Workshop on Access to and Uptake of Biosimilar Medicinal Products

A follow-up event to Process on Corporate Responsibility in the Field of Pharmaceuticals

Summary

Brussels, 6 October 2015
1. Introduction

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 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 biological medicines treatment leads to quicker recovery time and less additional treatments. For patients, one of the most important advantages of being treated with these medicines is the improvement in their quality of life over the long term.

Biological medicines represent 27% of pharmaceutical sales in Europe. The market continues to grow, with 5.5% increase of value sales today compared to 1.9% in 2012-2013, demonstrating the growing importance of these therapies in patient care.

However, the high cost of biological medicines, coupled with reduced pharmaceutical budgets due to austerity measures means that they are not accessible for all patients and they create financial challenges for healthcare systems. On the other hand, the entry of biosimilar medicines into markets as a result of biological originators’ patent expiries continues to pave the way in providing a sustainable supply of biological medicines across Europe.

To date, biosimilars account for less than 0.5% of the $221 billion market of biological medicines worldwide. With a global biosimilar market expected to reach $35 billion by 2020 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 workshop was a first follow-up event to the biosimilars-related activities under the Process on Corporate Responsibility / Access to Medicines in Europe (2010-2013), notably the Working Group on Market Access to and Uptake of Biosimilars.

The work on biosimilars has attracted wide-spread recognition and its concrete deliverables (see in Annex) have been endorsed by a broad range of stakeholders.

1 IMS Health 2014 - Assessing biosimilar uptake and competition in European markets
2. Objective

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, effective risk management 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 (1) publishing a yearly report on the impact of biosimilar competition in the EU prepared by IMS Health in close co-operation with the stakeholders and (2) organising a multi-stakeholder workshop on biosimilars on a yearly basis.

In 2015, the main objectives of the event were the following:

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

3. Main outcomes

What we build on

A biosimilar medicine is a biological medicine which is highly similar to another biological medicine already licensed for use. It is a biological medicine which has been shown not to have any meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.

Biotechnology has enabled the development of treatments for a variety of serious diseases, benefiting millions of people worldwide. These medicinal products help treat or prevent many severe diseases including cancers, heart attacks, stroke, diabetes, and autoimmune diseases, such as rheumatoid arthritis, multiple sclerosis
and inflammatory bowel diseases. There is already a lot of experience – over 30 years - with biological medicines in Europe: the first approved substance for therapeutic use was biosynthetic "human" insulin, first marketed in 1982.

In October 2015, the EU marked the 50th anniversary of the pharmaceutical legislation, a legislation which paved the way in 2005 for biosimilars by creating a dedicated and comprehensive regulatory pathway which was followed by many countries world-wide, including the US Federal Drug Agency.

The EMA celebrated in 2015 its 20th anniversary and highlighted the approval of the first biosimilar medicine in 2006 as a key milestone. Since then new frontiers have been reached with the authorisation of the first biosimilar monoclonal antibody, a more complex biological product, in 2013. We now have already 10 years of experience with biosimilar medicines. Since 2006, EU approved biosimilar medicines have already generated more than 400 million patient days of clinical experience worldwide.

The EU is also a leading industrial base for the development of biologicals and biosimilars thanks to the robust regulatory framework. This EU know-how is something we can be proud of and we should eagerly defend our leading role in this key area.

**Impact of biosimilars on competition**

Competition between biological medicines, including biosimilar medicines, creates increased choice for patients and clinicians and enhanced value propositions for individual medicines. Biosimilar medicines have a more sophisticated and costly development program and therefore cannot offer the same price reductions as generic medicines. Nonetheless there are significant savings associated with increased competition stimulated by the market entrance of biosimilar medicines.

Recent research provides clear evidence that the additional competition is bringing value and opportunity for both, earlier and wider patient access to treatment. However, to make the most out of biosimilars in our healthcare systems requires investment: Investment in unbiased information and education around biologic and biosimilar medicines, investment in experience and use, investment in establishing sustainable and appropriate procurement, and investment in transparent and clear decision-making frameworks.

The report "The Impact of Biosimilar Competition" prepared by IMS Health in co-operation with the European Commission and its stakeholders and launched at the workshop, shows that both, biosimilar medicines uptake and the impact of biosimilar competition varies between Member States, depending on the class of biological medicine as well as on the policies and procurement measures in place. In our current economic climate, there is an urgent need for Member States to control their budgets including the healthcare budgets, especially while our population is aging.
However, it is important to stress that we should also work on reducing health inequalities between and within Member States and improving access to quality medicines for patients in existing treatments and for innovative medicines. By bringing different stakeholders from across Europe together we can share information and learn from each other’s experiences to help reach the goal of sustainable and competitive markets for off-patent biologics.

Furthermore, an increase in competition in the biological medicines market can help us achieve the Commission’s goals of ensuring that patients can have access to a wider range of options for high quality treatment.

Member States’ perspective

Germany, Hungary and Sweden presented their recent experience with the uptake of biosimilar medicines showing that there are significant differences not only between national markets but also regionally in given Member States.

Member States find themselves in the dilemma of how to ensure and increase patient access to high quality treatments while taking into account the scarce financial resources. How can we reduce health inequalities and how to improve health outcomes? Having a long-term perspective when it comes to the procurement of biological medicines takes into consideration the sustainability of both, the healthcare systems and the European industrial base. In order to maintain a strong European biopharmaceutical industry, it should be considered that the price setting of medicines doesn’t eliminate the level playing field of competition.

In the EU, decisions regarding switching and interchangeability lie within the responsibility of each Member State. A robust regulatory framework and effective risk management, transparency with regard to biological medicinal products and continued education have been considered key elements for the uptake of biological medicines, including biosimilar medicines.

Based on the Swedish experience the key message for policy makers with regard to biosimilar medicinal products can be summarised as follows: "1. The need to drive the process. 2. The need to involve all stakeholders. 3. The need to communicate proactively."

Patients’ perspective

Recent work undertaken by patient organisations highlights that many patients are not yet very familiar with biological medicines, including biosimilars. Patients have specific concerns and questions, including around safety, efficacy, and choice of treatment. In particular, patients who had difficulties finding a suitable treatment and finally found a biologic they are doing well on, have concerns about switching
treatments. It should also be noted that many of the patients’ information needs apply to all biologic medicines, due to their specificities and differences from small-molecule medicines.

The availability of adequate, understandable and easily accessible information on biologicals, including biosimilars, is necessary to support informed decisions by treating physicians together with their patients. Already during the Pharmaceutical Forum which ran between 2005 - 2008, the quality criteria on information to patients were agreed. These remain pertinent today and should be applied to all information on biologicals, including biosimilars. The availability of information material in the patients' and physicians' native tongue is crucial; and medical professionals need to have the right knowledge and skills to communicate effectively with patients regarding treatment options and shared decision-making.

Stakeholders play an enormous role in supporting the dissemination of such information. The Consensus Information Paper: “What you Need to Know about Biosimilar Medicinal Products”⁴ which was prepared by a stakeholder working group (consisting of Member States', patients', physicians' and industry's representatives) during the Commission initiative Process on Corporate Responsibility in the Field of Pharmaceuticals, answers a number of the concerns raised in the event. The paper is available in 7 different languages. Therefore it would be conducive to make it widely available and visible also on the stakeholders’ websites and related communication / information activities.

The EC consensus document addresses key questions and concerns coming from patients. However, it is only able to address questions relating to the EU policy and regulatory framework. More simplified information resources could be foreseen for the patient community, including answers to questions that need to be addressed at national level. Patients, their advocates and their organisations are invited and should be supported in carrying out their intrinsic role in identifying bottlenecks, raising awareness and being a direct part of discussions on moving forward on acceptance and trust in biosimilars. Our goal is to have the best possible quality treatment for patients and we need them to take over a leading role in co-driving this process.

The next steps should include working on information that is up-to-date, evidence-based and focused on patients' identified information needs, together with patient organisations.

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Physicians’ perspective

The decision on which biological medicine to prescribe is in the hands of the clinical decision maker. It is therefore essential that physicians together with patients gain a thorough understanding of biological medicines, including biosimilar medicines, and express confidence in using either type of therapy.

Any measure aimed at increasing the prescriptions of biosimilars should ensure that physicians’ perceived concerns are understood and duly taken into account. They can rely on a robust post-marketing surveillance and pharmacovigilance system including the standardised naming and identification of medicinal products which facilitates the reporting of possible adverse events.

Health care professionals are often in the best position to help formulate key information and convey those to patients. In addition, physicians accumulate a significant number of years of experience with treating patients with biological medicines. Therefore it is of utmost importance that unbiased and unambiguous information is provided supporting physicians in conveying the message on biological medicines to patients.

Furthermore, the collaboration between patients and doctors in treatment decisions involving biological medicines is highly important to better take into account their needs and, where possible, their preferences. As such, the individual decision to switch from one biological medicine to another, whether it is an originator or a biosimilar, should be based on expected health outcomes. This decision should not be taken solely for economic reasons.

4. Outlook

The European Commission is committed to continue foster dialogue among stakeholders at European level as a means to ensure a long-term sustainable development and the best access for patients to safe and high quality medicines. It will pursue with a multi-stakeholder approach as it is considered the most fruitful with regard to building a common understanding and trust between doctors and patients, payers and the commercial operators. We plan to reconvene in a year time to reassess policy developments and real world evidence again.

Based on the fact that in the EU, decisions regarding pricing and reimbursement, interchangeability and prescription incentives lie within the responsibility of each Member State, a multi-stakeholder dialogue and co-operation is needed not only at EU but also at national level.

There is also a significant need to continue working together with all stakeholders and especially with patient groups and physicians to ensure patient-oriented and patient-friendly information on biosimilars is developed to solve the current information gap.
In order to monitor and follow the impact of biosimilar competition the European Commission and the stakeholders welcome the commitment of IMS Health issuing a yearly update of the report "The Impact of Biosimilar Competition".

The European Commission would like to thank all stakeholders involved for their commitment, engagement and contributions in the preparatory phase and during 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)

   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:**