The Critical Medicines Act

Breaking the dependency

The Critical Medicines Act seeks to build resilience in the EU's pharmaceutical supply chain

Introduction

In March 2025, the European Commission proposed the Critical Medicines Act (CMA)[1] to address growing vulnerabilities in the EU's pharmaceutical supply chain. The Act aims to improve the availability, supply, and production of critical medicines, including those used to treat rare diseases or those not consistently available across all EU markets.

Building on the work of the European Health Union and complementing broader EU legislative reforms, the CMA signals a decisive shift towards more direct intervention in pharmaceutical supply.

This report examines the European Commission's motivation for introducing the legislation, outlines the measures proposed under the CMA, and the implications for firms operating in, or exporting to, the EU life sciences market.

1 European Commission "Critical medicines Act", Accessed 24 July 2025

EU pharmaceutical reforms are a catalyst for change

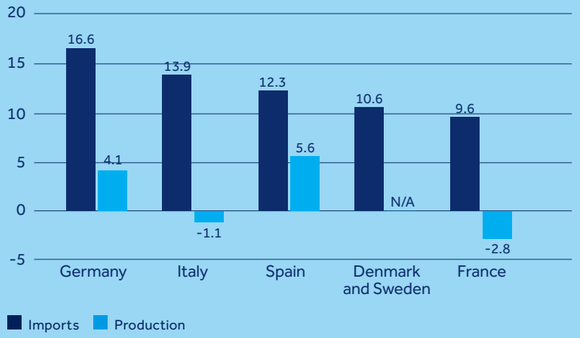
Europe's pharmaceutical sector remains a leader in research and development. However, the past two decades have exposed structural weaknesses in manufacturing and supply.

Nearly 70% of medicines dispensed in Europe are generics[2], yet production of their inputs, particularly active pharmaceutical ingredients (APIs), has increasingly moved outside the EU. Between 2000 and 2019, the value of imported medicaments[3] rose significantly in France, Italy, Germany, Spain, Denmark, and Sweden, while domestic production declined in the former two countries (Fig. 1).

Across these countries, import values increased by an average of 13.3% annually, compared with just 0.8% in domestic production[4], highlighting Europe's growing reliance on external sources for critical medicines.

2 IQVIA "Beneath the Surface: Unravelling the True Value of Generic Medicines", April 2024
3 Eurostat, Prodcom dataset: Sold production, exports and imports [ds-056120__custom_17555170], data extracted 22 July 2025. PRCCODE: 21201160, 21201180, 21201270, 21201340, 21201360, 21201380. Indicators: IMPVAL, PRODVAL
4 Average production excludes Denmark & Sweden due to insufficient available data

Fig. 1. Growth rate for value of medicaments imported and produced by selected EU countries
Value of medicaments imported and produced – compound annual growth rate (CAGR) 2000-2019 (%)

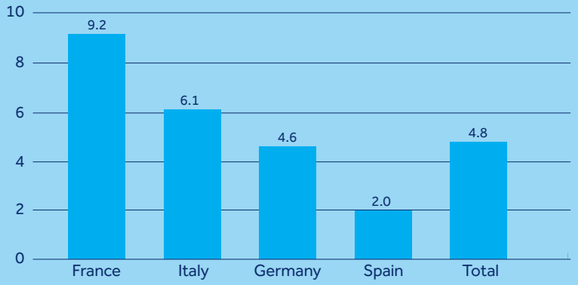


Source: Oxford Economics, Eurostat

That reliance is expected to persist. France is forecast to record the highest import growth (CAGR 9.2%) between 2025 and 2030 for medicines sourced from China, Japan, India, and the US.

Germany and Spain are projected to grow more slowly, at 4.6% and 2.0% respectively (Fig. 2). Across France, Italy, Germany, and Spain, the average forecast import growth is 4.8% annually.

Fig.2. Growth rates of value of medicines imported from China, Japan, India, and US
Value of imported medicines CAGR 2025-2030 (%)



Source: Oxford Economics

Geopolitical tensions cast a long shadow

The Covid-19 pandemic exposed the risks of overdependence on external suppliers. In 2020, India halted exports of over two dozen essential APIs and medicines, ranging from paracetamol to antibiotics. In the current climate of rising geopolitical tensions, protectionism, and global disruption, over-reliance on imported medicine poses serious risks to European patients.

Rising production costs have further eroded the competitiveness of European pharmaceutical manufacturers. Between January and March 2025, gas prices in Europe were three times higher than in the US (CEFIC, 2025)[5]. In May, Xellia Pharmaceuticals, the last major European producer of several key antibiotic APIs, announced a phased closure of its Copenhagen production facility, citing "intense price pressure" and "rising operational expenses"[6]. With half of its products on the EU's List of Critical Medicines, this development will surely only deepen Europe's dependency on imports.

In December 2023, the European Commission published the Union List of Critical Medicinal Products[7], developed with the European Medicines Agency and national agencies. The list, most recently updated in December 2024, includes more than 280 active substances, covering treatments for infections, mental health conditions, and cancer, amongst various others. Medicines are classified as "critical" if insufficient supply would pose serious harm to patients. The list is designed to be dynamic, guiding supply chain risk assessments and policy priorities.

5 CEFIC "Cefic Chemical Trends Report Q1 2025", 8 May 2025
6 Xellia Pharmaceuticals "Xellia announces multiyear plans to phase out Copenhagen site in strategic shift", 6 May 2025
7 European Medicines Agency "Union list of critical medicines"

The Critical Medicines Act: strengthening the supply base

The Act[8] introduces regulatory, financial, and structural measures to improve supply security, support EU-based production, and reduce external dependencies. Key measures will include:

- Improving EU manufacturing capacity: granting "strategic project" status to enable companies to increase EU/domestic production capacity through accelerated regulatory processes and funding, including via the EU4Health Programme.
- Enhancing supply security: expanding national public procurement programmes to ensure reliable supply chains for critical medicines and improve access to other treatments.
- Encouraging collaborative procurement: facilitating cross-border procurement and centralised purchasing on behalf of multiple countries or joint tenders.
- Using state aid guidelines: supporting member states in financing strategic projects that address specific vulnerabilities in supply chains.
- Sealing international partnerships: working with likeminded countries and regions to reduce reliance on single sources and reinforce global supply chain resilience.

Taken together, these measures create opportunities for companies capable of scaling EU-based production of critical medicines. Benefits include faster authorisations, improved funding access, and more stable procurement pipelines.

8 European Commission "Proposal for Critical Medicines Act", 11 March 2025

Why the Act must go further

While these emerging opportunities offer significant potential, they also introduce new responsibilities in regulatory compliance, transparent reporting, and strategic long-term planning. To navigate the evolving policy landscape effectively, firms must reassess their sourcing and investment strategies, evaluate operational risks, and revisit contract terms to ensure resilience and alignment with future requirements.

Industry bodies, including the European Federation of Pharmaceutical Industries and Associations (EFPIA), have raised concerns about the scope of the CMA. EFPIA has called for clearer criteria on when "collaborative procurement options would improve access beyond existing national pricing" structures.[9] It also argues the Act should address "fragmented national contingency stock requirements" that hinder the single market's functionality and limit coordination during supply disruptions.

The Critical Medicines Act represents a significant step in strengthening the EU's pharmaceutical resilience. It aims to secure access to essential medicines, rebuild manufacturing capacity, and reduce foreign dependency. For life science companies, the Act introduces both opportunity and complexity. To deliver its full potential, further alignment of national systems will be required, particularly on pricing and stockpiling, to ensure a unified response to medicine supply challenges across the EU.

9 European Federation of Pharmaceutical Industries and Associations "EFPIA response to the Critical Medicines Act ", 11 March 2025

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