

13 July 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 01 to 07 July 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/C/HE/237/Ad d.1	Switzerland	Date of Distribution: 05 July 2023 Deadline for Comments: Not Indicated	Medical devices - Addendum	The new regulations concerning medical devices (Medical Devices Regulation, MDR) and in vitro diagnostic medical devices (In vitro Diagnostic Medical Devices Regulation, IVDR) entered into force on 26 May 2017. In order to improve the safety and quality of medical devices, Switzerland adapted its legislation on medical devices in line with developments in European law. The new legislations in Switzerland are applicable since 26 May 2021 for medical devices (MedDO) and 26 May 2022 in vitro diagnostic medical devices (IvDO) like in the EU
G/TBT/N/E/SP/48	Spain	Date of Distribution: 04 July 2023 Deadline for Comments: 01 September 2023	Veterinary medicines	Regulate the obligations of wholesale distribution, sale retailer, internet sale of non-prescription drugs, conditions for carrying out veterinary prescriptions and restrictions on the use of antimicrobials, as well as establish the obligations in the use of medicines in the livestock farms
G/TBT/N/IN/D/287	India	Date of Distribution: 03 July 2023 Deadline for Comments: 31 August 2023	Medical textiles	To increase standard and quality of Medical Textiles Protection of human health or safety

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)

G/TBT/N/P HL/304	Philippines	Date of Distribution: 03 July 2023 Deadline for Comments: 21 July 2023	License to operate of health product establishments	<p>The regulation aims to introduce technical procedures on inspection and updated list of documentary requirements for the issuance of License to Operate aligned with international standards and automation of FDA licensing application systems. It also intends to repeal Administrative Order No. 2020-0017 (Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing AO No. 2016-0003). The regulation provides the list of updated documentary requirements for LTO applications, in addition to other technical requirements that shall be presented during inspection of the FDA-covered establishments.</p> <p>Further, the FDA's intention to comply with international standards in terms of health shall be institutionalized in the agency's regulatory process. Hence, compliance with the World Health Organization – Global Benchmarking Tool (WHO-GBT) is necessary.</p>
G/TBT/N/R US/146	Russian Federation	Date of Distribution: 04 July 2023 Deadline for Comments: 01 September 2023	Veterinary medicines	<p>The draft provides for the possibility of simplifying the procedure for bringing the registration dossier of veterinary medicinal products in line with the requirements of the Rules for certain groups of veterinary medicinal products. The draft also contains technical amendments.</p>

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

