

19 April 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 18 to 14 April 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/NA/RM/90	Armenia	Date of Distribution: 11 April 2023 Deadline for Comments: 20 May 2023	Labeling of medicinal products for human use and veterinary medicinal products	The draft provides for ensuring a phased transition to the implementation of the Requirements for the labeling of medicinal products for human use and veterinary medicinal products, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 76, the Rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by the Decision of the Council of the Eurasian Economic Commission dated November 3, 2016 No. 77 by establishing transitional periods for subjects of circulation of veterinary medicines.
G/TBT/NA/RM/92	Armenia	Date of Distribution: 11 April 2023 Deadline for Comments: 18 April 2023	Disinfectant, insecticide, and acaricide products for veterinary use	The draft provides for the Rules for regulation of the circulation of disinfectant, insecticide, and acaricide products for veterinary use not coming into direct contact with animals (being used in vitro in veterinary medicine) in the customs territory of the Eurasian Economic Union.
G/TBT/N/C/HN/1723	China	Date of Distribution: 11 April 2023 Deadline for Comments: 09 June 2023	Active implantable medical devices	This document specifies requirements for cardiac pacemakers. This document applies to those active implantable medical devices intended to treat bradyarrhythmias and devices

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)

				that provide therapies for cardiac resynchronization. This document also applies to some non-implantable parts and accessories of the devices. The tests that are specified in this document are type tests, and are to be carried out on samples of a device to show compliance.
G/TBT/N/C HN/1724	China	Date of Distribution: 11 April 2023 Deadline for Comments: 09 June 2023	Active implantable medical devices	This document specifies the requirements that are generally applicable to active implantable medical devices. This document applies not only to electrically powered active implantable medical devices, but also to active implantable medical devices powered by other energy sources(e.g., gas pressure or springs). This document also applies to certain non-implantable parts and accessories of active implantable medical devices.
G/TBT/N/T PKM/522	The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu	Date of Distribution: 11 April 2023 Deadline for Comments: 09 June 2023	Medical devices	The regulation is intended to stipulate the requirements of specific medical devices regarding pre-clinical performance.

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