EUROPEAN UNION
DELEGATION TO THE UNITED STATES OF AMERICA

COMMENTS BY THE EUROPEAN UNION TO THE BUREAU OF INDUSTRY AND SECURITY, OFFICE OF STRATEGIC INDUSTRIES AND ECONOMIC SECURITY, U.S. DEPARTMENT OF COMMERCE

REQUEST FOR COMMENTS: SECTION 232 NATIONAL SECURITY INVESTIGATION OF IMPORTS OF PHARMACEUTICALS AND PHARMACEUTICAL INGREDIENTS (90 FR 15951)

Submitted by:
The Delegation of the European Union
to the United States of America
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The European Union ("EU") takes note of the initiation, on 1 April 2025, of an investigation under Section 232 of the Trade Expansion Act of 1962, as amended, to determine the effect on United States ("U.S.") national security of imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. As indicated in the Federal Register Notice, the investigation includes both finished generic and non-generic drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items ("pharmaceuticals, inputs and derivatives"). In response to the public request for comments (as indicated at Federal Register Notice 90 FR 15951 of 16 April, Federal Docket Number Doc. 2025-06587), the EU takes this opportunity to convey the following views.

The U.S. continues to launch Section 232 national security investigations for what appears to be industrial policy reasons. The proliferation of such investigations and possible actions under the guise of national security to protect certain industrial sectors against foreign competition is of great concern to the EU.

The EU and its Member States have been close national security partners of the U.S. for decades and reject the notion that their exports or their industries could threaten U.S. national security. On the contrary, the EU and the U.S. are significant and reliable trade partners to each other for pharmaceuticals, inputs and derivatives. Maintaining a reliable and open trade relationship on these products is crucial to ensure a stable, secure and diversified supply to both U.S. and EU pharmaceutical industries and U.S. and EU patients and healthcare systems.

The fact is that there is an integrated transatlantic production, supply, research and development ecosystem of enormous benefits to both sides, which U.S. tariffs would unnecessarily put in jeopardy. 38% of all EU exports of pharmaceuticals go to the U.S. At the same time, the EU is also a crucial and reliable import partner for the U.S., supplying around 61% of U.S. import needs. The EU's top export items to the U.S. include blood-based products, packaged medicines and chemical compounds. In addition, the EU is also a very significant export destination for U.S. pharmaceuticals, inputs and derivatives, with 56% of total U.S. exports of those products destined to the EU.

Moreover, the EU is an important (and sometimes the only) supplier of active pharmaceutical ingredients to the US, including for (essential) medicines facing shortages.

U.S. import restrictions, such as tariffs, would likely impact negatively on the organisation of transatlantic supply chains, not only exacerbating existing shortages in the U.S., including for essential medicines, but also potentially contributing to new shortages negatively affecting the provision of (affordable) healthcare to US patients. Import tariffs will also have a negative impact and an upward pressure on prices, affecting the competitiveness of U.S. users of pharmaceuticals, inputs and derivatives and increasing costs for patients, hospitals, livestock farming and pet owners. This would contradict the U.S. policy objective of lowering drug prices as set out in the U.S. Executive Order of 15 April 2025.

The strong U.S.-EU relationship on pharmaceuticals is further underscored by the fact that we have in place a Mutual Recognition Agreement in the area of pharmaceuticals, which shows the high level of trust of our regulators in recognising the necessary standards put on production sites.

In addition, both the U.S. and the EU participate in the 1994 Agreement on Trade in Pharmaceutical Products, which eliminates tariffs and other duties on a significant number of pharmaceutical products and active pharmaceutical ingredients.

Largely thanks to such trading arrangements, U.S. and EU key industrial players in pharmaceuticals, inputs and derivatives have developed ever-more important ties, with EU and U.S. companies relying on each other for e.g. high-tech manufacturing capabilities or raw materials.

Moreover, the pharmaceutical industry functions through closely integrated global supply chains. As a result, tariffs on U.S. pharmaceutical imports from a major trading partner, such as the EU, could have very tangible negative impacts on the pharmaceutical sector, on healthcare systems and, most importantly, on patient access to treatments in the U.S. but also the EU.

Increasing uncertainty and decreasing predictability of business would also have a negative spill-over effect on future investments in R&D and clinical trials on both sides of the Atlantic.

U.S. measures on "derivative products", without clear definition and circumscription of the exact meaning and scope of "derivative products" would further exacerbate the negative impacts by creating additional and unnecessary confusion.

Therefore, both the U.S. and EU industries would be negatively affected by any import restrictions which might be taken by the U.S. either directly or indirectly via potential trade diversion effects.

The EU understands and supports the need for the U.S. to further enhance its resilience in this strategic sector. With the Commission's recent proposal of a Critical Medicines Act[1], the EU itself is aiming to reduce unwanted dependencies, strengthen the resilience of pharmaceutical supply chains and ensure the security of supply of medicines, without compromising their affordability.

The EU's Critical Medicines Act also provides for the possibility to conclude strategic international partnerships to reduce dependencies on certain countries and diversify sourcing of critical medicines, their active ingredients and key starting materials. Keeping market conditions predictable and undistorted and strengthening international cooperation are key to attain these key objectives shared by both the U.S. and the EU. Tariffs on EU imports would increase U.S. dependence on other regions, with subsequent detrimental effects on U.S. interests, including national security. As reliable trading partners, the U.S. should facilitate and strengthen its trade in pharmaceuticals, inputs and derivatives with the EU rather than hinder it by imposing trade restrictions. Rather than seeking to develop autonomous supply chains, the EU and the US should rather cooperate together to reduce their dependencies and to integrate their supply chains, thus ensuring supply and availability of critical medicines.

The EU urges the U.S. to take all relevant factors into account and to refrain from taking any unilateral action that could lead to negative effects on trade with the EU and instead invites the U.S. to consider differentiating its reactions based on the threat, if any, posed to U.S. national security, by any specific foreign suppliers or sources of supply, and to strengthen cooperation with the EU to address the shared need for reliable supply of pharmaceuticals, inputs and derivatives.

The EU would also like to recall that no exception in the WTO's General Agreement on Tariffs and Trade ("GATT") can justify unilateral measures, such as import restrictions, taken by a developed country for the purpose of protecting a domestic industry against foreign competition. In situations of unfair competition, the use of trade defence instruments may offer a remedy, provided the relevant criteria are met. While the GATT provides for security exceptions, the scope of these exceptions has

[1] Cf: Commission proposes new rules to ensure stable supply of critical medicines - European Commission.

been circumscribed carefully for specific situations and conditions, which do not appear to be present in this case – certainly as regards trade with the EU.

Without prejudice to its WTO rights, the EU therefore wishes to underline that the Department of Commerce's analysis of national security must be narrowly tailored to focus on real and direct threats to national security. Also, trade distortive actions based on national security cannot provide a lasting solution for any industry-based sector, including U.S. pharmaceuticals, inputs and derivatives.

It should also be noted that the experience with U.S. import measures under Section 232 with respect to steel and aluminium has shown that U.S. trading partners, including the EU, have not left such U.S. trade restrictive measures unanswered but have taken action to protect their rights and interests when necessary. The EU will consider its options for actions towards the U.S., in case of actions that the U.S. may possibly adopt as a result of its Section 232 investigation.

Against this background, for all the above-mentioned reasons and to conclude, the EU asks the U.S. Department of Commerce to refrain from the introduction of new Section 232 measures towards the EU on pharmaceuticals, inputs and derivatives.