

Across Europe - on average - 26% of all generic medicines have disappeared

Unsustainable pricing policies are one of the leading drivers of shortages

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Affordable generic medicines available on the market just 10 years ago are disappearing and supply is too consolidated, according to new data shared today. This rapid decline and consolidation, higher in certain therapy areas such as cancer care and antibiotics, risks creating more shortages and threatens vital access for patients.

The data showed that the whole generic medicines supply chain is under heavy pressure, with prices being pushed down to the limit of their sustainability. Strikingly, medicines supply consolidation is not just at the active ingredient level but also medicines, thereby creating risks of shortages and reducing access.

The system is broken and must be fixed.

Key Data:

- Of all the generic medicines available 10 years ago, 26% of generic medicines, 33% of antibiotics and 40% of cancer medicines have disappeared from European markets, on average.
- More than two-thirds (69%) of EU generic medicines on the market now have just one or two suppliers. If one manufacturer has a problem, there will likely be a medicine shortage causing disruption and possible harm for health care practitioners and for patients.
- 20 years ago, Europe used to make about half of the ingredients needed to make its medicines now it's down to about a fifth.

Policymakers at the national level need to change their policy approach to pricing of medicines with:

- Dynamic market rules to maintain more suppliers active in the market.
- Multi-criteria, multi winner tenders, beyond lowest price only.
- An inflation-linked-pricing adjustment mechanism.
- Open dialogue between suppliers and the medicines agency to rapidly address supply bottlenecks.

At the EU level, the focus needs to be on a streamlined policy framework with:

- Regulatory optimisation and digitalisation, including security of supply provisions in the revision of the pharmaceutical legislation.
- Security of supply safeguarded in all policies including in environmental legislation.
- Legal guidance on multi-winner and multi-criteria tenders in procurement which is requested by both industry, procurers, hospitals, and healthcare practitioners.
- An industrial policy that supports medicines manufacturing in Europe notably with efficient and competitive funding mechanisms.

Philippe Drechsle, Chair of Medicines for Europe manufacturing committee and Executive Committee member (Teva Pharmaceuticals Europe), said "This research made a health check of Europe's essential medicine cabinet. We found increasingly empty shelves and a limited variety of essential medicines. Many of these now have just



one manufacturer. The solutions are there to be implemented both at European and national levels. In the case of pricing, national laws tend to award drug suppliers based on the lowest generic price alone – and ignore important issues like sustainability, which swiftly leads to a less resilient industry, less robust supply chains and worse patient outcomes. This needs to be fixed. The EU has its role to play by adopting legislation that considers the impact of any new additional requirement on medicines availability across Europe. Our regulatory system is too costly, and the environmental obligations should deliver a win-win for the planet and patients' access to medicines".

Medicines for Europe Director General Adrian van den Hoven said "Antibiotic shortages this winter were a sad example of the policy gaps that make the supply of essential medicines so fragile. For years, generic medicine policies have been based on the lowest price only, with restrictive tender or reference pricing rules. These policies have fuelled market consolidation which make it difficult to respond to sudden demand surges. We are also working with the EU to improve disease forecasting in Europe to better plan manufacturing ahead of infectious seasons. These issues must be addressed in the revision of the EU pharmaceutical legislation."

Resource hub

The full data of the study are available here.

These results will be presented at a Politico webinar on 04 May entitled "Is Europe on the right path to prevent medicines shortages?". More information is available at https://www.politico.eu/event/is-europe-on-the-right-path-to-prevent-medicines-shortages/

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.