

Press Release

Commission study highlights market framework conditions are main driver for medicines shortages

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At any time, discontinuations in the supply of medicines are of great concern because they disrupt the normal course of a patient's treatment. Shortages may affect patient access and burden healthcare professionals. Today, the European Commission has published a [study](#):

- Looking at medicines shortages in member states and their root causes
- Assessing the EU legislative framework and national legislation on the supply of medicines
- Tabling 16 policies to reduce medicines shortages

The study confirms that shortages are often not so much a problem of whether a medicine is available but one of where it is available. Where shortage notifications have increased and involve older, off-patent medicines, this is widely attributed to the low profit margins associated with these products. Although the study shows that root causes are multifactorial along the entire pharmaceutical value chain, from manufacturing of raw materials to national pricing and procurement practices, the high prevalence of localised shortages in specific markets (as opposed to the rarer EU-wide shortages) suggests **that market failures are the true driver**.

The study calls for some clear policy reforms:

- Reform medicine procurement policies by incorporating requirements for more diversified, multi-winner tender – *this will reduce the consolidation of manufacturing which is a major shortage risk.*
- Establish and streamline harmonised reporting criteria for shortages – *this will enable manufacturers to understand where there are localised shortages and rapidly intervene to resupply.*
- Improve regulatory efficiency with EU-wide medicines packaging and labelling harmonisation that includes flexibilities for digital leaflets and multi-country/multi-language packaging and labelling – *this will make it easier for manufacturers to resupply multiple markets quickly in the event of a localised shortage and increase the efficiency of supply chains.*
- Set up stakeholder platforms between supply chain stakeholders and end users (patients, HCPs) at Member State level – *this will facilitate necessary local reforms to reduce shortage risks and rapidly mitigate shortages.*

Rebecca Guntern, President ad-interim of Medicines for Europe, commented on the publication: *“The Commission study on shortages by Technopolis confirms that current market framework conditions for off-patent medicines play against supply resilience. As long as healthcare systems only focus on the cheapest possible price for off-patent medicines and do not reward investments to ensure robust supply chains, the only option for companies is to be the cheapest or to leave the market. If we are to learn the lessons of Covid-19 regarding the need for secure supplies of critical and essential medicines, the European Commission must act now to require security of supply criteria in procurement and purchasing processes, to improve regulatory efficiency and to*

harmonise national shortage reporting. Every patient should be able to receive the prescription medicines they need, on time, every time. That is the essence of modern healthcare and we need to protect it and safeguard it.”

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.