Comments By the Government of the People's Republic of China

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
XRIN 0694-XC120

May 7, 2025

The Government of People's Republic of China ("GOC") takes note that on April 16, 2025, the U.S. Department of Commerce ("USDOC") published a notice of *Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients*, announcing that it initiated a Section 232 investigation to determine the effects on the national security by imports of 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. The GOC hereby responds to the request for comments by the USDOC as follows.

First, the GOC opposes the initiation of Section 232 national security investigation of imports of pharmaceuticals and pharmaceutical ingredients by the United States. The GOC notes that since 2017, the U.S. has continuously extended the concept of "national security", using it as a pretext to launch Section 232 investigations to impose trade protectionist measures such as additional tariffs on imported products of steel, aluminum, automobiles and automobile parts, etc. Recently, the USDOC adjusted the Section 232 measures on imported steel and aluminum and initiated the Section 232 investigations over

copper, timber and other products. The USDOC requested for public comments on Section 232 investigation of imports of pharmaceuticals and pharmaceutical ingredients without even announcing the initiation of the Section 232 investigations. It is inconsistent with the due process, and is also detrimental to the credibility and transparency of the government action.

Second, the tariffs imposed by the United States on steel and aluminum based on its Section 232 investigations have been found by the WTO panel to be in violation of the WTO rules. In 2018, in response to the United States' decisions to impose Section 232 tariffs on steel and aluminum, several WTO members jointly filed request for consultations under the WTO dispute settlement body. In 2022, the WTO panel unambiguously ruled that these tariffs on steel and aluminum, regardless of whether they are characterized as "ordinary customs duties" or "other duties or charges" under Article II:1(b) of the GATT 1994, are inconsistent with the rules and requirements of GATT 1994, and incompatible with the obligations that the United States ought to comply with the WTO rules. Besides, the exemptions for steel and aluminum products conferred an advantage to products from certain WTO members that had not been accorded immediately and

unconditionally to like products from all other Members, which is in a manner against the principle of Most-Favored-Nation. Therefore, the WTO panel rejected the grounds on which basis the United States applied the Security Exceptions to justify the use of Section 232 measures. In this regard, the WTO panel explicitly pointed out that the invocation of Security Exceptions is neither "self-judging" nor "non-justiciable" in WTO dispute settlement proceedings. The current Section 232 investigation on imported pharmaceutical products and the possible tariffs are also likewise in violation of the WTO rules without any doubt.

Third, the pharmaceutical supply chain of the United States does not face security issues, and the imported pharmaceutical products do not impair or threaten to impair the national security of the United States. The U.S. pharmaceutical industry focuses on innovation, specializing in R&D, production, and global market expansion of novel drugs, positioning itself at the high-value end of the supply chain. The Chinese pharmaceutical industry, on the other hand, excels in manufacturing, particularly in Active Pharmaceutical Ingredients(API) production, generic drug manufacturing, and large-scale pharmaceutical production, providing critical support to U.S. drug-makers. Global pharmaceutical industry as a whole is

inter-dependent. Unilateral restrictions will harm the interests of multiple parties and directly impact the global pharmaceutical industry chain. Relevant U.S. pharmaceutical companies will face risks such as increased production costs and disruptions in upstream and downstream cooperation. This is not conducive to countries giving full play to their comparative advantages and deepening cooperation. It will also backfire on the stability of the U.S. pharmaceutical industry itself, and the harmful consequences will ultimately be borne by U.S. businesses and the public.

Fourth, the United States' possible Section 232 measures on pharmaceuticals and pharmaceutical ingredients against trading partners including China will cause harm to the US domestic industry itself. According to disclosures by the U.S. Food and Drug Administration (FDA), 80% of U.S. pharmaceutical ingredients are imported from abroad. China and India are the primary source. India's active pharmaceutical ingredients are also dependent on upstream supplies from China, including antibiotics, antipyretics, antihypertensives, cardiovascular drugs, psychotropics, anticancer medications, etc. It is evident that the global pharmaceutical industry chain is characterized by both division of labor and cooperation. The United States is unable to

produce low-cost generic drugs on its own, which is why the supply chain has shifted to and relies on India and China. This is the result of market choice, rather than a "security threat" from one to the other. Severing this supply chain at will is neither necessary nor realistic. Pharmaceuticals are fundamental to human health and well-being. Unilateral restrictions could result in drug shortages in some regions, affecting the price stability and availability of pharmaceutical products. If the United States were to to impose tariffs on pharmaceuticals and pharmaceutical Ingredients, it could cause serious damage to its own interests. According to estimates by the Association for Accessible Medicines (AAM), if a 25% tariff were imposed on Chinese APIs, the price of U.S. generic drugs could increase by 30% to 50%. In addition, the risk of shortages of emergency drugs in the United States would also be exacerbated. The association has warned that U.S. small and medium-sized pharmaceutical companies could go bankrupt on a large scale due to the rising costs. As reported by *The Wall Street Journal*, the current U.S.' "reciprocal tariffs" have already spiked prices of heparin, an anticoagulant that patients with thrombosis need to inject daily. With 60% of U.S. heparin pharmaceutical ingredients sourced from China, tariffs could create a 30% short-term supply gap.

Heparin shortages or "supply cut" would endanger millions of patients in the U.S.. Patients may be forced to rely on high-priced black-market drugs, which pose severe safety risks. Unilateral trade restriction measures cannot achieve the goal of protecting the safety of the domestic industry, but rather can only lead to adverse effects on supply chain and domestic industry such as exacerbating supply shortages, undermining drug affordability and price stability, and disproportionately harming the health and well-being of the public, especially the medical security of low-and-middle income groups in the United States.

Fifth, the possible Section 232 measures may result in the retrogression of the global pharmaceutical industry. The affordability and availability of the pharmaceutical is directly related to the health of the patients. Evaluations by many relevant associations have revealed that the measures taken b the U.S. under the pretext of national security targeting the pharmaceutical ingredients supply from China would result in the regression of the global pharmaceutical industry. According to the IQVIA Institute's report on *Global Medicine Supply Chain Vulnerability Assessment (2024)*, if the supply of APIs from China were interrupted, global drug production could face

a setback of 6 to 10 years. The International Generic and Biosimilar Medicines Association (IGBA) cautions that sudden restrictions on Chinese supply chains would be a “blunt instrument”, potentially reversing global pharmaceutical accessibility by 8-12 years. It is evident that China's high-quality API supply has made a significant contribution to the global public health industry. China urges the U.S. not to use national security as an excuse to undermine the existing balanced and stable international trading order of the international pharmaceutical industry.

Finally, the GOC urges the U.S. government to adhere to the WTO rules and the panel’s rulings, refrain from abusing the concept of national security and terminate this Section 232 investigation. China hopes the U.S. could adhere to the principles of openness and inclusiveness, pursue mutual benefits and win-win results, work together with other WTO members to maintain the stability of the global pharmaceutical supply chain, enhance the resilience and inclusiveness of the global pharmaceutical industry chain, therefore jointly safeguard the stability and well-functioning of the global pharmaceutical industrial supply chain and the community of health for mankind.