26 November 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 09 to 15 November 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from: Republic of Korea, the Separate Customs Territory of Taiwan, Penghu, Kinmen, Matsu, and Ukraine

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/KOR/1239	Republic of Korea	**Date of Distribution:** 15 November 2024 **Deadline for Comments:** 14 January 2025	Medical Devices	The amendment aims to allow manufacturers and importers of medical devices to select and display a primary address where permanent contacts or visits are possible, rather than listing all addresses included in their manufacturing (import) business license on the container or exterior packaging of medical devices.
G/TBT/N/TPKM/551	the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	**Date of Distribution:** 15 November 2024 **Deadline for Comments:** 14 January 2025	Medical devices	In response to the amendments to the Tariff Codes, and the "Fee-Charging Standards for Lot Release, Reference Materials, and Testing of Foods, Drugs and Cosmetics," Attachment 1 to Attachment 3 of the "Regulations for the Inspection and Examination of Imported Medical Devices" are proposed to be modified based on the current situation.
G/TBT/N/UKR/316	Ukraine	**Date of Distribution:** 14 November 2024 **Deadline for Comments:** 13 January 2025	Medicines	the draft Resolution of the Cabinet Ministers of Ukraine aims to align the Procedure for the State Registration (Reregistration) of Medicines, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 376 of 26 May 2005 (as amended by the Resolution of the Cabinet of Ministers of Ukraine of 26 April 2024 No. 529), notified in document G/TBT/N/UKR/300, with the provisions of the Law of Ukraine No. 3910 "On Amendments to the Law of Ukraine "On Medicinal Products" on Labelling of Medicinal Products" of 21 August 2024, notified in document G/TBT/N/UKR/307.The amendments to the Procedure for the State Registration (Reregistration) of Medicines provide for the regulation of the peculiarities of state registration of medicines that are not registered at the time of the procurement procedure after determining the winner of the procurement procedure by verifying the authenticity of registration materials, as well as improving the procedure for making decisions on suspension, cancellation and termination of the state registration of medicines and

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				decisions to refuse state registration of medicines.This draft Resolution intends to ensure consistency in national legislation on the labeling of medicines with the requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.
G/TBT/N/UKR/313	Ukraine	**Date of Distribution:** 13 November 2024 **Deadline for Comments:** 12 January 2025	Medicines	The draft Resolution has been developed to align the procedures for state quality control of medicines and control over the compliance of immunobiological products used in medical practice with the requirements of national and international standards, in accordance with the provisions of the Law of Ukraine of 16 July 2024 No. 3860-IX 'On Amendments to Certain Laws of Ukraine on Parallel Imports of Medicines'.
G/TBT/N/UKR/315	Ukraine	**Date of Distribution:** 13 November 2024 **Deadline for Comments:** 12 January 2025	Medicines	the draft Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Procedure for Imports of Medicines into the Territory of Ukraine" has been developed to regulate the procedure for imports of medicines (except for active pharmaceutical ingredients) into Ukraine in order to ensure compliance with legislative requirements concerning the quality, safety, and efficacy of medicines in the process of their circulation. The Procedure outlines key mechanisms for regulating imports, including certification and quality control of imported batches of medicines, release of imported medicines for circulation within Ukraine; and recording data related to the circulation of imported medicine batches in the State Register of Medicines Put into Circulation that are Imported into the Territory of Ukraine.

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,

Digitally signed by
Catajay Neil Pinuela

NEIL P. CATAJAY
Director

BUREAU OF PHILIPPINE STANDARDS

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