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The challenge of manufacturing critical medicines in the EU

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Abstract

Over recent decades, freer trade and international specialisation have progressively concentrated pharmaceutical production, particularly for generic medicines, in a limited number of countries, especially China. As a result, excessive dependence on imported medicines has become a major vulnerability for the EU amid geopolitical tensions and the weaponisation of trade. In response, the EU has proposed the Critical Medicines Act, which seeks to strengthen supply security through trade strategies (such as supplier diversification) and by reinforcing domestic manufacturing capacity. Focusing on selected active pharmaceutical ingredients—the key inputs in medicines—included in the Union List of Critical Medicines, this article examines the complexity of pharmaceutical supply chains and the structural challenges affecting reshoring strategies. The article concludes by arguing that the EU should be highly selective in identifying which domestic production capacities to promote, not only to ensure the availability of essential medicines when imports become unreliable, but also to improve its bargaining power vis-à-vis foreign suppliers during geopolitical crises that may culminate in export restrictions.

Keywords

Health, Medicines, Chemicals, International trade, Industrial policy

Introduction

Over recent decades, the search for lower production costs has progressively concentrated the production of medicines and their components in a limited number of

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countries. The supply chain of a medicine comprises several inputs, the most important of which is the active pharmaceutical ingredient (API), the substance responsible for its therapeutic effect. The production of APIs relies on complex supply chains that involve precursors and key intermediates, which are transformed through chemical or biological processes into the final active ingredient. Other essential components include excipients, such as fillers, preservatives and coating materials, which contribute to the effectiveness of the medicine. The increasing international fragmentation of pharmaceutical supply chains has made them more vulnerable to disruptions. As recent crises have demonstrated, shortages may result from involuntary factors—such as pandemics, natural disasters and industrial accidents—as well as from voluntary measures, including export restrictions and strategic stockpiling decisions. The concentration of API production in a limited number of countries has therefore transformed pharmaceutical supply chains into a strategic vulnerability for the EU, contributing to the growing frequency of medicine shortages (Pharmaceutical Group of the European Union 2024, 5–6; 2026, 8–10).

In response to these challenges, the EU has progressively strengthened its policy framework on medicine shortages and supply-chain resilience, culminating in the 'Critical Medicines Act' regulation proposed in March 2025 (European Commission 2025). The proposal aims to improve the security of supply and availability of critical medicines by promoting the diversification of supply chains, facilitating joint procurement among member states, and strengthening European manufacturing capacity for critical medicines and the APIs required to produce them (European Council 2026).

This article examines the challenge of strengthening EU manufacturing capacity for critical medicines through 'reshoring strategies', namely, the relocation of previously offshored production activities back to the EU. To this end, the article analyses six APIs associated with medicines included in the Union List of Critical Medicines (European Medicines Agency 2026), examines the structure of their supply chains and evaluates the main constraints affecting the feasibility of reinforcing API manufacturing capacity within the EU. The article concludes by discussing the principal policy options available to improve the resilience and strategic autonomy of European pharmaceutical supply chains.

The critical medicines and their APIs

Since the EU seeks to reduce the risk of shortages of medicines considered essential for public health and patient safety, the European Commission, the Heads of Medicines Agencies[1] and the European Medicines Agency[2] have compiled the Union List of Critical Medicines. Medicines are classified as critical primarily according to two criteria: the severity of the conditions they treat and the availability of suitable therapeutic alternatives (European Medicines Agency 2025).

Although the Union List is defined at the level of finished medicinal products, many of the vulnerabilities associated with shortages originate upstream in the supply chains for APIs, which are indispensable inputs in pharmaceutical production.

For this reason, this article focuses on six APIs associated with medicines included in the Union List of Critical Medicines: amoxicillin, atracurium, ceftriaxone, clindamycin, hydrocortisone and paracetamol. All six APIs are off-patent in the EU and are predominantly supplied as generic medicines.[3] Generic medicines account for approximately 70% of pharmaceutical treatment volume in Europe (IQVIA 2024, 2) and are disproportionately affected by shortages (Napier et al. 2024, 5; Pharmaceutical Group of the European Union 2024, 20).

Each API fulfils a distinct therapeutic role within modern healthcare systems. Amoxicillin is one of the most commonly prescribed antibiotics for the treatment of bacterial infections, particularly in children and primary care, including respiratory, ear and urinary infections. Atracurium is used during surgery and intensive care to relax muscles and facilitate mechanical ventilation. Ceftriaxone is a broad-spectrum hospital antibiotic used to treat severe and potentially life-threatening infections, including pneumonia, meningitis and sepsis. Clindamycin is particularly important for treating serious infections in patients with penicillin allergies. Hydrocortisone is a corticosteroid used to treat severe allergic reactions, shock and hormone deficiencies, and it may be life-saving in emergency situations. Paracetamol is one of the most widely used medicines globally for the treatment of pain and fever.

To provide an indication of the EU's dependence on imported APIs, this study examines the HS6 trade classifications associated with the six selected APIs: amoxicillin (HS6 code 294110), atracurium (293349), ceftriaxone and clindamycin (294190), hydrocortisone (293721) and paracetamol (292429). Across all five HS6 product categories,[4] the EU records a trade deficit with the rest of the world in terms of both quantity and value. Figure 1 shows that over recent years, China's share of imports to the EU has increased significantly across all categories, reaching particularly high levels for hydrocortisone (293721) and amoxicillin (294110).

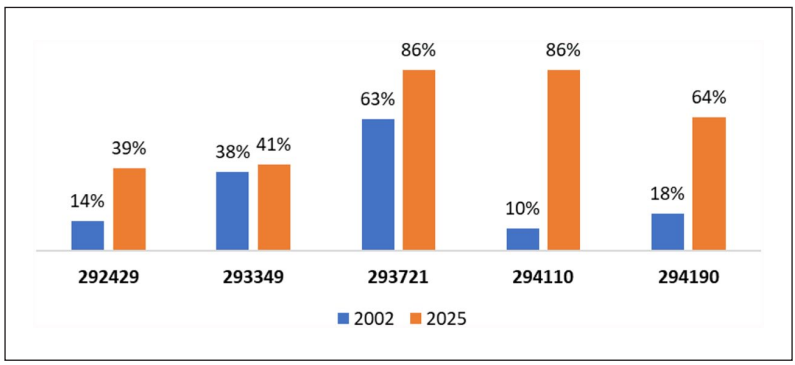

Figure 1. EU imports from China in quantity as a percentage of total extra-EU imports for the five product categories.
Source: Authors' elaboration based on Eurostat (2026).

The supply chains of the six APIs

The industrial production of APIs relies on various manufacturing processes, the main ones being extraction from natural sources, fermentation and chemical synthesis, although many medicines combine more than one of these methods.

Extraction from natural sources involves obtaining the active substance, or one of its key ingredients, from plants and other naturally occurring biological sources, followed by purification. This production route depends heavily on access to vegetable and animal raw materials, land availability, climate conditions and extraction infrastructure. Environmental impacts linked to land use, solvent consumption and biological waste can increase production costs.

Fermentation uses microorganisms, such as bacteria or fungi, grown in large industrial tanks (bioreactors) to naturally produce pharmaceutical substances. This method is widely used for antibiotics and other biologically derived medicines. Fermentation requires large industrial facilities and substantial upfront investment, including bioreactors, sterile production systems and purification infrastructure. Production conditions are also strongly influenced by access to low-cost energy, abundant water, and agricultural feedstocks such as sugars and nutrients.

Chemical synthesis produces APIs through sequences of industrial chemical reactions that transform chemical intermediates into the final pharmaceutical ingredient. These processes may involve oxidation, reduction, nitration, hydrogenation, purification and crystallisation. Chemical synthesis relies heavily on petrochemical raw materials, chemical intermediates, solvents, low-cost energy and integrated chemical supply chains. Production generally requires large industrial plants equipped with reactors, solvent recovery systems and waste-treatment facilities, involving substantial investment. Environmental regulation is also an important factor because chemical synthesis can generate significant waste and emissions and require solvent-intensive processing.

Among the six APIs analysed in this article, amoxicillin is manufactured by combining fermentation and subsequent chemical synthesis. Ceftriaxone and clindamycin are also produced through combined fermentation and chemical synthesis processes. Hydrocortisone has a more complex production process that begins with the extraction of natural steroid precursors from plants such as species of *Dioscorea* (yam plants) and soybeans, followed by multi-step chemical synthesis and biotransformation. By contrast, atracurium and paracetamol are primarily produced through chemical synthesis, although they differ significantly in molecular complexity.

More broadly, pharmaceutical manufacturing frequently relies on substances derived from crude oil and natural gas, such as toluene, xylenes, ethylene and propylene. These compounds are used either as building blocks for APIs[5] or, more indirectly, as solvents, reagents, catalysts and industrial processing materials throughout pharmaceutical production.

The challenges of rebuilding EU manufacturing capacity

Even assuming that the proposed Critical Medicines Act introduces EU-level financial instruments or grants greater flexibility to national governments in the use of state aid, significant challenges would still affect the maintenance and expansion of API production within the EU due to a range of structural constraints:

Unfair international competition

Sustainable expansion of API production within the EU is difficult to achieve in the absence of a level global competitive environment. Part of China's industrial efficiency reflects the significant role of state intervention through subsidies and influence over the allocation and pricing of key production factors, including credit, energy and land (European Commission 2024; United States Trade Representative 2026). China is therefore frequently targeted by trade-defence instruments, particularly in the World Trade Organization (2026) category 'Products of the chemical or allied industries'. At the time of writing, 360 anti-dumping measures are in force worldwide, of which 37% concern Chinese exports. Similarly, China is targeted by 51% of the 47 countervailing measures currently in force. These figures are consistent with the broader price differentials observed in this study: the average unit value of EU imports from China is systematically lower than that of the EU's exports to extra-EU countries across the product categories examined.

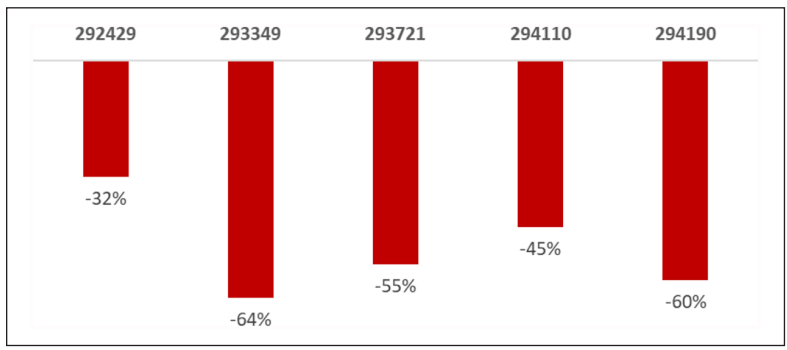

Figure 2. Difference between the average prices of China's exports to the EU and the EU's extra-EU exports for the five product categories.
Source: Authors' elaboration based on Eurostat (2026).

Although trade-defence instruments are applied by importing countries, they are typically introduced only after material injury to domestic producers has already occurred. Moreover, demonstrating the existence of state subsidies is often difficult, particularly when support mechanisms are indirect and opaque.

Energy costs

Energy costs are among the main structural disadvantages affecting European API manufacturing, particularly for fermentation-based and chemically synthesised products. Fermentation requires continuous temperature control, aeration, sterilisation and downstream purification, whereas chemical synthesis relies on energy-intensive operations such as controlled heating and cooling, pressure control, solvent recovery and multi-step transformations.

According to the International Energy Agency (2026, 113–14), electricity prices for energy-intensive industries in the EU were approximately twice as high as in the US and around 50% higher than in China in 2024. Natural gas prices show a similar pattern. While prices have declined from the exceptional peaks reached during the energy crisis, European gas prices remain structurally above those in major competing economies, reflecting the EU's greater reliance on imported liquefied natural gas and the progressive replacement of cheaper Russian-pipeline gas. Gas prices in major producers such as the US remain significantly lower, while gas prices in China have increased less than in the EU (Jagtenberg et al., 2025, 74–5).

Raw materials and the regulatory framework

Raw materials and environmental constraints differ significantly depending on the production process adopted. Extraction-based APIs rely on medicinal plants, naturally occurring compounds and biological materials, whereas fermentation-based production requires large quantities of water, sugars and nutrients to sustain microbial processes. Within the EU, the availability and affordability of these inputs are constrained by higher land and agricultural production costs and stricter environmental standards and water-management requirements. Climatic conditions and biodiversity constraints may also limit the domestic availability of certain natural compounds, thereby increasing dependence on imports of selected raw materials.

The greatest vulnerabilities concern chemically synthesised APIs, which depend heavily on petrochemical feedstocks, solvents, reagents, catalysts and intermediates derived from crude oil and natural gas, that is, segments of the upstream chemical industry in which the EU has progressively lost production capacity over recent decades (Cefic 2025, 74).

Compared with Asian countries currently specialising in the production of pharmaceutical inputs and intermediates, the EU imposes significantly stricter environmental and industrial regulatory requirements, particularly regarding industrial emissions, hazardous substances, waste-water treatment, waste management, chemical handling and permitting procedures under frameworks such as the Industrial Emissions Directive and the REACH Regulation. While these standards reflect important public health and environmental objectives, they also increase compliance costs, administrative complexity, investment requirements and permitting times for European manufacturers.

Capital investment and industrial scale

API manufacturing requires substantial fixed capital investment regardless of the production technology adopted. The economic sustainability of these investments depends heavily on the ability to operate at scale, since high fixed costs can only be absorbed efficiently through continuous high-volume production and economies of scale. However, even if European manufacturers were to receive public support to strengthen production capacity, they would still face structurally higher production costs than many Asian competitors, particularly in energy, environmental compliance and upstream inputs. In addition, the construction and operation of large industrial plants in Europe are often constrained by high population density, land-use conflicts, lengthy permitting procedures and local opposition to industrial facilities (the 'Not In My Back Yard'—or NIMBY—syndrome).

As a result, lower-cost Asian APIs have captured a substantial share of the global market, limiting the production volumes available to European producers and thereby reducing their ability to generate economies of scale and production efficiency.

These disadvantages are reinforced by differences in industrial organisation. In China and India, API production is frequently concentrated within highly integrated industrial ecosystems that combine petrochemicals, intermediates, solvents, fermentation capacity, utilities, logistics, API manufacturing and downstream pharmaceutical production. Although the EU continues to host important pharmaceutical and fine-chemistry clusters—particularly in Italy, Germany, Spain and Ireland—the European production base remains comparatively fragmented and less vertically integrated than the industrial ecosystems developed in China and India (Chemical Pharmaceutical Generic Association 2025, 30).

A strategy for the EU

The proposed Critical Medicines Act aims to strengthen European manufacturing capacity for critical medicines in response to the EU's growing dependence on a limited number of suppliers of essential pharmaceutical ingredients, particularly in China. If the EU intends to rebuild pharmaceutical manufacturing capacity through industrial policy, it will need to pursue a balanced strategy. On the one hand, policy efforts may focus on the selective reshoring of APIs for which European production could become economically viable through technological innovation. On the other hand, the EU will also need to strengthen the resilience of global supply chains for medicines whose production cannot realistically be repatriated because of cost structures and technological constraints.

Dependency risks in supply chains

The structural risks associated with these dependencies can be analysed through the concept of 'weaponised interdependence' (Farrell and Newman 2019). Supply-chain dependencies may become instruments of economic coercion when three conditions coincide: production is geographically concentrated in a limited number of suppliers, the

product is essential and not substitutable in the short term, and the importing country lacks a credible domestic alternative.

The first condition is structural. As shown in Figure 1, China's share of imports to the EU has increased substantially across several of the APIs analysed in this study, particularly hydrocortisone (HS6 code 293721) and amoxicillin (294110). The second condition derives from the inclusion of these molecules in the Union List of Critical Medicines. The third reflects the long-term erosion of upstream chemical and fermentation capacity in Europe, discussed above. Taken together, these conditions expose European pharmaceutical supply chains to the risk of external supply manipulation.

The evidence is not merely theoretical. During the early stages of the Covid-19 pandemic, India temporarily restricted exports of paracetamol and several other APIs to protect the country's domestic supply, giving limited warning to European generic manufacturers. Earlier examples—such as China's restrictions on rare-earth exports to Japan in 2010 or the reduction of Russian natural gas supplies to Europe in 2022—similarly illustrate how concentrated interdependencies may become instruments of geopolitical leverage. Pharmaceutical supply chains exhibit comparable vulnerabilities because many APIs and intermediates are highly concentrated, essential and difficult to rapidly substitute.

Selective reshoring

The domestic production of life-saving medicines could strengthen the resilience of pharmaceutical supply chains by reducing exposure to trade disruptions and external dependencies. However, given the complexity of pharmaceutical value chains and the structural disadvantages facing European manufacturing, reshoring strategies are likely to be more feasible for high-value, low-volume, quality-sensitive or strategically critical APIs, such as sterile injectables, complex APIs and certain antibiotics. In these cases, considerations related to supply security, strategic autonomy and regulatory oversight may justify production costs that are higher than those prevailing in low-cost manufacturing regions.

Technological innovation may help mitigate some of these structural constraints. Advanced manufacturing technologies—including continuous manufacturing, advanced chemical processing and improved biological production methods—may increase efficiency, reduce waste generation and lower operating costs. These innovations may be particularly relevant for chemically synthesised APIs such as atracurium and paracetamol, and may also support more sustainable production processes for steroid APIs such as hydrocortisone. Similarly, improvements in fermentation technologies may enhance the production of antibiotics that require large bioreactors and complex downstream purification stages, such as amoxicillin, ceftriaxone and clindamycin.

Digitalisation and automation may further support European pharmaceutical manufacturing by reducing labour intensity and improving operational efficiency. Technologies such as artificial intelligence, robotics, predictive monitoring systems, digital twins and automated quality-control systems may improve production reliability, strengthen

supply-chain traceability, reduce operational risks and lower environmental impacts. Together, these innovations could support the development of a more advanced, resilient and sustainable pharmaceutical manufacturing base within the EU.

Selective offshoring

During the expansion of globalisation, offshoring was largely driven by cost efficiency and was generally considered geographically and politically neutral. More recently, however, new approaches have emerged. Nearshoring seeks to reduce geographical distance and logistical complexity, while friendshoring involves sourcing critical inputs from politically aligned partner countries. In this context, the EU may attempt to strengthen pharmaceutical supply-chain resilience through diversification strategies and by redesigning the geography of production and sourcing in favour of countries that are geographically and politically closer. At the same time, European pharmaceutical firms may need to develop more stable, long-term relationships with foreign suppliers of critical inputs to improve the coordination, transparency and security of supply.

Nevertheless, diversification remains difficult after decades of concentration and consolidation of global pharmaceutical production, particularly for APIs and key intermediates whose manufacturing capacity remains heavily concentrated in China. Moreover, friendshoring strategies rely on the assumption that politically aligned countries will remain reliable suppliers during periods of crisis. The Covid-19 pandemic illustrated these limitations clearly, as several countries imposed export restrictions on personal protective equipment, vaccines and pharmaceutical products to prioritise domestic needs and national security.

Conclusions

The EU must recognise that, despite being one of the world's largest economies, it cannot rapidly reverse decades of de-industrialisation in the pharmaceutical and chemical sectors. Industrial policy should therefore focus on identifying those segments of pharmaceutical production, especially of critical APIs, that can realistically and sustainably be strengthened within Europe.

The strategic value of selectively rebuilding domestic production does not lie primarily in completely replacing imports, which, for many products, would be neither economically feasible nor efficient. Rather, it lies in creating a credible outside option that can improve the EU's bargaining position vis-à-vis foreign suppliers (that is, the countries in which the production of critical components is concentrated), even if such production capacity is not fully utilised under normal conditions.

The implementation of the Critical Medicines Act should therefore be evaluated not by the overall share of pharmaceutical production reshored to Europe, but by the credibility, scalability and technological readiness of the manufacturing capacity that can be mobilised during periods of crisis. Even relatively limited but strategically targeted

domestic production capacity, combined with diversified sourcing and coordinated EU procurement mechanisms, may significantly reduce the structural vulnerability of European pharmaceutical supply chains.

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Notes

1. The Heads of Medicines Agencies is the network that brings together the national medicines regulatory authorities of the European Economic Area to coordinate cooperation and regulatory activities in the field of medicines.
2. The European Medicines Agency is the EU agency responsible for the scientific evaluation, supervision and safety monitoring of medicines, and for providing scientific recommendations on their authorisation within the EU.
3. Generic medicines are pharmaceutical products that are equivalent to branded medicines whose patent protection has expired, are marketed at lower prices, and are the same in terms of API, dosage, safety, quality and therapeutic effect.
4. HS6 refers to the six-digit level of the Harmonized System (HS), the international classification system used for traded products in customs and international trade statistics.
5. For example, paracetamol production ultimately depends on petrochemical value chains: a key intermediate in its synthesis is phenol, which is generally produced from benzene, itself obtained through refinery and petrochemical processes involving hydrocarbons derived from crude oil.

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