

31 August 2023

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 19 to 25 August 2023.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from three (3) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/782/Add.1	Brazil	Date of Distribution: 22 August 2023 Deadline for Comments: Not Indicated	Medicaments - Addendum	RDC N° 204, December 27th, 2017 - previously notified through G/TBT/N/BRA/782- which provides for the classification in the priority category, of registration petitions, post registration and prior consent in clinical trial of medicines., was changed by Resolution 811, 18 August 2023
G/TBT/N/BRA/928/Add.4	Brazil	Date of Distribution: 22 August 2023 Deadline for Comments: Not Indicated	Medical devices - Addendum	Resolution 751, 15 September 2022 - previously notified through G/TBT/N/BRA/928/Add.2 - which contains provisions on risk classification, reporting and marketing registration regimes, and labeling requirements and instructions for use of medical devices, was changed by Resolution 810, 17 August 2023.
G/TBT/N/BRA/1143/Add.2	Brazil	Date of Distribution: 24 August 2023 Deadline for Comments: Not Indicated	Medicines based on substances categorized as antimicrobial - Addendum	Normative instruction 244, 21 August 2023, the list of substances classified as antimicrobial for use under prescription, alone or in association, which the resolution 471, 23 February 2023, which contains provisions on criteria for the prescription, dispensing, control, packaging and labeling of drugs based on substances

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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)

				classified as antimicrobials for use under prescription, alone or in combination.
G/TBT/N/CAN/692/Add.1	Canada	Date of Distribution: 21 August 2023 Deadline for Comments: Not Indicated	Medical devices - Addendum	On February 22, 2023, the Regulations Amending the Medical Devices Regulations (Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19) came into force. These regulations were notified in G/TBT/N/CAN/692 (dated 21 February 2023) and resulted in the creation of Part 1.1 of the Medical Devices Regulations (MDR).
G/TBT/N/TPKM/522/Add.1	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	Date of Distribution: 21 August 2023 Deadline for Comments: Not Indicated	Medical devices - Addendum	The purpose of this notification is to provide the final texts of "Product items of the medical device — Requirements for specifications, test methods and performance" and relevant dates of its implementation. The draft texts notified in "G/TBT/N/TPKM/522" were adopted without changes.

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

