European Commission

Stakeholder Event on Biosimilar Medicinal Products

Brussels, 14 September 2018

(Conférence Centre Albert Borschette, rue Froissart 36, 1040 Brussels – Room 0D)

AGENDA

09.30 **Introductory note**

09.40 **IQVIA Report 2018: The impact of biosimilar competition**
Per Troein, Vice President Strategic Partners, IQVIA

10:00-11:30: Session 1 Biosimilars use in Oncology

In this session, we will highlight the importance of biological, including biosimilar, medicines in cancer-care. Biosimilars are widely accepted in many complex disease areas such as immunology and supportive cancer-care, therefore the use of biosimilars in oncology should also be self-evident. Given that collaboration and multi-stakeholder approaches are important to the success of the uptake of biosimilars in oncology, the session will focus on the exchange of experiences from nurses, specialised pharmacists, patient organizations, physicians and competent authorities from Member States - with an emphasis on:

- An overview by the European Medicines Agency on the biosimilars approved so far and future forecast
- The role of physicians in prescribing biosimilars, thereby creating opportunities for sustainable cancer care
- The role of specialized pharmacists as a part of the multidisciplinary decision-making team
- The role of nurses in communicating with the patients and contributing to the improvement of patient adherence to therapy
- The role of patient organisations in the reduction of health inequalities and increasing access to medicines with the introduction of biosimilars
- The role of competent authorities of Member States in the decision making and use of biosimilars

Moderator: Josep Tabernero,
European Society for Medical Oncology (ESMO) President

Panel:

- Elena Wolff-Holz - European Medicines Agency;
- Rosa Giuliani – Medical Oncologist, S. Camillo-Forlanini Hospital, Rome;
- Johan De Munter, Oncology nurse – European Oncology Nursing Society;
- Lydia Makaroff (ECPC) – European Cancer Patient Coalition;
- Alain Astier,ESOP – European Society for Oncology Pharmacy;
- Mikael Svensson – SKL Swedish Association of local authorities and regions;
- James Kent - Specialist Procurement Pharmacist for London & East of England.

11.30 – 11.45 Coffee break

11.45 – 13:15	**Session 2: Sustainable procurement practices – the key to healthy competition**

As a follow up of the discussion at the EC 2017 Workshop, the session will provide the audience with an overview of pro-competitive best procurement practices which could be potentially replicated in other countries and serve as the real-life examples. The session will also identify procurement policies that place barriers to biosimilar medicines entry and access to originator biologics, creating the risk of instability and shortages. During the session, different stakeholders will address various aspects of relevance, for example, their particular roles within the process, governance of physician-led switching, as well as very practical aspects of tendering within the hospital setting.

Moderator: Per Troein,
Vice President Strategic Partners, IQVIA

Panel:

- Miguel Angel Calleja Hernandez – University Hospital Virgen Macarena Sevilla, President Spanish Association of Hospital Pharmacists;
- Dorthe Bartels – AMGROS, Regions' Procurement Pharmaceutical Organisation, Denmark;
- Simona Montilla, AIFA, Italy (excused);
- Jo De Cock - INAMI/RIZIV Belgium;
- Edouard Hatton, Ministère des Solidarités et de la Santé / Ministère de l'action et des comptes publics, France (excused);
- Marc Gabriel LLM., Partner Baker McKenzie;
- An Baeyens - European Commission.

13.15 – 14.30 Lunch break

14.30 – 16:00 Session 3: Improving the understanding of biosimilar medicines

Informational resources have increasingly been developed through consultative, collaborative processes with various stakeholder groups involved in the appropriate and efficient use of biosimilar medicines, including patients, healthcare professionals and regulatory authorities. This session will provide insights into different education materials developed to date, experiences in the utilisation of these materials for improved understanding of biologic, including biosimilar medicines before, during and after utilization of biosimilar medicines, and ongoing areas for collaboration that will empower stakeholders to make informed decisions about the use of biosimilar medicines.

Moderator: Nicola Bedlington,
Secretary General, European Patient's Forum (EPF).

Panel:

- Dr. Tilman Schöning ESOP (European Society for Oncology Pharmacy);
- Ber Oomen, ESNO (European Specialist Nurses Organisation);
- Rosa Gonzalez - Quevedo, European Medicines Agency;
- Jonathan Lind Martinsson -TLV Sweden (Dental and Pharmaceutical Benefits Agency);
- Tibor Hlavaty Slovakia – United European Gastroenterology;
- Dr Anton Franken Netherlands, Biosimilars Nederland (IBN) and Dutch Institute for the rational use of medicines (IVM).

16:00 Wrap up / Closing note

16:30 End of workshop