10 May 2024

NOTICE TO RELEVANT STAKEHOLDERS

Dear Sir/Ma'am:

This refers to the draft regulations distributed through the World Trade Organization – Technical Barriers to Trade (WTO-TBT) website (www.epingalert.org) from 27 April to 03 May 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Ecuador, Philippines, Republic of Korea, Japan and Brazil:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ECU/526	Ecuador	**Date of Distribution:** 3 May 2024 **Deadline for Comments:** 2 July 2024	Hygienic products for industrial use	Regulatory project "Partial reform of the substitute technical health regulations for obtaining health notification and control of hygienic products for industrial use, hygienic disinfectant products for hospital use, food grade disinfectant products and the establishments where they are manufactured, put together , store, distribute, import and market."
G/TBT/N/PHL/302/Rev.1	Philippines	**Date of Distribution:** 3 May 2024 **Deadline for Comments:** 20 May 2024	Drug products and raw materials - Revision	FDA Memorandum Circular (FMC) No. 2013-032, entitled "Requirements for the Immediate Release of Products Covered by the FDA at the Bureau of Customs", was issued, wherein only valid FDA License to Operate (LTO) and Certificate of Product Registration (CPR) were required to be presented to the Bureau of Customs (BOC) for the release of pharmaceutical products. However, there is a need to strengthen market control within the distribution chain through measures to ensure that the public only receives quality-assured pharmaceutical products. The infiltration of substandard and counterfeit pharmaceutical products into the supply system shall be prevented through risk-based surveillance schemes and rigorous control.
G/TBT/10.7/N/171	Republic of Korea	**Date of Distribution:** 2 May 2024 **Deadline for Comments:** Not indicated	Medicinal products for human use	This Agreement lays down the conditions under which one Party will accept the pharmaceutical GMP conformity assessment results (e.g. GMP inspection certificates) performed by the other Party's competent authority, and vice versa. This Agreement applies to GMP medicinal products for human use and facilitates market access by eliminating technical barriers to trade with respect to medicinal products.

G/TBT/N/JPN/809	Japan	**Date of Distribution:** 2 May 2024 **Deadline for Comments:** Not indicated	Shitei Yakubutsu (designated drug)	Proposal for the additional designation of 1 substance and 3 substance groups as Shitei Yakubutsu, and their proper uses under the Act.
G/TBT/N/BRA/1448/Add.1/Corr.1	Brazil	**Date of Distribution:** 29 April 2024 **Deadline for Comments:** Not indicated	Medical devices and in vitro diagnostic (IVD) medical devices - Corrigendum	The Resolution 848, 06 March 2024 - previously notified through G/TBT/N/BRA/1448/Add.1 - which contains provisions on essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices, was rectified. The republished text is available only in Portuguese and can be downloaded at: https://www.in.gov.br/en/web/dou/-/retificacao-556236998

To access the notification form, right click the document symbol to open the hyperlink. Should you have any queries on this matter or request for full text of draft regulation in English, please do not hesitate to email us at BPS@dti.gov.ph copy bps.smd@dti.gov.ph.

Thank you.

Sincerely,

FERDINAND L. MANFOSTE
Officer-in-Charge