

Press Release

Decisive action on medicines shortages should be included in pharmaceutical and industrial strategies

For Immediate Release

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Medicines for Europe applauds that the European Parliament has clearly recognised the key role that off-patent medicines bring to patient access to essential medicines and have called to examine measures aimed at stimulating healthy competition for generic and biosimilar medicines.

The Own Initiative Report, led by members of the parliamentary committee for Health (ENVI), has adopted constructive initiatives to tackle the root causes of medicines shortages that the European Commission should include in the forthcoming pharmaceutical and industrial strategies.

Concrete policy solutions include targeted guidelines on medicines procurement to help Member States improve their unsustainable purchasing practices. This can be achieved by implementing the MEAT criteria and awarding more than one company in tender decisions to build a secure supply framework nationally.

The report factors in best practice initiatives from the COVID19 outbreak such as dialogue with industry and pragmatic regulatory flexibilities. The latter can mitigate shortages by allowing flexibilities on pack size and the introduction of electronic product information/e-leaflet. To enable regulatory authorities to promptly share key information, the report calls for regulatory optimization. This can be achieved by amending the EU Variations Regulation and implementing telematics reform. The report also provides a clear signal to strengthen pharmaceutical supply chains, with support from the EU and Member States to introduce the right incentives to encourage manufacturing in Europe.

The EP also outlines the existing framework for wholesalers' and manufacturers' obligation to supply and report disruptions. While all companies have well defined supply obligations under existing contracts with established penalties for failure to supply, doubling penalties and fines on companies will discourage them from participating in tenders and will not help solve 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.