Summary report – 7th Biosimilar Multistakeholder Event, Brussels (Belgium), 13.12.2023

On the 13th of December, the European Commission organised the seventh multistakeholder event on biosimilar medical products, aiming to raise awareness about biosimilars towards all stakeholders and demonstrate their potential to improve access to and affordability of medicines. The event took place in Brussels, Belgium (hybrid), with over 80 participants joining in person and more than 300 connections online. Together with 19 speakers coming from different stakeholder groups, they discussed the impact of biosimilar competition, upcoming losses of exclusivity in the biologics pipeline, disparities in biosimilar uptake and access, as well as the consequences of product formulation and administration for healthcare professionals, patients and health systems.

The event was opened by Rainer Becker (Director DG SANTE D), who welcomed the attendees and highlighted the opportunities biosimilars can bring, but also the remaining challenges for health systems to fully exploit the savings from biosimilar competition. Therewith, he also announced the recent publication of the EU4Health call for tenders specifications to support the uptake of biosimilars in a multistakeholder approach. After this keynote speech, Ljiljana Vukota (NGO "Everything for Her") shared both her and other **patients' journey and experiences with the use of biosimilars**, stressing the importance to inform patients and ensure trust about the value of biosimilars to patients and healthcare systems. Following that, Per Troein and Max Newton (IQVIA) presented the key findings of the 2023 report on the **impact of biosimilar competition in Europe**. This year's main observations included: persisting access disparities between countries; slowed growth of biosimilar savings from list prices, reflecting the profile of losses of exclusivities; recognition of interchangeability as an important policy step among many others; and the lack of biosimilar pipeline for a significant number of biologics losing exclusivity soon, especially in the area of lower-sales value and orphan medicines.

Building on the latter observation, a panel discussion was dedicated to **upcoming losses of exclusivity in the biologics pipeline and addressing the challenges and lack of biosimilar competition**. It was moderated by Petra Wilson (Health Connect Partners), with representatives from the payer (Yannis Natsis (ESIP)), industry (Julie Maréchal-Jamil (Medicines for Europe)), healthcare providers (Prof. Dr. Wolf-Dieter Ludwig (CPME)), patients (Dimitrios Athanasiou (World Duchenne Organization BoD and Rare Diseases Greece)), and regulatory side (Steffen Thirstrup (EMA)). Asking panellists and the audience about challenges to bring a biosimilar to launch, development and clinical trial costs, expected profitability, regulatory pathways, healthcare provider and patient hesitancy, as well as the complexity of newer biologics were frequently mentioned. In response to that, some aspects of the proposed Pharma Reform, assessing the necessity of phase III clinical trials for certain biosimilars, streamlining regulatory pathways and optimising tendering practices were put forward as potential parts of the solution.

Following the networking lunch, the event continued with a session on **disparities in biosimilar uptake and access: opportunities across countries, regions and sectors**, chaired by Johan Pontén (TLV, SE). Sabine Vogler (GÖG, AT) started with an opening presentation on challenges and good practice examples in pricing, reimbursement and demand-side measures to enhance the uptake of biosimilar medicines, pointing out the importance of having a good mix of demand/supply policies and gathering evidence on their impact. Harald Mische (DG SANTE) gave an overview on how the proposed EU pharmaceutical legislation will stimulate market entry of biosimilar medicines, including through a broadening of the Bolar exemption, procedural facilitation of authorisations, repurposing of off-patent medicines and modulation of incentives. Esa Heinonen (Fimea, FI) discussed what regulators can do to enhance the uptake of biosimilars, provided an update on the HMA Biosimilar Working Group activities and called for improved collaboration between the various stakeholders. Despoina Makridaki (EAHP) shared challenges and opportunities for biosimilar uptake specific to the inpatient

sector, based on EAHP's access to medicines, biosimilar and procurement position papers. She noted that barriers should be faced in a collaborative way and policies should incorporate the expertise and scientific knowledge of specialists, not in the least hospital pharmacists. Finally, Chara Kani (EOPPY, EL) and Agnieszka Beer (Ministry of Health, PL) shared national best practices, challenges and future actions, for instance regarding biosimilars pricing, HTA, switching and communication strategies.

The event concluded with a last session on **product formulation/administration and its consequences for patients, healthcare professionals and systems**, chaired by Carlos Martin Saborido (Ministry of Health, ES). René Anour (EMA BWP) explained how formulation and device differences between the originator and biosimilars are handled in the regulatory EU-context, providing some hands-on examples. Adrian van den Hoven (Medicines for Europe) shared insights on the topic from an industry perspective, demonstrating how biosimilars can drive improvements and innovation in medicines and the delivery of patient care, and highlighting how a multi-stakeholder approach remains highly relevant to achieve access. Bernard Duggan (IE, HSE) presented the Irish best-value-biologics programme and explained how through a gainshare arrangement part of the savings were used to fund service delivery and enhancements for the benefit of patients. Lastly, Ana Soldo (HR, Croatian Chamber of Pharmacists) gave a presentation on the role of pharmacists, how they can support the use of biosimilars, and in particular educate patients, healthcare professionals and journalists.