Position Paper (updated)

The Severe Impacts of Potential U.S. Tariffs on Pharmaceuticals

7 April 2025

Background

The 1994 Agreement on Trade in Pharmaceutical Products eliminates tariffs and other duties on a significant number of pharmaceutical products and active pharmaceutical ingredients (APIs). The European Union and the United States, among others, participate in this Agreement, reviewed four times since its establishment to update and expand the list of items covered.

The U.S. Administration has recently announced trade initiatives with the aim to incentivise production of pharmaceuticals in the U.S. and strengthen its strategic autonomy. These trade policy measures would include the introduction of tariffs (up to 25%) to be applied to pharmaceutical products and APIs imported into the U.S.

The impact of potential tariffs

The pharmaceutical industry functions through a robust and resilient global supply chain. As a result, any tariff on pharmaceuticals has 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 a growth in volume.[1]

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:

(1) The U.S. has been benefiting from support from the European Union in shortages emergencies. 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,[2] and a solution to such shortages has very often come from Europe.

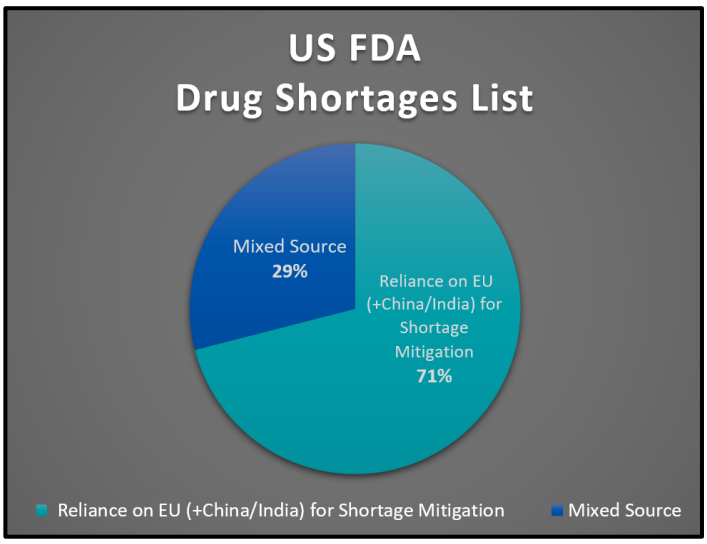
- ➔ This was recently the case with Hurricane Helene, which hit a North Carolina plant making more than 60 percent of the nation's IV and peritoneal fluid bags, and products were diverted from Europe to the US;[3]
- ➔ During the Covid-19 emergency, *injectable dexamethasone* was considered as an effective corticosteroid therapeutic for critically ill patients (*eg.,* those with severe breathing problems), resulting in a 610 percent increase in demand; that shortage was also

[1] AAM Press Release of 2 February 2025
[2] https://www.thinkglobalhealth.org/article/importing-generic-drugs-could-ease-us-shortages
[3] https://www.npr.org/2024/11/07/nx-s1-5179041/hospitals-face-months-of-iv-fluid-shortages-after-helene-damages-n-c-factory

mitigated by Europe based manufacturers.[4] This was the case for several treatments in intensive care units during Covid-19;[5]

➔ Similarly, quality problems with suppliers to the US market required further European support.[6]

For the 106 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:



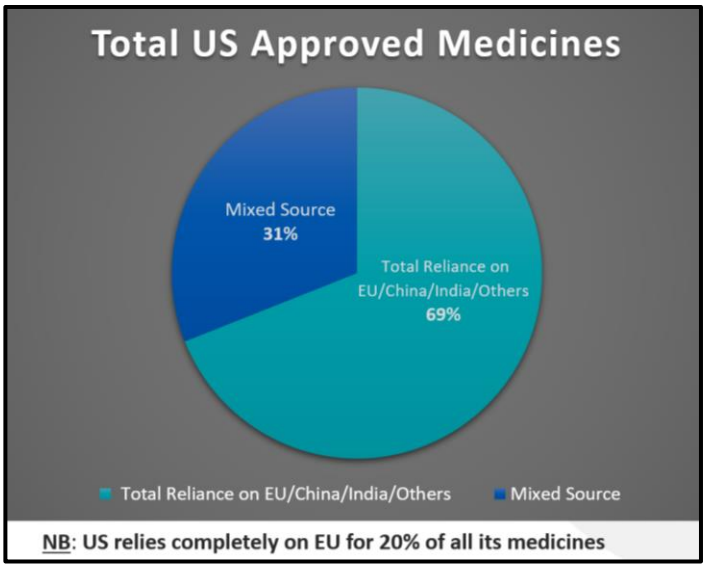
For a significant number of APIs, the U.S. healthcare system relies on EU and China as the only manufacturers. FDA figures confirm that the number of registered facilities making APIs in China more than doubled between 2010 and 2019,[7] and U.S. imports of Chinese pharmaceuticals has grown by 485% between 2020 and 2022.[8]

Therefore, tariffs would likely exacerbate the existing shortages in the U.S. and would most likely contribute to a huge wave of additional shortages, including for most products in the essential medicines list (as described in the following section).

(2) **Potential tariffs on EU exports would increase U.S. dependence on other regions, with subsequent effects also on U.S. national security**. For a significant number of APIs, the EU and China are the only manufacturers and trade of these products to the U.S. remains fundamental for the U.S. healthcare system. FDA figures confirm that the number of registered facilities making APIs in China more than doubled between 2010 and 2019,[9] and U.S. imports of Chinese pharmaceuticals have grown by 485% between 2020 and 2022.[10]

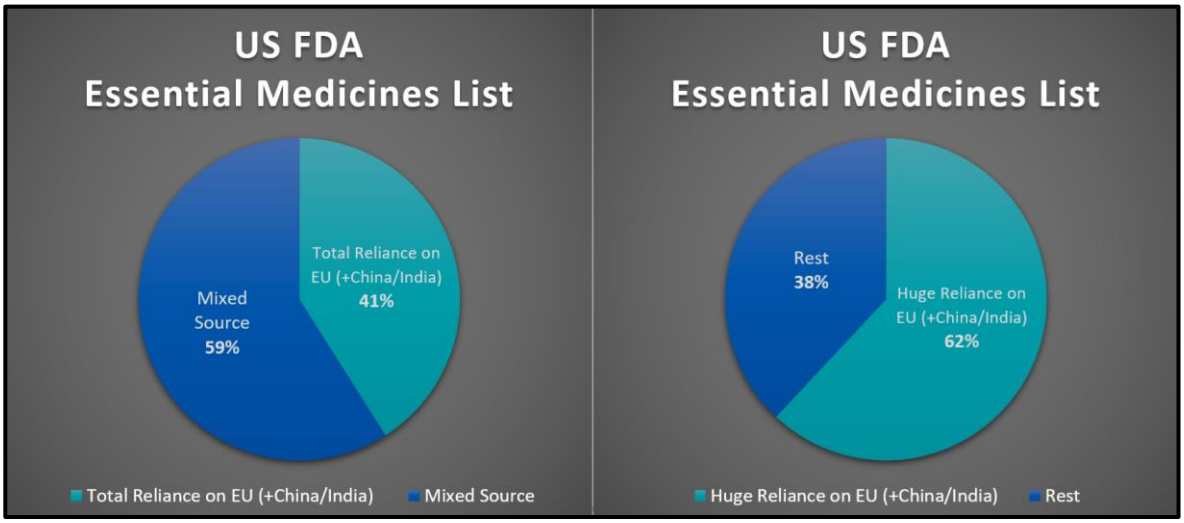
[4] https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf, p. 22
[5] Recent research based on the Covid-19 experience in the U.S. confirms the importance of stimulating trade in the global pharmaceutical supply chain: https://pmc.ncbi.nlm.nih.gov/articles/PMC9350259/
[6] 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
[7] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
[8] https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/
[9] https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019
[10] https://www.atlanticcouncil.org/blogs/econographics/the-us-is-relying-more-on-china-for-pharmaceuticals-and-vice-versa/

At the same time, a Medicines for Europe analysis of API supplier locations for the U.S. market conducted 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, of which 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 well higher than 15%.[11]

In regard to 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:



Therefore, tariffs hitting pharmaceuticals imported from the EU, besides breaching the WTO's 'most favoured nation' principle that requires Members to offer the same tariff to all other WTO members, would have a huge impact not only on access to healthcare in the U.S., but

[11] 2024 Outlook of Active Pharmaceutical Ingredients: the post-pandemic reshaping, CPA (Chemical Pharmaceutical generic Association)

also on overreliance on China and other regions for these medicines, including antibiotics. For many medicines and active pharmaceutical ingredients, the EU is the only alternative to other regions (*eg*., China). The U.S. would need many years to build its own manufacturing from scratch and this will be unprofitable for years even with tariff protection. This would also trigger serious considerations in relation to U.S. strategic autonomy and nation security.

(3) **Tariffs will increase healthcare costs for American patients directly, undermining the huge efforts 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 also undermine the huge effort by the European industry to support the U.S. to lower medicine costs over the years. For instance:

- ➔ 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, biosimilars have saved $36 billion to 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.[12] Currently, biosimilar medicines are becoming increasingly available in the U.S., and tariffs would undermine these huge efforts and the resulting benefits.
- ➔ 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.[13] This shows the essential relevance of our sector for critical health needs, which would be put at risk if tariffs were introduced.

(4) **Risk of EU retaliation**. The introduction of tariffs would create a high risk that the EU might impose retaliatory tariffs on medicines, which, as a result, would lead to severe disruptions for access to medicines 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.

Conclusions

Medicines for Europe reiterates its efforts 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,[14] Medicines for Europe does not welcome any tariff on pharmaceuticals. Off-patent medicines manufacturers cannot absorb more costs in a highly competitive market. Our industry established strong cooperation with the U.S. government, the EU

[12] https://biosimilarscouncil.org/resource/2024-us-generic-biosimilar-savings-report/
[13] https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf, p. 30
[14] https://accessiblemeds.org/resources/press-releases/aam-comments-new-tariffs/

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 EU to focus on strengthening the EU manufacturing competitiveness through the pharmaceutical reform, the Critical Medicines Act and the Biotech Act while remaining open to international trade and cooperation.