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EU Reliance on Third-Country Imports of Active Pharmaceutical Ingredients: Obstacles and EU Countermeasures

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ABSTRACT

The European Union's growing reliance on active pharmaceutical ingredients (APIs) imported from non-EU nations has become a pressing concern for the stability of its pharmaceutical supply networks and the protection of public health. Over the past several decades, much of the API manufacturing for generic drugs has relocated beyond EU borders—mainly to China and India—resulting in a concentration of production risks and increased exposure to global disruptions. Crises such as the COVID-19 pandemic and the war in Ukraine have further highlighted how political and health emergencies can severely hinder access to essential medicines. This paper explores the EU's current regulatory and policy measures designed to diversify API sources, encourage local manufacturing, and enhance strategic self-sufficiency. It also investigates the underlying factors contributing to drug shortages and the associated threats to healthcare systems and economic stability within the Union. Ultimately, the study emphasizes the importance of a unified, EU-wide strategy to safeguard medicine availability and reinforce the resilience of Europe's pharmaceutical industry.

Keywords: Supply chains, API, Active pharmaceutical ingredients, Strategic autonomy, Diversification, Critical medicinal products

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Introduction

The European Union (EU) possesses a highly developed and globally competitive pharmaceutical industry that not only leads in medicinal product manufacturing but also contributes substantially to the EU economy, employing nearly 800,000 individuals [1]. Historically, this sector has been defined by its strong emphasis on research and development, particularly in the creation of innovative medicines—a focus that was reaffirmed during the COVID-19 pandemic.

Over the past several decades, however, the landscape of pharmaceutical production within the EU has shifted considerably. While manufacturing in Europe continues to prioritize innovative drugs that require sophisticated technology, expert personnel, and complex production systems, a large proportion of active pharmaceutical ingredient (API) manufacturing—especially for generic medicines—has increasingly moved beyond European borders. This trend is particularly significant as generics constitute approximately 70% of all prescriptions in Europe [2]. Consequently, the EU's supply chain resilience and its ability to maintain uninterrupted access to critical medicines are under growing pressure.

Recent international disruptions, including the COVID-19 pandemic and ongoing geopolitical conflicts, have amplified the vulnerabilities in European pharmaceutical supply networks. The resulting shortages of key medicinal products threaten public health and disrupt healthcare delivery systems, thereby endangering patients' access to essential treatments [3].

A detailed assessment of these shortages reveals a multifaceted issue that spans every stage of the pharmaceutical value chain—from production and quality control to economic decisions, logistical obstacles, and competitive

pressures. A recurring problem lies in the insufficient diversification of suppliers, which creates fragile points in the supply chain and heightens the risk of disruption [4].

When analyzing the scarcity of critical medicinal products—those lacking effective substitutes and whose absence poses severe risks to patients—it is necessary to differentiate between generic (non-patented) and innovative (patented) medicines. The economic dynamics governing generics often diverge from those influencing innovative drugs. Furthermore, cost-containment strategies prevalent across EU healthcare systems, such as public procurement processes, typically prioritize the lowest-priced offers [5].

The COVID-19 pandemic underscored the EU's strategic weaknesses in sustaining domestic production of essential pharmaceuticals. Export restrictions imposed by non-EU nations during this period exposed Europe's heavy reliance on external suppliers for APIs [6, 7]. This situation revealed the urgent necessity of reinforcing economic resilience and supply chain stability, as global disturbances—stemming from health emergencies, geopolitical conflicts, or economic uncertainties—can profoundly impact the EU's healthcare systems, as well as its social and economic security.

Materials and Methods

This study adopts a systematic review approach to analyze the challenges and prospects linked to the European Union's dependency on imported active pharmaceutical ingredients (APIs) and medicinal products from non-EU countries. The review encompassed regulatory, institutional, and academic literature addressing the EU's reliance on foreign API sources. Data were collected from official European and national regulatory documents, including communications from the European Commission, European Parliament, European Medicines Agency, and the Critical Medicines Alliance, along with peer-reviewed articles from Medline, PubMed, Scopus, and Google Scholar.

Search terms used in the review included active pharmaceutical ingredients, API, critical medicinal products, diversification, strategic autonomy, and supply chains. Sources were selected based on their publication within the past five years, relevance to the subject of API dependency and medicine shortages, and the reliability of their evidence **(Figure 1)**. Within this analytical framework, the study examined European and national regulatory strategies developed to reinforce the security of medicine supply and to advance the EU's goal of strategic autonomy in the pharmaceutical domain.

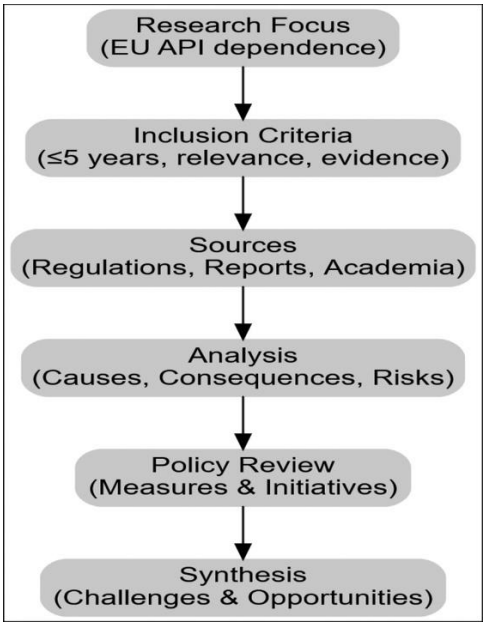

Figure 1. Study design.

Special emphasis was placed on uncovering the underlying factors contributing to the EU's dependence on external sources for active pharmaceutical ingredients and on assessing its repercussions, particularly the recurrent shortages of vital medicines. The review also examined the broader implications of this dependency, including

risks to public health and the Union's economic stability. Furthermore, it analyzed both current regulatory measures and newly proposed EU legislative frameworks aimed at expanding supply diversity, promoting regional manufacturing capacity, and reinforcing the overall robustness of pharmaceutical supply systems.

Results and Discussion

Findings from a collaborative study conducted by EU Member States under the "EU4Health" program indicate that more than half of all reported medicine shortages stem from challenges associated with the production process. This category also encompasses cases linked to disruptions in the supply of active pharmaceutical ingredients **(Figure 2)** [8].

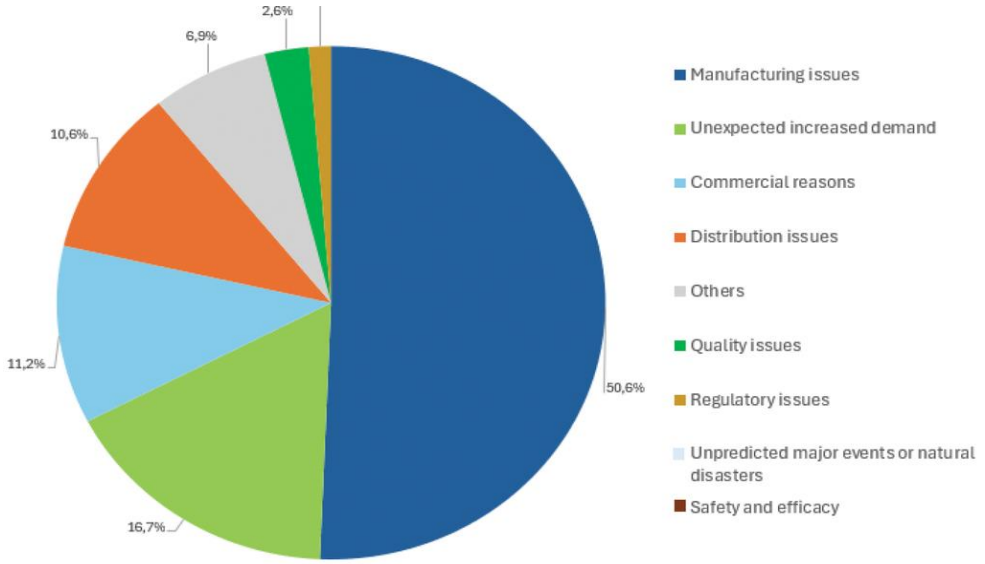

Figure 2. Root causes of medicine shortages in 2022 and 2023 in EU/EEA countries, categorized according to the working group of single points of contact classification (Joint Action CHESSMEN).

For nearly ten years, the issue of medicine shortages has remained a consistent priority on the European Union's policy agenda. The Pharmaceutical Strategy for Europe, introduced in 2020, underscored the necessity of building a robust and adaptive regulatory framework for medicinal products. It also called for stronger support mechanisms for the pharmaceutical industry to encourage research, innovation, and technological advancement that address genuine therapeutic needs while ensuring that medicines remain both accessible and affordable [9]. Among its core actions, the Strategy proposed launching a structured dialogue focused on the industrial dimension of supply security. This initiative, initiated in 2021, convened a wide spectrum of stakeholders—including API manufacturers, distributors, healthcare professionals, patient associations, and national regulatory authorities—to exchange perspectives and coordinate efforts [10].

In 2023, the European Commission issued a communication presenting targeted actions to enhance the EU's ability to prevent and manage shortages of critical medicines. The document reaffirmed that pharmaceutical companies bear primary responsibility for maintaining adequate supply levels, whereas national authorities are tasked with monitoring and managing availability within their jurisdictions. While most shortages are handled at the national level, the Commission emphasized that in situations where essential medicines lack therapeutic alternatives and no national solution is viable, joint EU-level coordination becomes essential to safeguard supply continuity and fortify the long-term stability of the Union's pharmaceutical systems.

Further, the 2022 European Commission communication drew particular attention to securing the availability of essential critical medicines [11]. It advocated the development of a unified EU-wide list of such drugs prior to finalizing the revised pharmaceutical legislation. This list—compiled collaboratively by the European Commission, the European Medicines Agency (EMA), and the network of national regulatory authorities—was first released in December 2023 [12]. It contains over 270 active substances covering major therapeutic areas, including infectious diseases, cardiovascular illnesses, psychiatric disorders, and cancers. The list serves as a

foundational tool for assessing supply chain vulnerabilities and prioritizing areas that require focused interventions to strengthen resilience and guarantee medicine availability.

The European Union's dependence on imports of active pharmaceutical ingredients from third countries: challenges to supply security

The heavy reliance of EU Member States on imported active pharmaceutical ingredients (APIs) and finished medicinal products from non-EU regions poses a considerable threat to the stability of pharmaceutical supply chains and the protection of public health across the Union. This issue has received increasing attention from researchers and international bodies seeking to assess its scale, root causes, and policy implications.

The report "International trade of pharmaceutical products and issues of national security" underscores the concentration of API manufacturing in Asia, revealing that up to 80% of chemical substances used in EU pharmaceutical production originate or are synthesized outside the region—mainly in China and India [13]. Such geographic dependence introduces systemic vulnerabilities and heightens concerns about Europe's health sovereignty and national security.

In a 2023 European Parliament report, current API production levels within the EU were analyzed alongside initiatives to repatriate manufacturing and stimulate local production capacities [14]. Similarly, a 2021 analysis published by EFPIA offered comprehensive insights into the production, trade, and dependency structures of the EU-27 pharmaceutical sector. While recognizing that medicine shortages result from multiple interlinked factors, the study reinforces the argument that dependence on a limited number of supplier nations for strategically significant materials aggravates supply chain fragility [15].

The European Commission's report "Strategic dependencies and capacities" (2021) formally classified API dependency as a strategic vulnerability for the EU. The report highlighted China's dominant position as a supplier and advocated for diversification of sourcing channels along with the strengthening of EU-based production for critical raw materials. Complementing this perspective, the Stiftung Wissenschaft und Politik (SWP) study titled "The EU's Open Strategic Autonomy in the Field of Pharmaceuticals" (2023) [16] provided a deeper examination of Europe's dependency on Chinese imports, focusing especially on antibiotic production. Given the indispensable role of antibiotics in healthcare systems, potential disruptions in their supply could have severe repercussions for public health [16].

The report "Safer Together: Strengthening Europe's Civilian and Military Preparedness and Readiness" by Sauli Niinistö offers critical insights into the vulnerabilities of global pharmaceutical supply chains. It underscores that Europe's heavy dependence on a small number of suppliers or specific geographic regions for key active pharmaceutical ingredients (APIs) and finished medicinal products exposes the Union to severe shortage risks. The analysis further explains that geopolitical tensions, pandemics, or natural disasters can swiftly disrupt these tightly interconnected distribution networks, resulting in critical medicine deficits. To mitigate such risks, the report recommends strategies such as diversifying supply chains, building strategic reserves at both national and EU levels, and enhancing transparency across production and distribution channels. Implementing these measures could substantially strengthen supply continuity and reduce threats to public health and collective security [17].

In response to these persistent vulnerabilities, the European Commission launched the Critical Medicines Alliance (CMA) in October 2023 [18]. Conceived as a collaborative consultation platform, the Alliance unites diverse stakeholders—ranging from representatives of EU Member States and industry leaders to civil society organizations and scientific experts. Its central mission is to identify high-priority action areas and recommend practical solutions to bolster the supply of essential medicines throughout the EU, thereby improving prevention and management of drug shortages. One of its key objectives is to ensure open and inclusive dialogue between the European Commission, EU policymakers, and relevant stakeholders, with a particular focus on pharmaceuticals most vulnerable to supply disruption.

Throughout 2024, the CMA convened multiple working sessions, culminating in a comprehensive strategic report released on 28 February 2025. This document presented concrete policy recommendations that later informed the European Commission's drafting of the Critical Medicines Act [19].

Conclusion

The persistent shortage of essential medicines, compounded by the EU's reliance on imported active pharmaceutical ingredients, poses a profound and complex challenge that demands coordinated, supranational

intervention to address a fundamentally global issue. Efforts led by the European Commission must consider the economic disparities and pharmaceutical infrastructure gaps among Member States, particularly those with lower GDPs or limited manufacturing capacity. Neglecting these differences risks channeling resources disproportionately toward Western European nations, where the pharmaceutical industry is already well established.

To achieve true pharmaceutical sovereignty and long-term resilience, future EU strategies must prioritize technology transfer, regional capacity development, and balanced investment across the Union—bridging Western and Eastern Europe alike. Only through such an equitable and integrated approach can the EU enhance its collective autonomy, safeguard medicine availability, and ensure fair access for all Member States.

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