

22 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 11 to 17 May 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Israel, Ukraine, Brazil, and Mexico:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/ISR/1342	Israel	Date of Distribution: 16 May 2024 Deadline for Comments: Not indicated	Dietary supplements	The Ministry of Health published a new draft of regulations titled "Protection of Public Health Regulations (Food) (Import of dietary supplements by a Proper Importer) 5783-2024. The current import regime includes obtaining prior approval for importing dietary supplements, including importing raw materials, and performing a release procedure after inspection at the quarantine station. into force on date of publication.
G/TBT/N/UKR/282/Add.1	Ukraine	Date of Distribution: 16 May 2024 Deadline for Comments: Not indicated	Medicines, active pharmaceutical ingredients - Addendum	Ukraine notifies the adoption of the Order of the Ministry of Health of Ukraine No 561 "On Approval of Amendments to the Annexes to the Medicines Quality Certification Procedure for International Trade and Confirmation for Exported Active Pharmaceutical Ingredients" on 02 April 2024. The Order was registered in the Ministry of Justice of Ukraine on 17 April 2024 and published on 07 May 2024. The Order entered into force on 07 May 2024.
G/TBT/N/BRA/1324/Add.1	Brazil	Date of Distribution: 14 May 2024 Deadline for Comments: Not indicated	Medicaments and medicines - Addendum	Resolution 620, 09 March 2022 - previously notified through G/TBT/N/BRA/1324 - which contains provisions on the Certification of Good Practices for conducting Bioavailability/Bioequivalence studies of medicaments and defines which Bioavailability/Bioequivalence studies of medicines must be carried out in certified research centers, was changed by Resolution 858, 06 May 2024.
G/TBT/N/BRA/1376/Add.1	Brazil	Date of Distribution: 14 May 2024	Pharmaceutical equivalence	Resolution 621, 09 March 2022 - previously notified through G/TBT/N/BRA/1376 - which contains provisions on petitions for license

BUREAU OF PHILIPPINE STANDARDS

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)

		Deadline for Comments: Not indicated	centers - Addendum	requests, license renewals, post-qualification modifications, testing outsourcing, suspensions and cancellations of Pharmaceutical Equivalence Centers, was changed by Resolution 856, 03 May 204
G/TBT/N/BRA/1538	Brazil	Date of Distribution: 14 May 2024 Deadline for Comments: Not indicated	Medicaments	This Draft Resolution contains provisions on Inspection Guide for Bioavailability/Bioequivalence Centers for Medicines.
G/TBT/N/MEX/530	Mexico	Date of Distribution: 14 May 2024 Deadline for Comments: 13 July 2024	Medical devices	Objective: To establish the health information requirements that must be contained in the labeling of medical devices for human use, their correct use and traceability, which are intended for users, marketed and made available in national territory. Field of applicationIt is mandatory. mandatory throughout the national territory for establishments dedicated to the manufacture, packaging, distribution and import of medical devices for marketing or supply purposes in Mexico. Medical devices are crucial in the prevention, diagnosis and treatment of diseases, as well as the rehabilitation of patients.

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,

NEIL P. CATAJAY
Director