Press Release

New report highlights market access barriers for EU-based generic and biosimilar companies in third countries

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Medicines for Europe is launching a study of market barriers faced by EU generic and biosimilar pharmaceutical companies operating in 11 key third-country markets.

The analysis looks at the barriers that EU-based companies experience in different markets. The findings confirm that major trading partners are pro-actively investing in pharmaceutical manufacturing, with targeted support for the sector. This highlights the need to rapidly introduce an EU Critical Medicines Act.

The analysis found the main barriers to be:

- **Public Procurement rules**: Prioritising domestic suppliers in tenders, limiting access for EU companies.
- **Regulatory Assessments**: Complex regulations and lack of harmonisation cause delays and higher costs.
- **Local Manufacturing preferences**: Local content rules disadvantage EU manufacturers.
- **Local rules on pricing and reimbursement:** Price controls and reimbursement policies significantly influence patient access.
- **Intellectual property rules:** Patent linkage systems and patent extensions delay the timely entry of generic and biosimilar medicines.

The findings underline the need for strong EU trade and external policies to remove these barriers, which undermine the competitiveness of EU-based pharmaceutical companies and restrict access to more affordable generic and biosimilar medicines.

Medicines for Europe supports an open, fair and assertive trade policy. This policy should recognise the global nature of pharmaceutical supply chains and strengthen existing partnerships while forging new ones, and assertively address market access barriers and the enforcement of trade commitments.

Commenting on the launch of the study, Medicines for Europe International Affairs Committee Chair David Jauch said "*We hope that this study will contribute to achieving strategic trade and partnership objectives in the next Commission mandate. The goal must be to foster better and faster patient access to generic and biosimilar medicines in third countries and create new growth opportunities for EU-based generic and biosimilar pharmaceutical companies. The report clearly shows that our trading partners are taking action to support the off-patent medicines sector, something to be reflected in the EU Critical Medicines Act that will support European companies on the global trade stage.*"

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Resource hub

Medicines for Europe's report *Market Access Barriers: An overview of key barriers to generic and biosimilar market entry in select EU trading partners* can be accessed at: https://www.medicinesforeurope.com/wp-content/uploads/2024/10/Market-Access-barriers-30-10-2024-final-revs.pdf

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.