Workshop on Access to and Uptake of Biosimilar Medicinal Products

A follow-up event to Process on Corporate Responsibility in the Pharma Sector

Brussels, 6 October 2015, 10.30am

Auditorium, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

Avenue d'Auderghem 45, Brussels

Context:

Biotechnology has enabled the development of treatments for a variety of serious diseases. Worldwide, many million patients have already benefited from approved biological medicines. These medicines help treat or prevent many rare and severe diseases including cancers, heart attacks, stroke, multiple sclerosis, diabetes, rheumatoid arthritis and autoimmune diseases. They are showing to have better long term outcomes with fewer costly side effects. Studies show as well that this leads to quicker recovery time and less additional treatments. For patients, one of the most important advantages of being treated with these new drugs is the improvement in their quality of life over the long term.

With a global biosimilar market expected to reach $35 billion by 2020[1] and a significant number of patents and/or data protection of originator's biologics expiring, biosimilars are considered an expanding market. In the EU, the most advanced market for biosimilars world-wide based on the number of authorised products (19) since 2006, the next wave just started in 2014 with the authorisation of the first biosimilar monoclonal antibody, a complex biological product. Since then, the biosimilar market offers even greater challenges for manufacturers but also greater market opportunities and, even more important, improved benefits for patients.

The envisaged workshop is a follow-up to the biosimilars-related activities under the *Process on Corporate Responsibility / Access to Medicines in Europe* (2010-2013),

[1] Allied Market Research, "Global biosimilars/follow-on-biologics market (types, applications and geography) - Size, Share, Global Trends, Company Profiles, Demand, Insights, Analysis, Research, Report, Opportunities, Segmentation and Forecast, 2013 - 2020" published in July 2014

notably the *Working Group on Market Access to and Uptake of Biosimilars.* The work on biosimilars (co-ordinated by the then Directorate-General Enterprise and Industry of the European Commission (today DG Internal Market, Industry, Entrepreneurship and SMEs) has attracted wide-spread recognition and its concrete deliverables (see in Annex) have been endorsed by a broad range of stakeholders.

Rationale:

It is essential that physicians and patients share a thorough understanding of biological medicines, including biosimilar medicines, and express confidence in using either type of therapy. This can be achieved by maintaining a robust regulatory framework and effective risk management, transparency with regard to biological medicinal products, and continued education on biological medicines, including biosimilar medicines. Additionally, factual information on the state of play of the uptake of biosimilar medicinal products in the EU Member States are of interest for the stakeholders as well not only due to commercial reasons but above all as an instrument to make high-quality biologics available to a wider range of patients.

Therefore, the European Commission decided to follow-up these activities by:

- publishing a yearly report on the market penetration and uptake of biosimilars in the EU prepared by IMS Health in close co-operation with the stakeholders
- To organise a multi-stakeholder workshop on biosimilars on a yearly basis.

Objectives of the event:

- To provide a regular opportunity for gathering all relevant interested parties in order to facilitate a multi-stakeholder exchange of information, experiences and reflection on the state of play, explanations for differences in market uptake amongst the EU Member States and possible future trends of the market uptake of biosimilars

- In particular, to give a floor for patients, doctors and payers to express their views on biosimilar related developments at European but also at national level

- To present a regular update about market evolution and clinical experience of biosimilars (in terms of both, volumes and prices)

- To stimulate an open discussion and explore needs for action and in particular with regard to further political activities and initiatives at European level

European Commission

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Agenda

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10.30 **Welcome note**

Carlo Pettinelli, Director Consumer, Environmental and Health technologies, European Commission

10.35 **Outcomes of the Working Group Biosimilars of the Process on Corporate Responsibility in the Pharma Sector**

Thomas Heynisch, Deputy Head of Unit Biotechnology and Food Supply Chain, European Commission

10.45 **IMS Health / EC Report: The impact of biosimilar competition**

Per Troein, Vice President Global Strategic Planning, IMS Health

11.15 **Plenary discussion on the Report**

Moderator: Per Troein, Vice President Global Strategic Planning, IMS Health

11.45 Member States' Perception and Perspectives on Biosimilars

The first session focuses on the experiences with biosimilars from the payers' perspective. In their presentations, representatives from Germany, Hungary and Sweden will report on the current situation, the challenges and discussions in the Member States. Following the floor will be opened for comments and further discussions.

Presentations:

Germany –**Silke Baumann**, Head of Division Pharmaceutical Supply in the Statutory Health Insurance, Federal Ministry of Health

Hungary – **Beatrix Horváth**, Head of Department of Pharmaceuticals and Medical Devices, Ministry of Human Capacities

Sweden - **Gustaf Befrits**, Health Economist, Stockholm County Council

Panel discussion:

Moderator: Thomas Heynisch, European Commission

Silke Baumann, Head of Division Pharmaceutical Supply in the Statutory Health Insurance, Federal Ministry of Health, Germany

Beatrix Horváth, Head of Department of Pharmaceuticals and Medical Devices, Ministry of Human Capacities, Hungary

Gustaf Befrits, Health Economist, Stockholm County Council, Sweden

Robert Johnstone, Board Member European Patients Forum & International Alliance of Patients Organisations (IAPO), United Kingdom

Paul Cornes, Consultant Oncologist. Bristol Haematology & Oncology Centre, United Kingdom

Klaus Martin, Senior Director Business and Product Development, Polpharma Biologics

Virginia Acha, Executive Director, Research, Medical & Innovation, Association of the British Pharmaceutical Industry (ABPI), United Kingdom

12.45-13.45 Lunch break

13.45 Patients' perception and perspectives

This session will discuss some general aspects from the patients' point of view, including awareness regarding biosimilars; concerns around safety and efficacy; the importance of good-quality information that meets patients' needs; shared decision-making and patient-professional communication to increase trust and enable patients to make informed decisions. Specific experiences of patients will be highlighted based on the findings of two recent patient surveys on biosimilars and biologicals.

Presentations:

Marco Greco, Chair of European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) and Board Member of European Patient Forum (EPF)

Alex Wyke, Founder and CEO, PatientView

Panel discussion:

Moderator: Marco Greco, European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) and European Patient Forum (EPF)

Alex Wyke, Founder and CEO, PatientView

Alison Lightbourne, Policy Manager, International Alliance of Patients' Organizations

Merete Lund Hetland, Professor in Rheumatology, MD, PHD, DMSc; Head of the DANBIO database, Denmark

Silke Baumann, Head of Division, Pharmaceutical Supply in the Statutory Health Insurance, Federal Ministry of Health, Germany

Martin Schiestl, Chief Science Officer, Sandoz

Fabio Bisordi, Director, Global Head of International Regulatory Policy, Roche

Martina Weise, Head of Unit on Diabetes/Cardiovascular Disorders, Federal Institute for Drugs and Medical Devices, Germany and Vice-Chair EMA Biosimilar Medicinal Products Working Party (BMWP)

14.45 -15.15 Coffee break

15.15 Doctors' perception and perspectives

Moderator: Prof. André Herchuelz, Standing Committee of European Doctors (CPME)

For medical professionals, it is essential that biosimilars are as efficient and safe as the original biopharmaceuticals. Clinical efficiency and safety, interchangeability, and post marketing surveillance are critical issues for doctors and influence the acceptance of biosimilars. This session will address doctors' views on biosimilars, as well as their experience in using these compounds in clinical practice.

Presentation:

André Herchuelz, CPME, Professor of Pharmacology, Director of Laboratory of Pharmacology, ULB, Belgium

Panel discussion:

Moderator: André Herchuelz, Professor of Pharmacology, Director of Laboratory of Pharmacology, ULB, Belgium

Cornelia Sander, Scientific Officer, Deutsche Morbus Crohn / Colitis ulcerosa Vereinigung (Inflammatory Bowel Disease Patient Association), Germany

Andrew Borg, Professor of Medicine and Chairman of the Government Formulary Committee, Malta

Mathias Flume, Head of Pharmacy Department, Health Fund Physicians Association Westfalen-Lippe, Germany

Philip Ball, PhD, Executive Director Biologics, Policy and Strategy, Allergan

Keith Watson PhD, Director, Global Regulatory Affairs, AbbVie

Ana Hidalgo-Simon, Head of Specialised Scientific Disciplines Department, Human Medicines Evaluation Division, European Medicines Agency

16.15 Summary, findings and wrap up

Christian Siebert, Head of Unit Biotechnology and Food Supply Chain, European Commission

16.45 End of the event

1. Annex: Deliverables of the Working Group on Biosimilars

The Working Group on Biosimilars elaborated according to its Terms of Reference three main deliverables:

1. "What you need to know about Biosimilar Medicinal Products. A consensus information document" with a specific Q&A for patients, physicians and payers" (available in EN, FR, DE, IT, ES, PL, PT, i.e. ca. 75% of the EU's population has access to this document in their native tongue.)

The aim was to encourage healthcare professionals, patients and national competent authorities through a multi-stakeholder consensus information paper to address the information gap concerning biosimilar medicinal products, thus creating conditions conducive to possible economic gains as a consequence of increased use and to improve information for patients about biosimilars as a high-quality treatment option.

Content:

- Concept of biologicals and biosimilars
- Process and scientific rational behind their approval
- Economic consequences
- Questions and Answers for patients, physicians, payers

2. Overview on reimbursement status of biosimilar medicinal products in EEA countries

In order to be able to have an informed discussion on the acceptance of biosimilars in different Member States reliable information had to be compiled from public authorities. The table contains information of the year 2012 on the reimbursement status, i.e. to what extent biosimilars in the different countries are hospital-only medicines or primary sector medicines, since pricing and reimbursement structures / decisions varies between the two sectors. It was the first fact finding exercise of this kind in the EU.

3. IMS study on „Biosimilar accessible market: Size and biosimilar penetration"

This comprehensive document containing more than 40 slides was prepared by IMS Health, a provider of pharma data analysis, on behalf of EuropaBIO/EFPIA and EGA. IMS was asked to generate market size and penetration statistics referring to year 2011 for the three therapy areas (growth hormone, epoetin, granulocyte colony-stimulating factor) where biosimilars were then authorised.

Please consult:
http://ec.europa.eu/growth/sectors/healthcare/competitiveness/corporate-responsibility/index_en.htm