biosimilar medicines
better access. better health.

Market review
Biosimilar medicines policy 2023
Policy statement

The Biosimilar Market Access Committee (Biosimilar medicines Group, a Medicines for Europe sector group) undertook a 2023 Biosimilar market review consisting of updates on biosimilar medicines policy across Europe (28 European countries).

The highlights of this overview have been consolidated below and illustrate both key challenges and recommendations on how to improve specific policy interventions (e.g. pricing and reimbursement, procurement, prescribing and dispensing) to enhance biosimilar medicines use and competition in the biologics market in Europe.

MOST EU-AUTHORISED BIOSIMILAR MEDICINES ARE AVAILABLE AND ACCESSIBLE ACROSS ALL EUROPEAN COUNTRIES

Since the approval of the first biosimilar medicine in the EU in 2006, the number of biosimilar medicines available across European countries has increased substantially providing a wide range of benefits to healthcare systems and giving patients the opportunity to have access to treatments across various therapeutic areas.
In 2023, the vast majority of authorised biosimilar medicines targeting immune mediated diseases or cancer, are available in all the surveyed countries.

By contrast, for some other therapeutic indications, authorised biosimilar medicines are available in most but not all surveyed countries such as diabetes (insulin analogues available in 50% of countries), fertility (follitropin) and anti-coagulants (enoxaparin) available in 80% of countries.

The positive clinical experience gathered with EU-authorised medicines has led most countries to use biosimilar medicines to expand access to affordable biological therapies while providing financial relief for healthcare systems.

Policy makers should ensure that policy frameworks optimally support competition through the use of authorised biosimilar medicines across all therapy areas.

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EXTERNAL REFERENCE PRICING (ERP) REMAINS THE 2ND MOST USED POLICY INTERVENTION DESPITE DELETERIOUS IMPACT ON SUSTAINABILITY

The medicines market in Europe is highly regulated, with governments usually resorting to a combination of policy measures to control prices for pharmaceuticals. For biosimilar medicines, these measures include mandated price discounts (below the reference product), external reference pricing, maximum capped prices or negotiated prices.

Despite the recommendation of EURIPID[1] (the system that provides countries with data on medicines prices) not to apply this policy to off-patent multisource medicines, 50% of the countries surveyed indicated that External Reference Pricing (ERP) policies applied to biosimilar medicines. While the primary objective of ERP is to keep medicines affordable and accessible for all patients, applying this policy to biosimilar medicines undermines competition and sustainability in the market as it leads to a double price cut for the biosimilar medicine where the price is linked to the originator medicine. In some cases, the prices of biosimilar medicines might even go below what is commercially sustainable for pharmaceutical manufacturers. This can be detrimental to the biosimilar medicines industry as well as for the quality of healthcare, as these artificially low prices might endanger the security and continuity of supply - defeating the access and affordability objectives.

To foster a highly competitive European biosimilar market environment, it is essential to foster dynamic competition, by ensuring balanced price control measures, combined with biosimilar use incentives (demand-side policies).

THE OVERWHELMING MAJORITY OF SINGLE-WINNER TENDERS AND CONTINUED FOCUS ON PRICE-ONLY AT ODDS WITH EU GOOD PROCUREMENT PRACTICES

Biosimilar medicines are predominantly available in the hospital setting across surveyed countries where tenders are a very common procurement tool. In practice, fewer than 40% of countries consider price alongside other additional criteria when attributing tenders for biosimilar medicines. Therefore, 60% of tender awards are based solely on price as the criterion.

Furthermore, over 80% of countries report that hospital tenders are designed for single winners, leaving only 20% of countries where modalities allow for multiple winner tenders that reduce the risk of supply disruptions.

This aligns with the recent findings European Commission study on medicines procurement showing that procurers focus primarily on cost-minimisation, through price-only, single-winner tenders. This encourages

[1] European Pharmaceutical Pricing Database (EURIPID), EURIPID guidance document on external reference pricing (ERP) euripid (d3erarkwm819zv.cloudfront.net)

bidders to offer the lowest-price possible and provides no reward for security of supply measures or environmentally sound manufacturing. Over time, this leads to overreliance on a single manufacturer to supply the market and increases the risk of shortages. This risk is compounded by mounting inflation across Europe and the increase in production costs leading to consolidation at all levels of the pharmaceutical supply chain.

To improve access to medicines, we need European-wide legal guidance on medicines procurement covering security of supply, MEAT criteria and biosimilar competition.

BIOSIMILAR UPTAKE IS INFLUENCED BY THE AVAILABILITY OF CLEAR INFORMATION AND GUIDELINES ON BIOSIMILAR USE AS WELL AS THE EXISTENCE OF INCENTIVES FOR THE HEALTHCARE COMMUNITY

The HMA/EMA which speak on behalf of the European network of medicines agencies have developed a clear scientific guidance on biosimilar medicine interchangeability, although this guidance is not yet implemented everywhere. For example, one third of EU countries surveyed reports that there remains distinct prescriber switching policy guidance for 'treatment naïve' and 'treated' patients, despite the HMA/EMA guidance clarifying this matter. Moreover, biosimilar medicines are recommended for treatment initiation in fewer than 50% of surveyed countries. By failing to implement the HMA/EMA guidance, patients and healthcare systems are losing out on many of the access and savings benefits offered by biosimilar medicines competition.

Biologic pharmacy substitution (no involvement of the clinical decision maker) is still a rather limited policy which is legally possible in 20% of surveyed countries.

Despite years of effort by authorities, three quarters of countries still report a need for further information and education for the healthcare community.

Finally, across Europe, the number of policy incentives available to foster competition in the biologics market via biosimilar medicines uptake is very low, with fewer than 10% of countries providing support for prescribers.

To improve biosimilar uptake, focus is needed on translating the scientific evidence into biosimilar use guidance for Healthcare Professionals, on continuous outreach and information for patients and Healthcare Professionals, alongside tailored incentives, including benefit-sharing schemes.