

03 February 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 21 to 27 January 2023.

Relative thereto, we respectfully invite stakeholders to comment on the four (4) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/JPN/761	Japan	Date of Distribution: 23 January 2023 Deadline for Comments: 21 February 2023	Pharmaceutical products: biological products	The Minimum Requirements for Biological Products will be amended as follows ; To add the standard for a vaccine product to be newly approved; "Nasally Live Attenuated Influenza Vaccine", "Adsorbed Diphtheria-purified Pertussistetanus-inactivated polio Haemophilus TYPE b Combined Vaccine". Partially amended to "Diphtheria Toxoid", "Adsorbed Diphtheria Toxoid", "Adsorbed Diphtheria Toxoid for Adult Use", "Adsorbed Diphtheria-tetanus Combined Toxoid", "Tetanus Toxoid", "Adsorbed Tetanus Toxoid", "Adsorbed Purified Pertussis Vaccine", "Adsorbed Diphtheriapurified Pertussis-tetanus Combined Vaccine", "Adsorbed Diphtheria-purified Pertussistetanus-inactivated polio (Sabin strain) Combined Vaccine", "Freeze-dried Haemophilus TYPE b Vaccine (Tetanus Toxoid Conjugate)", "Inactivated Polio Vaccine (Salk Vaccine)". To delete "Adsorbed Diphtheria-purified Pertussis-tetanus-inactivated polio (Salk Vaccine) Combined Vaccine".
G/TBT/N/KEN/1375	Kenya	Date of Distribution: 23 January 2023 Deadline for Comments:	Medical oxygen	This Part 1 of KS 2170 prescribes the requirements and test methods for compressed medical oxygen intended for inhalation

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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)

		19 March 2023		
G/TBT/N/KO/R/1126	Republic of Korea	Date of Distribution: 25 January 2023 Deadline for Comments: 25 March 2023	Medical devices	The proposed amendments to the Regulations on Standard Specification of Medical Devices are as follows: 1) Establishment of Medical Device Standards - Establishment of new standards and specifications to ensure product safety and performance of 7 types of medical devices, including high-intensity focused Ultrasonic surgical systems and mammographic x-ray systems (stationary, analogue). 2) Align With International Standards - Ensuring product performance and safety by applying the international standards (IEC, ISO) of test criteria and methods to 23 types of medical devices, including anaesthesia systems (gas) and incubators (infant).
G/TBT/N/LTU/48	Lithuania	Date of Distribution: 25 January 2023 Deadline for Comments: 25 March 2023	Pharmaceutical products: doping substances (non-approved substances and anti-estrogenic substances) for sports purposes	The draft law restricts production, processing, acquisition, wholesale or retail sale, storage, transportation within the state, import or export of certain doping substances (non-approved substances and anti-estrogenic substances) for sports purposes.

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

