

The EU must stop the offshoring of essential medicines manufacturing investments: ambitious, open and coherent policies must support competitive, robust and sustainable production of APIs and medicines

The European Union must play a decisive role in supporting the production in Europe of APIs and medicines with immediate, robust and ambitious policies that prioritise patient access, while expanding and bolstering its competitiveness and geopolitical position by remaining open and attracting investments.

A variety of recent studies¹ show the state of pharmaceutical intermediates, active pharmaceutical ingredients (API) and finished medical products production in Europe. Despite having a strong industrial base, a significant part of the production of API has moved to Asia, where investment and operating costs are 20-40% lower, mainly due to lower labour and environmental costs. Another key factor of offshoring is unsustainable pricing policies in Europe that do not provide any predictability for manufacturers by actively encouraging a “race to the bottom” to the lowest price. Pricing rules do not reward investment in supply security or in environmental improvements – two core objectives of EU pharmaceutical policy.

In parallel, the European Structured Dialogue on security of medicines supply indicates that this mix of unsustainable pricing and economic policies is particularly extreme for off-patent medicines. The primary driver is the race to the lowest-price generic, which leads to essential medicines being regarded as other non-essential commodities, challenging all investments needed to produce such medicines with state-of-the-art European standards and technology, as well as regulatory costs due to complexity and lack of harmonisation of regulatory and intellectual property frameworks.

A study commissioned by Teva Pharmaceuticals covering 3,000 patients across 6 European countries, showed how the vast majority (84%) of patients want their government to support pharmaceutical manufacturing investments in their region to avoid over-dependencies on countries outside of Europe. This is a clear call which cannot be ignored.

Medicines for Europe and the European Fine Chemicals Group believe that EU industrial policies must support the manufacturing footprint with the following conditions:

1. Procurement, pricing and reimbursement reforms in EU Law to reduce market consolidation, encourage investments in security of supply, reinforce the competitiveness of European manufacturing and support the green transition for medicines manufacturing.
2. Encourage access to manufacturing incentives such as funds to support manufacturing investments in new technology and innovation by adapting the EU State Aid Framework.
3. Regulatory efficiency must be optimised with digitalisation, interoperability of the regulatory operational system and more harmonisation of regulatory interactions

• ¹ Sept 2020: [pro-Generika \(D\) study mapping global API production](#)
• Jan 2021: [EFCG IQVIA study to analyse causes and consequences](#)
• June 2021: [Access to medicinal products - Study requested by the ENVI committee](#)
• July 2021: Sicos and the French pharmaceutical value chain PwC Study of API supply vulnerabilities for the European pharmaceutical industry
• September 2021 – [Structured Dialogue on security of medicines supply](#)

4. Future policy, requirements or regulation changes need to be accompanied by a thorough impact assessment on the competitiveness of the European industry and the effect on supply diversity in the off-patent sector.
5. Develop a security of supply partnership with the US to encourage more manufacturing investments.

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](https://twitter.com/medicinesforEU).

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European Fine Chemicals Group

EFCG, The European Fine Chemicals group, represents the European manufacturers of Fine Chemicals, Intermediates and Active Pharmaceutical Ingredients (APIs). Our members are the backbone of the pharmaceutical supply chain, supplying its essential building blocks and our vision is to help create a world where access to safe and good quality nutrients and innovative medicines is guaranteed for all. We promote a fairer and safer environment for future generations and we champion sustainable processes and enforced regulations that deliver safe products and enhance growth, employment and environmental performance. EFCG upholds the highest quality and safety standards in our industry and strongly advocates for all companies producing and selling in the EU to be held to the same high standard.

EFCG operates as a Sector Group within Cefic, the European Chemical Industry Council*. Founded in 1972, Cefic is the voice of large, medium and small chemical companies across Europe, which provide 1.1 million jobs and account for 15% of world chemicals production. *EU Transparency Register n° 64879142323-90

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