03 February 2025

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 11 to 17 January 2025.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/UKR/330	Ukraine	**Date of Distribution:** 16 January 2025 **Deadline for Comments:** 17 March 2025	Medicines	This order, "The Order of the Ministry of Health of Ukraine No. 1891," issued on November 12, 2024, aims to ensure that the manufacturing conditions of medicines procured by authorized healthcare sector entities align with Good Manufacturing Practice (GMP) requirements. The regulation specifies procedures for confirming GMP compliance for medicines registered by competent authorities in countries such as the United States, Switzerland, Japan, Australia, Canada, or a Member State of the European Union, including those registered through the EU centralized procedure. Confirmation of compliance is granted by the competent authority of these jurisdictions based on inspection results to validate adherence to GMP standards. This framework facilitates the procurement of medicines that meet internationally recognized safety and quality benchmarks, ensuring the reliability of medicines used in the healthcare sector.
G/TBT/N/ECU/513/Add.3	Ecuador	**Date of Distribution:** 14 January 2025 **Deadline for Comments:** Not indicated	Medicines in general	This Substitute Sanitary Technical Regulation concerns the sanitary registration, control, and surveillance of medicines for human use in Ecuador. It establishes the legal and technical requirements to ensure the quality, safety, and efficacy of medicines and defines the criteria for issuing sanitary registration certificates and for controlling and monitoring these products.

BUREAU OF PHILIPPINE STANDARDS

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Membership:
- International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

				The regulation, issued through Resolution No. ARCSA-DE-2024-058-DASP by the National Agency for Sanitary Regulation, Control and Surveillance (ARCSA) on December 30, 2024, will take effect six months after its issuance, regardless of its publication in the Official Journal. The Ministry of Production, Foreign Trade, Investment and Fisheries, through its Under-Secretariat for Quality, oversees the regulatory framework, with the TBT enquiry point serving as the contact for further information.
G/TBT/N/ECU/546/Add.1	Ecuador	**Date of Distribution:** 14 January 2025 **Deadline for Comments:** Not indicated	Medicines in general, processed natural products for medicinal use, homeopathic products or medicines and medical devices	This Substitute Sanitary Technical Regulation addresses the monitoring and control of advertising and promotion for general medicines, processed natural products for medicinal use, homeopathic products, and medical devices in Ecuador. Issued via Resolution No. ARCSA-DE-2024-048-DASP by the National Agency for Sanitary Regulation, Control, and Surveillance (ARCSA) on December 13, 2024, the regulation follows WTO transparency and notification guidelines. It was notified for public comment on September 10, 2024, under document G/TBT/N/ECU/546 through the WTO Eping platform for 60 days. The regulation will take effect six months after its publication in the Official Register and is overseen by the Ministry of Production, Foreign Trade, Investment, and Fisheries, specifically the Under-Secretariat for Quality. Contact for further details is available through Eduardo Yépez at the TBT enquiry point in Quito, Ecuador.
G/TBT/N/ECU/547/Add.1	Ecuador	**Date of Distribution:** 14 January 2025 **Deadline for Comments:** Not indicated	Biological products for human use	This Substitute Sanitary Technical Regulation governs the registration, control, and surveillance of biological products for human use in Ecuador. Issued under Resolution No. ARCSA-DE-2024-049-DASP by the National Agency for Sanitary Regulation, Control, and Surveillance (ARCSA) on December 20, 2024, the regulation establishes guidelines for ensuring compliance with safety and quality standards for biological products.

				The regulation will take effect six months after its issuance, irrespective of its publication in the Official Register. Further details can be obtained from the Ministry of Production, Foreign Trade, Investment, and Fisheries, specifically through the TBT enquiry point headed by Eduardo Yépez in Quito, Ecuador.
G/TBT/N/KOR/1257	Republic of Korea	**Date of Distribution:** 14 January 2025 **Deadline for Comments:** 15 March 2025	Pharmaceuticals	The proposed amendments aim to: A. Support the reduction of time and cost required for developing standards and test methods by developing monographs of unregistered medicines of the Korean Pharmacopoeia. B. Distribute high-quality medicines by improving some standards, specifications, and general tests to meet the latest scientific standards, reflecting difficulties from the pharmaceutical industries. The main points of the amendments are as follows: A. Establishment of monographs for unregistered medicines and amendment of official substances (Refer to Annex 3, Annex 4, and Annex 5 of the draft) B. Establishment of tests in General Information (Refer to Annex 6 of the draft) - Establishment of alternative animal tests for pyrogen tests - Establishment of information on leachable/extract content management for quality control of containers/packaging or drug delivery system (DDS) C. Establishment of the second quantitative method for 5 items including “Kamisoyosan Extract Granules” and amendment of Korean names of residual pesticides (24 types) in purity tests for 155 items including “Terminalia Fruit” in Part Ⅱ of Monographs (Refer to Annex 4 of the draft)) D. Amendment of Korean names of residual pesticides in crude drug tests and reference standards, and

				change of range for measuring thiamethoxam, of General Tests (Refer to Annex 5 of the draft)

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

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