generic medicines
better access. better health.

Market review
Generic medicines policy 2023
Policy Statement

The Generic Market Access Committee (Generic medicines Group, a Medicines for Europe sector group) undertook a 2023 Generic medicines market review consisting of updates on generic 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 of medicines) to ensure access to medicines across Europe.

EXTERNAL REFERENCE PRICING (ERP) REMAINS THE SECOND MOST USED POLICY INTERVENTION DESPITE A DELETERIOUS IMPACT ON SUSTAINABILITY, AVAILABILITY AND SUPPLY

The pharmaceutical market in Europe is highly regulated with governments usually relying on a combination of different policy measures to control the prices of pharmaceuticals. For generic medicines, these policies include mandatory price discounts below the reference product, external reference pricing, maximum capped prices or prices negotiated with authorities.

Despite the recommendations from EURIPID[1], (the system that provides countries with data on medicines prices) not to apply this policy to off-patent multisource medicines, 60% of the countries surveyed indicated that External Reference pricing (ERP) policies applied to generic medicines. While the main objective of ERP is to keep medicines affordable and accessible for all patients, applying this policy to generic medicines threatens competition and sustainability in the market. Generic medicines already operate in a highly competitive environment and applying ERP leads to a double price cut for generic medicines where the price is linked to the originator medicine. Firstly, ERP applies a price cut to the reference product price which automatically lowers the linked generic medicine price, then ERP is applied a second time to the already reduced generic medicine price. In some cases, the prices of generic medicines go below what is commercially sustainable for generic pharmaceutical manufacturers which leads to the withdrawal of medicines. This has been confirmed

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

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in the European Commission study on medicine shortages where it states that 90% of withdrawals are linked to this commercial unattractiveness.[2] This can be deleterious to the generic medicines industry, also for the quality of healthcare, as these artificially low prices might endanger the security and continuity of supply, hampering the access and affordability objectives of healthcare systems in Europe.

To increase accessibility to affordable medicines for patients in Europe, it is essential to foster competitive and dynamic policies by ensuring balanced price control measures, combined with demand-side policies that incentivise the use of generic medicines, benefiting patients' access to affordable, high-quality, and essential medicines.

CLAWBACK/PAYBACK IS THE MOST COMMON POLICY USED AS A COST-CONTAINTMENT MEASURE IN EUROPE REGARDLESS OF ITS NEGATIVE IMPACT ON THE MARKET

Generic medicines face strong market conditions, not only with price regulations but also with short-term and drastic cost containtment measures such as clawback and payback mechanisms, or mandatory discounts and rebates. Among the countries surveyed, 50% have clawback/payback mechanisms in place for generic medicines where low cost generic medicines compensate for overspending on expensive on-patent medicines. In Romania, this unfair policy led to the withdrawal of thousands of generic medicines from the market. These policies not only affect the sustainability of the generic medicines industry but endanger the supply reliability of medicines. Applying these measures, which are often applied in conjunction, lead to unsustainable prices as they are drivers of market consolidation, increasing the risk of a shortage of medicines and ultimately hampering patients' access to affordable and essential medicines.

[2] European Commission study on Public Procurement of Medicines, 2022. https://op.europa.eu/en/publication-detail/-/publication/1f8185d5-5325-11ec-91ac-01aa75ed71a1/language-en/format-PDF/source-245338952. See page 51 where the study analyses withdrawn products has most 78% having sales of less than €30 000/year. This is significantly lower than the estimated cost of maintaining generic medicines on the EU market by Technopolis (€180 000). The report also states: "*The large majority of medicines that are permanently withdrawn from a particular market involve products with low sales revenues in those markets, for which the MAH has decided that the generated revenue on the product no longer justifies the costs of maintaining the product on that market." (P,101)*

Governments should apply policies that optimise the use of generic medicines ensuring long-term competition without short-term cost containtment measures that further lower the price.

THE MAJORITY OF TENDERS ARE NOT IN LINE WITH EU GOOD PROCUREMENT PRACTICES AS THEY ARE MOSTLY SINGLE-WINNER TENDERS WITH CONTINUED FOCUS ON LOWEST PRICE CRITERION ONLY

Generic medicines are available at pharmacies both at hospital and retail levels but the vast majority of the tenders are at hospital level where 85% of the surveyed countries have tenders in place.
In practice, only 35% of the European countries allow more than one winner per tender and fewer than 30% of the countries consider price alongside other additional criteria when attributing tenders.
This is in line with the recent findings of the European Commission study on procurement of medicines showing that procurers focus primarily on cost-minimisation via price-only, single winner tenders. This encourages bidders to offer the lowest price possible and does not reward security of supply measures or environmentally sound manufacturing. Subsequently, this leads to overreliance on a single manufacturer to supply the market, increasing the risk of shortages of medicines. In addition, this risk is compounded by rising inflation across Europe and the increased production costs leading to consolidation at all levels of the pharmaceutical supply chain.

To improve and increase patients' access to medicines, a European-wide legal guidance is needed on medicines procurement covering security of supply, MEAT criteria and generic medicines competition.