European Commission

STAKEHOLDER EVENT ON BIOSIMILAR MEDICINAL PRODUCTS

Brussels, 30 October 2019

(Conférence Centre Albert Borschette CCAB, Room AB-0D, Rue Froissart 36, 1040 Brussels)

Draft Agenda

Welcome

***Stefano Soro**, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), European Commission* **9.30 - 9:40**

Introductory presentation: Potential tools to optimize the benefits of biosimilars from the societal perspective

***Zoltán Kaló**, Prof. of Health Economics, Centre for Health Technology Assessment, Semmelweis University, Budapest, Hungary* **9.40 - 9:50**

SESSION 1 **9:50 - 11:00**

WHAT ARE THE FORCES DRIVING THE BIOSIMILAR MARKET?

The development of a competitive and sustainable off-patent medicines market is a key challenge for payers, regulators and companies supplying medicines to the market. Several European and national bodies have highlighted the importance of timely availability of biosimilars to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems. Policies should be also designed to ensure the long-tem sustainaibility and availability of these products.

IQVIA Report 2019: A Snapshot of the biosimilar market dynamics

***Per Troein**, IQVIA* **9:50 - 10:10**

Market dynamics from a DG COMP perspective

***Rainer Becker**, Directorate-General for Competition (DG COMP), European Commission* **10:10 - 10:30**

Discussion **10:30 - 11:00**

***Moderator**: **Zoltán Kaló**, Prof. of Health Economics, Centre for Health Technology Assessment, Semmelweis University, Budapest, Hungary*

***Panel**: Per Troein (IQVIA), Rainer Becker (EC, DG COMP), Isabell Remus, (Medicines for Europe), Kristine Peers (General Counsel EFPIA)*

COFFEE BREAK **11:00 - 11:15**

SESSION 2 **11:15 - 12:30**

HOW TO ENSURE A SUSTAINABLE BIOSIMILAR MARKET?

To create and maintain a sustainable market, a good balance between price- and demand-side policies is needed. In this session, a panel of representatives from different EU Member States and the European Commission will speak about their visions of healthcare policies for greater equity and quality of care. Sharing their experiences will help identifying best practices to improve access to biological medicines and to leverage the full benefits of biosimilar medicines.

Member States experiences with biosimilars

***Mathias Flume**, Head of Business Unit Prescription Management, Kassenärztliche Vereinigung Westfalen Lippe, KVWL, (Germany)* **11:15 - 11:25**

***Tomáš Tesař**, Member of the Reimbursement Committee at Slovak Ministry of Health, Union Health Insurance Fund (Slovakia)* **11:25 - 11:35**

***Floriane Pelon**, Direction de la Sécurité Sociale, Ministère des solidarités et de la santé (France)* **11:35 - 11:45**

Sustainable procurement of medicines: a perspective from DG GROW

***An Baeyens**, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), European Commission* **11:45 - 12:00**

Discussion **12:00 - 12:30**

***Moderator**: **Per Troein**, IQVIA*

***Panel**: Mathias Flume (DE), Tomáš Tesař (SK), Floriane Pelon (FR), Evert Jan van Lente (Medicine Evaluation Committee MEDEV), Dorthe Bartels (AMGROS - Regions' Procurement Pharmaceutical Organisation, Denmark), Kelly Burke (Medicines for Europe), Mareike Ostertag (Director Regulatory and Science Policy, Novartis).*

LUNCH BREAK **12:30 - 14:00**

SESSION 3 **14:00 - 15:45**

HOW TO IMPROVE EARLY ACCESS TO BIOSIMILARS?

Learning from examples

Patient access to originator biological medicines is often restricted due to cost-efficiency reasons. Biosimilars offer an opportunity for patients to broaden access to treatment with biological medicines. In this session, we will explore what is needed to unlock the full potential of biosimilars by exchanging views between healthcare professionals, Member States Competent Authorities and the European Medicines Agency.

The success story of biosimilars

***Rosa Gonzalez-Quevedo**, European Medicines Agency EMA* **14:00 - 14:15**

Perspectives from physicians, pharmacists, patients, nurses and Member States on instruments/ways to foster biosimilars access to patients

Physicians

***Matti Aapro**, Executive Board member of the "European School of Oncology" (ESO), board member of "European CanCer Organisation" (ECCO)* **14:15 - 14:25**

Pharmacists

***Arnold G. Vulto**, Prof. of Hospital Pharmacy & Practical Therapeutics, Erasmus University Medical Center, Rotterdam, The Netherlands* **14:25 - 14:35**

Patients

***Zorana Maravic**, Director of Group & Project Development, Development Manager for Central and Eastern Europe, EuropaColon, Digestive Cancers Europe* **14:35 - 14:45**

Nurses

***Louise Parker RN**, Lead Nurse - Rheumatology & Connective Tissue Disease, Royal Free London NHS Foundation Trust, European Specialist Nurses Organisations* **14:45 - 14:55**

Public Competent Authorities

***Nicolai Brun,** Director of Division of the new Medical Evaluation & Biostatistics division, Danish Medical Agency DKMA, Denmark* **14:55 - 15:05**

Akos Karsay, *Department of item based medicines, National Institute of Health Insurance Fund, Budapest, Hungary* **15:05 - 15:15**

Discussion **15:15 - 15:45**

Moderator*:* ***Arnold G. Vulto****, Prof. of Hospital Pharmacy & Practical Therapeutics, Erasmus University Medical Center, Rotterdam, The Netherlands*

Panel*: Matti Aapro (European School of Oncology ESO, European CanCer Organisation ECCO), Usman Khan (European Patient's Forum EPF), Ber Oomen (European Specialist Nurses Organization ESNO), Nicolai Brun (Danish Medical Agency DKMA), Akos Karsay (National Institute of Health Insurance Fund, Budapest), Rosa Gonzalez-Quevedo (European Medicines Agency EMA).*

CONCLUSIONS **15:45 - 16:30**

Building on lessons learnt: preparing for the future

General discussion and wrap-up **15:45 - 16:15**

Moderator*:* ***Stefano Soro****, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), European Commission*

Panel*: Per Troein (IQVIA), Rainer Becker (EC, DG COMP), Zoltán Kaló (Prof. of Health Economics, HU), Mathias Flume (DE), Tomáš Tesař (SK), Floriane Pelon (FR), Evert Jan van Lente (Medicine Evaluation Committee MEDEV), Dorthe Bartels (AMGROS, Regions' Procurement Pharmaceutical Organisation, Denmark), Rosa Gonzalez-Quevedo (EMA), Matti Aapro (European School of Oncology ESO, European CanCer Organisation ECCO), Arnold G. Vulto (Prof Hospital Pharmacy & Practical Therapeutics, NL), Usman Khan (European Patient's Forum EPF), Ber Oomen (European Specialist Nurses Organization ESNO), Nicolai Brun (Danish Medical Agency), Akos Karsay (National Institute Health Insurance Fund, HU), Adrian van den Hoven (Medicines for Europe), Bernard Grimm (Healthcare Biotech Director, EuropaBio).*

Closing Note

Stefano Soro*, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), European Commission* **16:15 - 16:30**

END OF WORKSHOP **16:30**