharmacists and payers share experiences and lessons learned, including identification of remaining challenges.

Chair:

Josep Tabernero, President-Elect of ESMO, Chair of the Cancer Medicines Working Group

Introductory presentation:

- **Gustaf Befrits**, Administrator/Health Economist, Stockholm County, Sweden

Panel:

- **Lydia Makaroff**, Director, European Cancer Patients Coalition (ECPC)
- **Ber Oomen**, Executive Secretary, European Specialist Nurses Organisations (ESNO)
- **Thijs J. Giezen**, Hospital Pharmacist, Foundation Pharmacy for Hospitals in Haarlem, NL
- **Sander W. Tas**, Rheumatologist, Academic Medical Center Amsterdam, NL

14:45 – 16:15 Session 3

Building stakeholder confidence in biosimilar medicines through evidence-based information sharing

As both clinical experience and real world evidence increases, knowledge sharing and identifying best practices can support the appropriate use of biologics, including biosimilar medicines. This session will focus on providing an update of the latest available clinical experiences with biosimilar medicines, focusing on switching between biological medicines and “interchangeability” and provide an overview of best practices in pharmacovigilance for biological, including biosimilar medicines. Additionally this session will provide clarity regarding the European scientific and medical term and experience with “interchangeability” and the US FDA legal term and regulatory requirements for “interchangeability”.

Chair:
Sol Ruiz, Chair of the Biologicals Working Party (also CAT and CHMP member)

Panel:

- **Hans Ebbers**, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht University, NL
- **Gianluca Trifiro**, Assistant Professor, Dept of Clinical and Experimental Medicine and Pharmacology,
- **Benedicte Lunddahl Rasmussen**, Head of section - Danish Medicines Agency Denmark

- **Pekka Kurki,** Assistant Professor, Clinical Immunology, University of Helsinki, Finland (former Chair of the EMA Biosimilar WP)
- **Sue Lim,** Senior Staff Fellow , Center for Drug Evaluation and Research, Food and Drug Administartion (FDA), USA

16:15 – 16:30 Wrap up / Closing note

16:30 – End of workshop