

26 September 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 16 to 22 September 2023.

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

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/B/RA/1503	Brazil	Date of Distribution: 19 September 2023 Deadline for Comments: 06 November 2023	Medicaments	<p>This Draft Resolution contains provisions on the health requirements relating to non-clinical safety studies for the market authorization of industrialized medicines for human use.</p> <p>The non-clinical studies of medication safety of this draft resolution must follow guidelines from The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)</p>
G/TBT/N/ISR/1293	Israel	Date of Distribution: 20 September 2023 Deadline for Comments: 18 November 2023	Medical electrical equipment	<p>Revision of the Mandatory Standard SI 60601 part 1, dealing with medical electrical equipment. This draft standard revision adopts the International Standard IEC 60601-1 – Edition 3.2: 2020-08 with a few changes in the normative references that appear in the standard's Hebrew section.</p> <p>The major differences between the old version and this new revised draft standard are an outcome of adopting Amendment 2 to the International Standard.</p> <p>Both the old standard and the new proposed standard will apply from the entry into force of this revision for a period of 4</p>

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)

				years. During this time, medical electrical equipment may be tested according to any of these standards.
G/TBT/N/MAC/24	Macao, China	Date of Distribution: 21 September 2023 Deadline for Comments: Not Applicable	Chinese medicinal materials, their prepared portions and extracts	Technical requirements for import applications of Chinese medicinal materials, their prepared portions and extracts.
G/TBT/N/RUS/149	Russian Federation	Date of Distribution: 21 September 2023 Deadline for Comments: 20 October 2023	Medical products	The draft amendments to the Decision of the Council of the Eurasian Economic Commission No. 83 of November 3, 2016 provides for the establishment of uniform approaches to the procedures for conducting pharmaceutical inspections of clinical centers for compliance with the requirements of the Rules of Good Clinical Practice
G/TBT/N/TPKM/520/Add.1	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	Date of Distribution: 21 September 2023 Deadline for Comments: Not Indicated	Medical equipment - Addendum	The purpose of this notification is to provide the final texts of "Regulations Governing the Classification of Medical Devices" and relevant dates of its implementation. The draft texts notified in "G/TBT/N/TPKM/520" were adopted with minor 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