Medicines for Europe
Submission to the U.S. Section 232 Investigation on the National Security Implications of Pharmaceutical Imports, XRIN 0694-XC120

6 May 2025

Introduction

These written comments are submitted by Medicines for Europe in response to some of the questions raised in the context of the U.S. Department of Commerce's Section 232 investigation into the effects of imports of pharmaceuticals, active pharmaceutical ingredients (APIs), and derivative products on the national security of the United States (Docket Number BIS-2025-0022, XRIN 0694-XC120)[1].

Medicines for Europe represents the European generic, biosimilar, and value-added pharmaceutical industries. Our sector is a key supplier of affordable, high-quality medicines both in Europe and internationally, including to the United States. As an interested party to the consultation, we appreciate the opportunity to provide our input and have structured our responses in accordance with the questions posed by the U.S. Department of Commerce.

Comments on the investigation questions

Question (i): the current and projected demand for pharmaceuticals and pharmaceutical ingredients in the United States

As of 2023, the United States (U.S.) pharmaceutical market size is valued at 602.19 billion USD. For 2024, the U.S. pharmaceutical market size was estimated at around 634.32 billion USD, with projections indicating growth to 1,093.79 billion USD by 2033, reflecting a compound annual growth rate (CAGR) of 6.15%. This growth is due to the increase of chronic diseases, geriatric population, growing healthcare expenditure, and significant efforts to improve the levels of affordability & accessibility of pharmaceuticals (see here and here). Therefore, the demand for finished pharmaceuticals and active pharmaceutical ingredients (API) in the U.S. is expected to increase.

However, we should note the major divergence between the on- and off-patent pharmaceutical market in the U.S.. While the generic medicine market has been continuously expanding in volume terms, offering treatment for more patients, the market has been shrinking in value terms, the U.S. generic medicine market has declined by $6.4 billion over the past five years[2]. This dramatic fall in market value has encouraged industrial consolidation and put pressure on all generic medicine manufacturers.

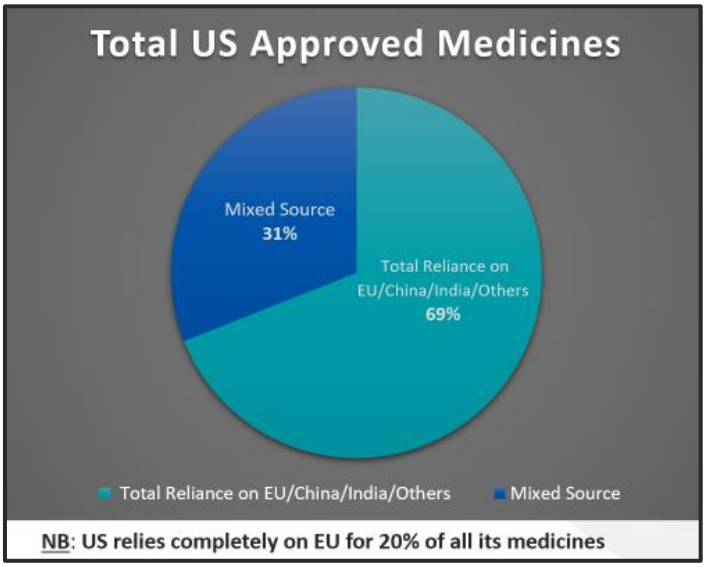
[1] https://www.regulations.gov/document/BIS-2025-0022-0001
[2] https://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf

Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11- F: +32 (0)2 736 74 38
www.medicinesforeurope.com

Questions (ii), (iii) and (iv):

(ii) the extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand; (iii) the role of foreign supply chains, particularly of major exporters, in meeting United States demand for pharmaceuticals and pharmaceutical ingredients; and (iv) the concentration of United States imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks

The pharmaceutical industry functions through a robust and resilient supply chain which is global. A Medicines for Europe analysis of API supplier locations for the U.S. market in 2022 revealed that for 20% (677/3505) of the approved APIs in the U.S., Europe is the *only* supplier, and for 69% (2378/3505) of all the U.S. approved APIs, the U.S. relies *totally* on non-U.S. manufacturers (EU, China, India, others), as shown in the table below:



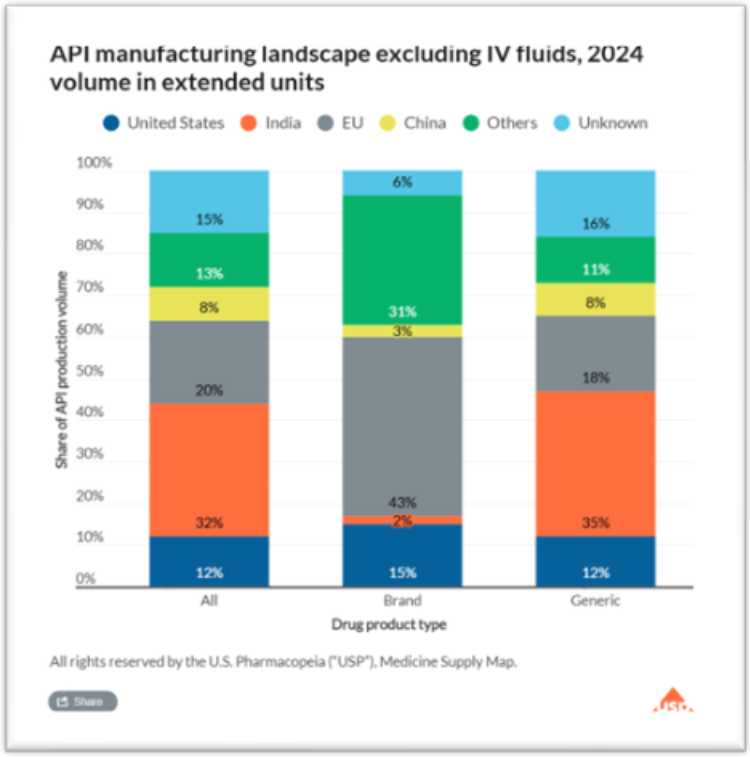
Moreover, in 2023, the U.S. imported 70% of APIs in volumes, as follows: 15% from China, 25% from EU and 30% from India. However, India imports around 25% of its APIs and 70% of key starting intermediates from China, on which, therefore, also India is heavily dependent. As a result, today the actual dependence of the U.S. on China is indirectly much higher than 15%.[3]

At the same time, FDA figures confirm that the number of registered facilities making APIs in China more than doubled between 2010 and 2019,[4] and U.S. imports of Chinese pharmaceuticals have grown by 485% between 2020 and 2022.[5]

A recent analysis on U.S. prescription APIs divided by type of product and published on USP Quality Matters website on 17 April 2025 confirms the strong interdependence among regions, showing the key role of foreign exporters for meeting the U.S. demand for APIs.[6]

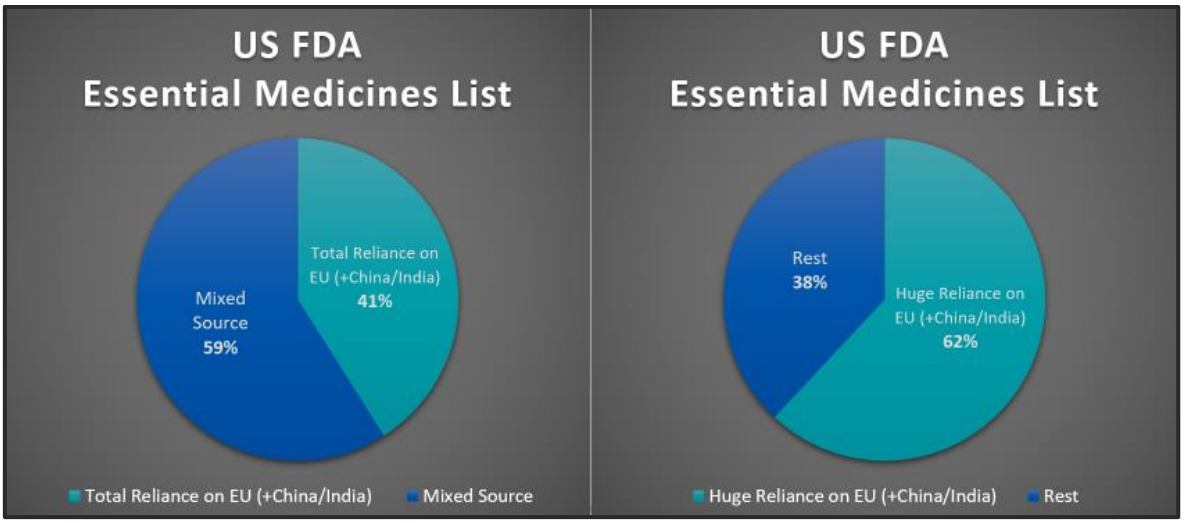
[3] 2024 Outlook of Active Pharmaceutical Ingredients: the post-pandemic reshaping, CPA (Chemical Pharmaceutical generic Association)
[4] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
[5] https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/
[6] https://qualitymatters.usp.org/over-half-active-pharmaceutical-ingredients-api-prescription-medicines-us-come-india-and-european

Table: Volume share of US prescription API, by country (2024)

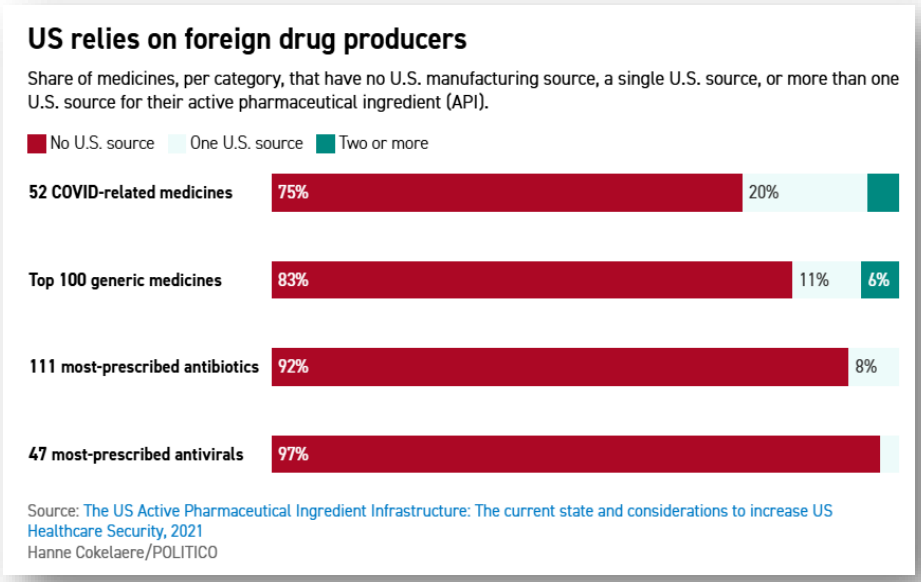


The table above excludes intravenous (IV) fluids from the analysis (Sodium Chloride Injection, Bacteriostatic Sodium chloride Injection, Dextrose Injection, Potassium Chloride Injection, Lactated Ringer's Injection) as their large volumes can significantly skew the analysis. This means that the share of generic medicines and API produced in the US would be higher than in the table above if it included IV fluids.

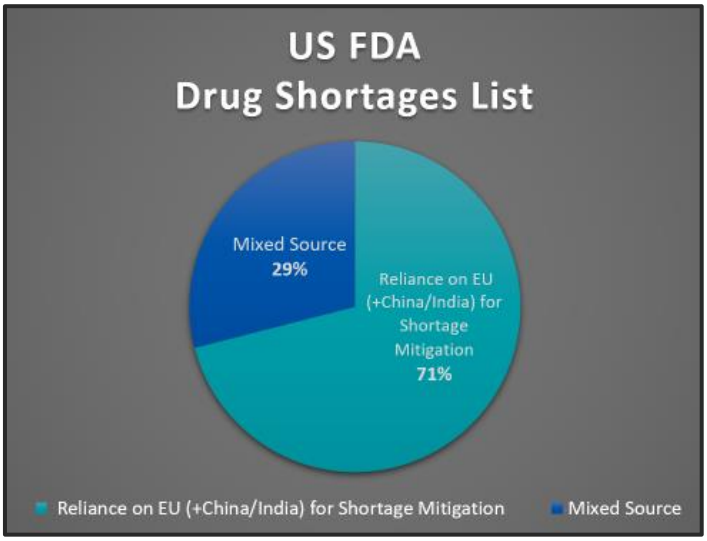
Looking at the US FDA Essential Medicines List, the U.S. relies *totally* on non-U.S. manufacturers for 41% (93/227) and mainly on non-U.S. suppliers for 62% (141/227) of the medicines on the list, as shown in the table below:



The table published by Politico in April 2025 shows the fundamental role played by the generic medicines sector and by non-US supply sources for very key treatments:[7]



Moreover, looking at the medicines on the US FDA shortage list, 71% (75/106) of shortage mitigation supplies come from outside the U.S. – including from the European industry, as shown in the table below. European sources are commonly sought by the FDA when there are shortages due to the similar regulatory and scientific standards used in the EU. In fact, the EU and the US have extensive regulatory cooperation and apply a mutual recognition agreement (MRA) for the quality of manufacturing known commonly in the industry as current good manufacturing practice (cGMP).



[7] https://www.politico.eu/article/us-donald-trump-pharma-tariffs-drug-production/

Therefore, a two-fold conclusion can be drawn based on the data above:

(1) the global interdependence of the pharmaceutical supply chain is a key factor in the current dynamics of the pharmaceutical market; **(2)** in light of this, any disruption to the current global supply chain for pharmaceuticals, APIs and derivatives, such as tariffs, would most likely have the unintended effect of exacerbating existing shortages in the U.S. and contributing to a new wave of additional shortages, including for most products in the *essential medicines list*.

This was underlined by former FDA Commissioner Scott Gottlieb in a recent public intervention,[8] where, referring to antibiotics and life-saving generic medicines, he mentioned that "*we're not just going to see prices increase, we're going to see companies stop manufacturing them, because the margins on those drugs are very slim. And whereas the branded companies can shift manufacturing to the United States, they can absorb some of the increases on a temporary basis […]. When it comes to the generic medicines, they do not have a lot of cushion, and I think a lot of these generic manufacturers are going to get out of this market if tariffs were imposed on them and then we are going to have drug shortages*." This was also one of the key factors taken into consideration during the first term (2017-2021) Administration of President Trump when tariffs on pharmaceuticals were considered.

This is also confirmed by the constant efforts that the U.S. and the EU have deployed to avoid sanctions for pharmaceutical products over the decades due to the acknowledgement of the very direct impacts that these have on patients.

It is therefore fundamental to avoid any tariffs on pharmaceuticals or APIs and instead to work on strengthening cooperation to ensure a strong and resilient global supply chain.

Question (v): the impact of foreign government subsidies and predatory trade practices on United States pharmaceuticals industry competitiveness

The European Union applies a zero-tariff policy on the import of medicines and active ingredients from the U.S. in accordance with the WTO plurilateral agreement on pharmaceuticals since 1994.

The European Union applies a strict policy of control over any subsidies provided to industry – including the pharmaceutical industry – known as EU state aid policy. This policy requires any form of financial support from EU Member States to be the subject of a review by the European Commission Competition Directorate. This ensures that any financial support would not distort competition on the EU internal market. This strict policy has harmed EU pharmaceutical manufacturers as they have not been able to compete with manufacturers benefiting from subsidies in other jurisdictions – most notably in Asia.

EU and national funds can only be authorised in Europe for pre-competitive financial support such as basic research.

Question (vi): the economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction

[8] CNBC Television, 15 April 2025

The EU does not artificially suppress prices. Medicines prices on the free (private insurance) market are freely determined by manufacturers. The prices paid by public health insurers (similar to Medicare, Medicaid or US military coverage) are set by a 'reference price'. The reference price is designed to stimulate competition from generic medicines after patent expiry and subsequently to encourage price competition between generic medicine manufacturers. The reference price is typically an average based on the price offerings of generic manufacturers with a certain market share. When the reference price is lowered artificially (not by an offer from a manufacturer), there can be shortages of medicine as manufacturers may withdraw from the market.

There is no discrimination in pricing between EU and non-EU manufacturers. This is also guaranteed for American manufacturers as they benefit from the protections of the WTO Government Procurement Agreement (GPA) which requires the EU to provide reciprocal market access to US based manufacturers.

Question (vii): the potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies

While it is hard to predict export restrictions, this is an aspect that needs to be prioritised in advance in international plurilateral negotiations, with the aim to prepare to potential health emergencies and establish strengthened (rather than reduced) cooperation between regions in those cases. Considering the current global interdependence in the pharmaceutical supply chain, a purely national pharmaceutical supply chain seems unrealistic. Therefore, working towards shared commitments on keeping stability and reliability of the pharmaceutical global supply chain also in emergencies and crises is an essential constructive diplomatic policy effort that needs to be undertaken now.

The EU does not apply export restrictions on medicines – even to countries where the EU applies trade sanctions like Russia. During major health crises like the Covid-19 pandemic, the EU did not apply export restrictions on exports to the U.S. including on medicines that were experiencing a demand surge in Europe such as intensive care unit medicines or repurposed medicines like dexamethasone that was found to be effective for the treatment of severe Covid-19. The EU was also the leading exporter of Covid-19 vaccines to developing countries and many of these vaccines (around half a billion doses) were donated by the EU to countries with limited financial capacity to procurement them through the COVAX facility.

When the U.S. has had major medicine shortages such as after natural disasters, the EU has worked closely with the U.S. government to ensure the supply of medicines from European manufacturers to the U.S.

Question (viii): the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance

European generic medicine manufacturers have invested a lot into U.S. manufacturing historically. However, the decline in market value and the competition from Asian exporters has impacted the ability of our industry to sustain manufacturing in the U.S. and in Europe. This pressure has forced our industry to consolidate production over the last 15 years. For example, in Europe, most of the medicines on the EU critical medicines list (mainly anti-infectives and hospital medicines) have experienced consolidation and today around 80% of these medicines have just a single supplier. This is like the consolidation of supply of essential medicines in the U.S.. Our association advocates for security of supply criteria to be included in generic medicine market policies (pricing and procurement policies) to reverse this consolidation trend. Our American counterpart association, the Association for Accessible Medicine (AAM) has a similar outlook for the U.S. market. Even for the generic

medicines that our members produce in the U.S. (such as hospital IV solutions), there is consolidation of manufacturing because most hospital procurement in the U.S. is conducted through bulk procurement contracts with limited consideration for security of supply.

Increasing domestic capacity would mean shifting production of all components of medicines to the U.S., which would be an extremely long, costly and complex process taking well over a decade. As shown in a recent detailed analysis published on Brookings, building a new manufacturing plant "*can cost upward of a billion dollars*" and the cost of site construction might rise further because of the 25 percent the higher costs of steel, a fundamental input in industrial construction. Creating a new manufacturing plant also implies very complex and long regulatory procedures and approvals that can take many years. As concluded in the analysis, it cannot be expected that generic medicines producers will make significant shifts of manufacturing in the U.S. "*because the return on investment for such major capital investments will be too low and uncertain. In turn, tariff pressure for both domestic and foreign manufacturers of generics will test their already low margins, potentially leading to product discontinuations or cost cutting that erodes quality. Any production disruptions in the already fragile generic injectable markets are likely to result in shortages*". [9] This is confirmed by other recent analyses.[10]

As generic manufacturers would not see a sufficient return on their investment under the current market rules in the U.S., it is unlikely that major investments will take place after the imposition of tariffs. This means that generic manufacturers exporting essential medicines from Europe to the U.S. will be economically harmed by tariffs and possibly stop their production or their exports to the US. As stated by former FDA Commissioner Scott Gottlieb (and mentioned above) in a recent public intervention[11] when referring to antibiotics and life-saving generic medicines, "*we're not just going to see prices increase, we're going to see companies stop manufacturing them, **because the margins on those drugs are very slim**. And whereas the branded companies can shift manufacturing to the United States, they can absorb some of the increases on a temporary basis […]. **When it comes to the generic medicines, they do not have a lot of cushion, and I think a lot of these generic manufacturers are going to get out of this market if tariffs were imposed on them** and then we are going to have drug shortages*." (emphasis added)

Question (ix): the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

The pharmaceutical industry functions through a robust and resilient supply chain which is very global. As a result, any tariff on pharmaceuticals would have very tangible negative impacts on the pharmaceutical sector, on healthcare systems and, most importantly, on patient access to treatments.

Moreover, the generic and biosimilar medicines sector in particular operates in a highly competitive market, with high volumes and very low margins. In the U.S., generic medicines represent around 90% of the medicines dispensed and the overall value of all generic sales in the U.S. has gone down by $6.4 billion in five years despite

[9] Publication by Marta E. Wosińska, Ph.D., senior fellow at Center on Health Policy. Former director of Bureau of Economics at FTC, chief healthcare economist at US HHS, director of economics staff at US FDA, economic advisor to US Senate Finance Committee, available at: https://www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out/

[10] See, for instance: https://www.fiercepharma.com/manufacturing/tariff-hits-generic-drugs-could-blow-back-everybody-says-usp-chief-call-increased

[11] CNBC Television, 15 April 2025

a growth in volume.[12] The very low margins that characterize the generic sector are a key factor that often leads to the unavoidable need to withdraw from the market.

In such a situation, the introduction of tariffs on pharmaceuticals and APIs entering the U.S. can only exacerbate an already stressed supply chain, with severe consequences and serious implications.

For instance, the U.S. has benefited from support from the European Union in shortages emergencies. This would become extremely complicated in case tariffs were introduced. While shortages have been identified by the U.S. Administration as a priority, most shortages in the U.S. relate to hospital injectable generic medicines,[13] and a solution to these shortages has very often come from Europe:

(1) This was recently the case with Hurricane Helene, which hit a North Carolina plant making more than 60 percent of the nation's IV and peritoneal fluid bags, and products were diverted from Europe to the US.[14]

(2) During the Covid-19 emergency, *injectable dexamethasone* was considered as an effective corticosteroid therapeutic for critically ill patients (*eg.,* those with severe breathing problems), resulting in a 610 percent increase in demand; that shortage was also mitigated by Europe based manufacturers.[15] This was the case for several treatments in intensive care units during Covid-19.[16]

(3) Similarly, quality problems with suppliers to the US market required further European support.[17] For example, the US and Europe have recently suffered from shortages of the paediatric medicine human growth hormone due to some originator companies facing manufacturing problems.[18] European biosimilar medicine manufacturers played a key role in mitigating those shortages in both the US and Europe by expanding capacity.

Shortages are costly. The Department of Health and Human Services (HHS) estimates hospitals can spend 600 million USD annually to manage shortages.10 HHS has also linked shortages to higher prices, finding that prices for medicines in shortage average 16.6% higher than when not in shortage. Further, patients who opt to use alternative treatments can expect to pay at least three times more for them.[19]

---

[12] AAM Press Release of 2 February 2025

[13] https://www.thinkglobalhealth.org/article/importing-generic-drugs-could-ease-us-shortages

[14] https://www.npr.org/2024/11/07/nx-s1-5179041/hospitals-face-months-of-iv-fluid-shortages-after-helene-damages-n-c-factory

[15] https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf, p. 22

[16] Recent research based on the Covid-19 experience in the U.S. confirms the importance of stimulating trade in the global pharmaceutical supply chain: https://pmc.ncbi.nlm.nih.gov/articles/PMC9350259/

[17] A recent study confirms that over 63 percent of U.S. medicines shortages between 2013 and 2017 were related to quality issues: https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf

[18] https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=888&loginreturnUrl=SSOCheckOnly; https://www.npr.org/sections/health-shots/2023/05/15/1176220138/families-scramble-to-find-growth-hormone-drug-as-shortage-drags-on

[19] HHS Office of the Assistant Secretary for Planning and Evaluation (HHS ASPE). Impact of Drug Shortages on Consumer Costs. May 2023. https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf; FDA. Novel Drug Approval for 2024. https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024; FDA. Generic Drug Facts. https://www.fda.gov/drugs/generic-drugs/generic-drug-facts; FDA. Generic Drug Facts. https://www.fda.gov/drugs/generic-drugs/generic-drug-facts
Sources originally cited by:
https://prod.cms.us.sandoz.com/sites/spare37_sandoz_com/files/Media%20Documents/Sandoz_Solving%20America%27s%20Drug%20Shortage%20Dilemma%2C%20For%20Good_9.24.24%5B58%5D.pdf

Tariffs will also increase healthcare costs for American patients directly, undermining the huge efforts of our industry to help the U.S. lower medicine costs over the years. Tariffs will almost immediately be added to the cost of medicines in the U.S. affecting insurance premiums or out of pocket payments, or both. This would not be aligned with other important initiatives by the current U.S. Administration aiming at stimulating greater and faster competition on the market by new entrants, such as the Executive Orders aimed at reducing anti-competitive regulatory barriers[20] and at lowering drug prices[21]. This would also undermine the huge effort by the European industry to support the U.S. to lower medicine costs over the years. For instance:

(1) The European off-patent industry pioneered biosimilar medicines technology, and the European Medicines Agency (EMA) collaborated very closely with the FDA to align on biosimilar medicines regulation. This dramatically lowered healthcare costs and increased access to biologic medicines in the U.S. despite all the difficulties faced in rapidly implementing this due to resistance from incumbent companies. As a result, biosimilar medicines generated $36 billion in savings for the US healthcare system since 2015 ($12.4 billion only in 2023) and have been used in almost 2.7 billion days of patient therapy, supporting more than 495 million incremental days of therapy.[22] Currently, biosimilar medicines are becoming increasingly available in the U.S., and tariffs would undermine these huge efforts and the resulting benefits.

(2) In 2020, during the Covid-19 emergency, *albuterol inhalers* became the alternative to nebulizers in hospitals, with a 400% increase in demand, resulting in a shortage impacting around 25 million people in the U.S. who suffer from asthma and other lung diseases. The severe shortage was solved when the FDA approved the first generic *albuterol inhalers* for in April 2020.[23] This shows the essential relevance of our sector for critical health needs, which would be put at risk if tariffs were introduced.

Additionally, tariffs would create a risk of EU retaliation. The introduction of tariffs would create a high risk that the EU might impose retaliatory tariffs on medicines or other products, which, as a result, would lead to severe disruptions for access to medicines both in Europe and in the U.S. The efforts that the U.S. and the EU have deployed to reduce/remove tariffs or avoid sanctions for pharmaceutical products over the decades have always been sustained by the acknowledgement of the very direct impacts that these have on patients. A trade war is always a hugely disruptive event.

Conclusion

Medicines for Europe reiterates its desire to work with the U.S. industry and government to jointly tackle concerns over medicines dependence. Europe is a major supplier of generic medicines and active pharmaceutical ingredients. Europe or the U.S., alone, will struggle to build competitive manufacturing and strategic autonomy.

In line with the position of the U.S. off-patent industry,[24] Medicines for Europe does not welcome any tariff on pharmaceuticals. Off-patent medicines manufacturers cannot absorb more costs in a highly competitive market

[20] https://www.whitehouse.gov/presidential-actions/2025/04/reducing-anti-competitive-regulatory-barriers/
[21] https://www.whitehouse.gov/presidential-actions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/
[22] https://biosimilarscouncil.org/resource/2024-us-generic-biosimilar-savings-report/
[23] https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf, p. 30
[24] https://accessiblemeds.org/resources/press-releases/aam-comments-new-tariffs/

and the consequences of this would be to the detriment of patients. Our industry established strong cooperation with the U.S. government, the EU and industry on several occasions under President Trump's first term in office. This cooperation reduced shortages of critical medicines dramatically in both regions and could be a model for future cooperation.

Medicines for Europe calls on the U.S. and the EU to strengthen their collaboration on pharmaceuticals and remain open to international trade and cooperation.