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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Products: Quality, Safety, Innovation

Multi-stakeholder Event on Biosimilar Medicinal Products

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Brussels, Belgium

Summary

Disclaimer: the views expressed in the meeting and debates are personal views of the individual speakers. The European Commission thanks all speakers and audience for their active participation.

The European Commission's multistakeholder event on biosimilar medical products aimed to highlight the potential of biosimilars for health systems sustainability and to educate and raise awareness about biosimilars towards all stakeholders. Over 250 attendees joined in person and online to listen to 22 speakers from a range of sectors discuss the impact of biosimilar competition in Europe, the interchangeability, switching and substitution of biosimilars, how to build trust in (clinical) oncology biosimilars, and ultimately how to untap the full potential of biosimilars.

INTRODUCTORY NOTES

The meeting was opened by the Acting Deputy Director General for Health, John Ryan, who welcomed participants and set the scene: biosimilars continue to deliver significant savings to healthcare systems. More biologics than ever, especially in the field of oncology, will lose their exclusivity in the next ten years. Not only does this open up many opportunities, but it also addresses inequalities in cancer care, as through biosimilars we can enable savings and increasing patients' access to affordable medicines; thereby supporting **Europe's Beating Cancer Plan**. Adopted on 25 November 2020, the **Pharmaceutical Strategy for Europe** aims at creating a future-proof regulatory framework and at supporting industry in promoting research and technologies that reach patients in order to fulfil their therapeutic needs while addressing market failures. It will also consider the weaknesses exposed by the coronavirus pandemic and take appropriate actions to strengthen the system, as well as address market competition considerations. The reform of the EU pharmaceutical legislation is the centrepiece of the Strategy. As there are factors beyond the European regulatory framework, for example, national pricing and reimbursement policies, national decision-makers play an important role. The EU, therefore, supports the exchange of best practices between Member States, including on policies to support biosimilar competition, so that they can share what works and what does not work. To this end, the 2023 EU4Health Programme allocated a budget of 1.5 million Euro for capacity building to strengthen the uptake of biosimilars in a multi-stakeholder approach.

Following this opening keynote, a psoriasis patient shared her perspective and experience on **how biosimilars impacted her access to affordable medicines**. She showcased that biosimilars can lead to access to more affordable medicines, as well as speeding up access and eligibility conditions for treatment.

Per Troein, VP, Strategic partners, IQVIA, and **Max Newton**, Global supplier & association relations, IQVIA, presented the 2022 report on **The Impact of Biosimilar Competition in Europe ([1])**. The methodology was outlined, followed by the five key conclusions recognising that: (1) the direct impact of COVID-19 has largely passed; (2) EU savings from the impact of competition have reached over 30 billion Euro - biosimilar savings account for 2-8% of the drug budgets; (3) access to biologics is increasing in all countries, but not evenly; the disparity between countries is also increasing; (4) high proportions of EU spending expect competitors, but not all molecules are attractive for competitors to enter; and (5) biologic losses of exclusivity are increasing, and research has already started, but for 50% of biologics there is no biosimilar in development and availability of recently launched biologics is low. The presentation as followed by a question and answer session.

INTERCHANGEABILITY OF BIOSIMILARS

([1]) https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2022

The **interchangeability of biosimilars** was introduced by **Harald Mische**, Directorate-General for Health and Food Safety (DG SANTE), European Commission. It was noted that despite the more than 15 years of experience with biosimilars and the savings potential they may offer to the health systems, **patient uptake and acceptance of biosimilars has not spread evenly** among the different Member States in the EU. Factors limiting their uptake are **complex** and may depend on the local context and organisational setting of health care. However, biosimilar use may also be influenced by the **perception and knowledge that health care providers and patients** have about biosimilars. The recently published **EMA/HMA statement on the scientific rationale supporting interchangeability ([2])** of biosimilar medicines in the EU, provides a clear EU-wide confirmation that biosimilars have a comparable efficacy, safety and immunogenicity compared with their reference products. Clarity was provided on the **terminology** to refer to interchangeability, switching and substitution practices in the EU. It was stressed that the decision on whether to allow **switching** and **substitution** of the reference biological medicine and the biosimilar falls under the **responsibility of Member States**.

Liese Barbier, Postdoctoral Researcher Pharmaceutical Sciences KU Leuven, Belgium spoke on the available evidence on interchangeability of biosimilars. Relevant research articles were then discussed and four conclusions were made: (1) the suggestion of switch-related adverse effects is not supported by current evidence; (2) all biosimilars in the EU are proven highly similar to and interchangeable with their reference products; (3) clinical switch studies are not able to detect potential rare adverse effects; risk management should be based on pharmacovigilance; and (4) additional systematic switch studies are not needed to support the switching of patients. The road ahead was identified as leveraging EU-developed one-voice information and guidance at the national level for homogenous (scientific) messaging across Member States, and informing stakeholders being a joint effort between regulators (central & national) and learned healthcare professionals and patient societies.

Steffen Thirstrup MD, Affiliate Professor and Chief Medical Officer at the European Medicines Agency (EMA) shared information on the **Joint EMA-HMA statement on interchangeability of biosimilars** which states: "*HMA and EMA consider that once a biosimilar is approved in the EU it is interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa) or one biosimilar can be replaced with another biosimilar of the same reference product*." It was highlighted that the EU approval of biosimilars is based on rigorous scientific principles and the evidence in support of interchangeability was demonstrated. The requirement to develop a joint position harmonising the EU approach was explained; it was emphasised once again that decisions regarding in-pharmacy substitution remain within the remit of Member States' competences.

The session concluded with an opportunity for participants to ask questions

NATIONAL BIOSIMILAR POLICIES ON SWITCHING AND SUBSTITUTION

Harald Mische chaired the sub-session on national policies on switching and substitution of biosimilars and referred to the disparity in uptake throughout the EU but also within countries, for example, regional differences and differences between in-patient and out-patient sector. He reminded participants of the importance of the national health system context (e.g. procurement for in-patient) as well as differences in acceptance by health professionals and patients of switching and substitution policies. He stressed that there is no 'one size fits all' solution, and that policies cannot just be copied and pasted but need to be adapted to the national and organisational setting. Different Member States then shared their experiences, challenges and best practices on the implementation of policies aimed at supporting biosimilar competition.

Peter Schneider, from the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies at the Pharmacoeconomics Department of the Austrian National Public HealthInstitute (GÖG) gave an overview of different biosimilar policies in the EU, presenting the

([2]) https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf

results of a survey on biosimilar policies in 24 countries launched in May 2022. The pricing of biosimilars and price link policies were highlighted, as well as the reference price system, and prescription by International nonproprietary name (INN). The presentation concluded with a discussion on classification of policies, supply-side versus demand-side measures and whether points of administration pose a challenge to regulations.

Olga Pitsillidou, Officer, Health Insurance Organisation, Cyprus, gave an overview of biologic policies and procurement methods in Cyprus.

Helga Festoy, Head of Unit Norwegian Medicines Agency, Norway, informed participants on the experience with their national legislation on substitution of biosimilars in community pharmacies and the impact on sales of insulin glargine and teriparatide after substitution was introduced.

Nadia Amer, Project Officer Health Products Department National Health Insurance Fund CNAM, France, then gave a numerical overview of biosimilars, followed by identification of the main incentives per stakeholder, and concluding with an outline of the key challenges faced.

Bente Glintborg, Senior rheumatologist and head of the DANBIO steering committee, Denmark, spoke of the national tender system under the Danish Medicines Council and the nationwide DANBIO registry. The conclusion was that in Danish rheumatology, a range of mandatory biosimilar switches have been performed and that data from DANBIO have confirmed the interchangeability of originators and biosimilars (i.e. infliximab, etanercept, adalimumab).

The session was concluded with an interactive Q&A session, discussing how the EMA/HMA joint statement might impact national policies or clinical practice. Comments were made on the necessity to reconsider the need for conducting Phase III Clinical Trials for biosimilars.

BUILDING TRUST IN ONCOLOGY BIOSIMILARS: CLINICAL PRACTICE

The session, chaired by **Peter Schneider**, highlighted the potential of (upcoming) biosimilar competition in the oncology field, shared the perspectives of patients and health professionals regarding the use of biosimilars in oncology and its implications (i.e. the different benefits and challenges), and emphasised how improved information, communication and education for patients and other stakeholders is critical to promoting biosimilar use EU-wide.

Ward Rommel, the Chair of the Association of European Cancer Leagues (ECL) Access to Medicines Task Force addressed improving biosimilar access to the benefit of patients The point was made that some progress had been made, but not enough, with lung cancer survival rates in Belgium used as an example. The conclusion was that safe and effective drugs needed to be made available at a fair price, transparently, and using a needs-driven model for drugs development.

Rosa Giuliani, consultant in medical oncology and the European Society for Medical Oncology (ESMO) Director of Public Policy presented the **perspective from an oncology clinician**. The relevance of biosimilars to the practice were explained, including how confidence was built; sharing knowledge results in understanding biosimilars. Comments were made on the necessity to consider new ways of looking at drug development, questioning the need for phase III trial validation for biosimilars as, according to Dr. Giuliani, those have never added crucial information for clinicians. She stressed the importance to incorporate ways that are more flexible and more smart.

Tilman Schöning, Deputy Head of Pharmacy Heidelberg University Hospital, the Vice President of the European Society of Oncology Pharmacy (ESOP) adressed **the role of pharmacists in oncology biosimilar treatment**, where the implementation steps for new oncology biosimilar medicines in clinical practice was explained, including the decision pathway. The criteria for product evaluation of biosimilar drugs were highlighted. The presentation concluded by highlighting the crucial role that pharmacists play in providing information, enhancing confidence in biosimilars and ensuring a safe handling of biosimilar medicines.

Adriano Friganovic adressed the **role of nurses in switch management between similar biological medicines**. He is from the European Specialist Nurses Organisation (ESNO), who aim to promote, support and develop academically accredited training programs for qualified specialist nurses to address quality and safety of care and mobility of workforce within Europe. ESNO has created a communication and information guide for nurses on switch management between similar biological medicines; a survey on nurses' knowledge and attitudes towards Biosimilars has been created as part of evidence-based nursing practice. ESNO pointed to online educational material ([3]) on biosimilars for nurses. This was followed by an interactive Q&A discussion with the audience, highlighting that trust, education and knowledge sharing are crucial to support the use of biosimilars in the oncology area.

PANEL DISCUSSION ON UNTAPPING THE FULL POTENTIAL OF BIOSIMILARS

The final session turned to **untapping the full potential of biosimilars**, chaired by **Sanja Matic**, Head of Department for utilisation and prices of medicines at HALMED, Croatia. Discussion followed with panellists including **Simone Boselli**, the Public Affairs Director, EURORDIS-Rare Diseases Europe; **Yannis Natsis**, the Director of the European Social Insurance Platform (ESIP); **Julie Maréchal-Jamil**, the Director Biosimilar Policy & Science, Medicines for Europe; **Rosa Giuliani**, the Director of Public Policy at the European Society for Medical Oncology (ESMO); **Despoina Makridaki**, the Director of Pharmaceutical Services at the Sismanoglio-Amalia Fleming General Hospital of Attica and Member of the Board and Scientific Committee of the European Association of Hospital Pharmacists (EAHP); and **Ber Oomen**, the Executive Director of the European Specialist Nurses Organisation (ESNO). The panellists were asked: (1) after 15 years of knowledge on biosimilar development, approval, and uptake strategies, which are the most important lessons learnt; (2) with the upcoming large losses of exclusivity of medicines, what specific challenges do participants expect to face, and what opportunities are there to fully untap the potential. And more specifically, how can the time between loss of exclusivity and biosimilar uptake be reduced, and to increase uptake; and (3) where biosimilar use will be in five years hence and what steps are needed to get there.

CONCLUSIONS

Harald Mische, DG SANTE, concluded the meeting by thanking participants for their active contributions. He **summarised** that during the meeting, many relevant stakeholders contributed with their policies and their challenges; the good news is the tools and policies to enable the uptake of biosimilars exist. Success stories have been identified, which underline that when biosimilars are tapped into, they generate not just savings, but huge patient benefits in terms of access. Many products will lose their IP exclusivity in the next years which has the potential for important savings in terms of health budgets. He pointed to the fact that for 50% of biologics there is no biosimilar in development, which causes the serious risk of evergreening with its massive cost implications in the long run for healthcare systems; this requires further discussion and reflection. Regarding policies, interchangeability is not a 'solve all' solution; the EMA/HMA paper on interchangeability makes it clear that biosimilars are interchangeable. Other complementary policies will be needed for successful biosimilar uptake; at the heart of these policies is building trust, education and knowledge sharing. All stakeholders need to be involved to enable the 'buy-in' of biosimilars and to make biosimilar policies successful. Given the importance of procurement policies, DG SANTE is soon to publish a study on this topic in order to improve biosimilar uptake. As a final point, he highlighted that DG SANTE is looking forward to more of these types of discussion, in various formats, including potentially in another multi-stakeholder biosimilar workshop next year.

([3]) https://www.esno.org/assets/files/Biosimilars%20Guideline%20V2%20EN.pdf