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GEDSA Engaged with FDA and USTR – An Important Syringe Tariff Update

The Global Engineered Device Supplier Association (GEDSA) has been actively engaged with the U.S. Food and Drug Administration (FDA) regarding recent concerns over syringes that are manufactured in China. An important development in this matter came in the August 16th safety communication from the FDA, which addressed the evaluation of plastic syringes manufactured in China. In their communication, the FDA states, **"The FDA is not recommending a transition away from all enteral syringes manufactured in China at this time."**[1] This announcement represents an about-face from the position the FDA took prior to its extensive evaluation of enteral syringe manufacturing operations in China.

GEDSA has also been involved with the Office of the United States Trade Representative (USTR) since the White House announced a proposed 50% tariff on syringes imported from China on May 14th, 2024.[2] Subsequent to that announcement, the public was given the opportunity to submit comments regarding the proposed tariffs. GEDSA submitted comments detailing specific ways in which the syringe tariff would negatively impact patient safety and access to these medical devices.[3] The USTR took all comments into consideration and on September 13th they released a Notice of Modification[4] where the tariff determinations, and how they would be enacted, were described.

In the USTR's tariff determination, enteral syringes were given an exemption, under HTSUS code 9903.91.10, until January 1st, 2026. Unfortunately, the initially proposed tariff of 50% was increased by the USTR to 100% for all syringes imported from China. Based on further details provided by U.S. Customs and Border Protection, the 100% tariff on all non-exempted syringes from China went into effect on September 27th, 2024 and the 100% tariff will be applied to all syringes from China once the enteral syringe exemption ends on January 1st, 2026[5].

While we appreciate the USTR's consideration of GEDSA and other's comments on the syringe tariff, and we appreciate the short-term exemption for enteral syringes, we are concerned that this isn't enough time for the manufacturing infrastructure of enteral syringes, which are federally regulated medical devices, to be transitioned out of China, where the majority of the world's enteral syringe supply comes from. As a result, we believe that the syringe tariff may negatively impact patients who receive enteral nutrition and medications. GEDSA, along with its members, will continue to work with the USTR, FDA, the Institute for Safe Medication Practices (ISMP), the Centers for Medicare & Medicaid Services (CMS), and other agencies and organizations in an effort to minimize the negative consequences that the syringe tariff may have on patient safety and access to these medical devices.

[1] https://ow.ly/CaY450TfQoy
[2] https://ow.ly/i4lS50TJO4J
[3] https://ow.ly/PXPa50TJP3M
[4] https://ow.ly/UyMo50TJP6v
[5] https://ow.ly/qGeb50TJYLq

The Global Engineered Device Supplier Association (GEDSA™) is a 501(c)(6) non-profit trade association with the mission of advancing patient safety through engineered device solutions and initiatives that are coordinated among stakeholders spanning across the healthcare spectrum worldwide.