

11 January 2024

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 30 December 2023 to 05 January 2024.

Relative thereto, we respectfully invite stakeholders to comment on the eleven (11) notified draft technical regulations from five (5) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/R/US/155	Russian Federation	Date of Distribution: 04 January 2024 Deadline for Comments: 18 January 2024	Medicinal products	Extension of the deadline for the establishment by the authorized bodies of the Eurasian Economic Union Member States of a temporary procedure for the circulation of medicines until December 31, 2024 to ensure the marketing authorization of medicines in an unstable geopolitical situation, in order to protect the life and health of the population of the Member States, ensure the drug safety and sustainability of supply of medicines within the Eurasian Economic Union
G/TBT/N/KOR/1189	Republic of Korea	Date of Distribution: 04 January 2024 Deadline for Comments: 23 January 2024	Quasi-drugs	Proposed amendments to the "Regulations on the Approval, Notification, and Evaluation of Quasi-Drugs" as follows: - The re-evaluated smoking cessation products (non-ignited) in a form similar to a manufactured cigarette shall be subject to safety and efficacy assessment. - Addition of Cetylpyridochloride dose standards as an ingredient of concern for safety and efficacy

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/KOR/1190	Republic of Korea	<p>Date of Distribution: 05 January 2024</p> <p>Deadline for Comments: 04 March 2024</p>	Labelling for medicinal products	<p>Article 6-3 and Annex 2 of the regulation designating the medicines to be displayed in Braille and code of voice/sign language video and providing its related information was newly established to strengthen the accessibility to medicine safety information for the visually and hearing impaired.</p>
G/TBT/N/JPN/791	Japan	<p>Date of Distribution: 05 January 2024</p> <p>Deadline for Comments: 03 February 2024</p>	Biological products	<p>The Minimum Requirements for Biological Products will be amended as follows:</p> <ul style="list-style-type: none"> · GENERAL RULES <p>The standard for "Tissue Culture Tick-borne Encephalitis Virus Vaccine", "Pneumococcal 20-valent Conjugate Vaccine" and "Freeze-dried Human Protein C Concentrate" those are to be newly approved will be added.</p> <ul style="list-style-type: none"> · GENERAL TESTS <p>Regarding the standard for "Antibody Assay against Measles Virus", "Enzyme-linked Immunosorbent Assay" will be added.</p> <p>The Public Notice on National Release Testing will be amended as follows:</p> <p>The criterion, fee, and quantity for "Tissue Culture Tick-borne Encephalitis Virus Vaccine", "Pneumococcal 20-valent Conjugate Vaccine" and "Freeze-dried Human Protein C Concentrate" that are to be newly approved will be added. And the criterion, fee, and quantity for "Freeze-dried Inactivated Tissue Culture Rabes Vaccine", "Freeze-dried Human Fibrinogen", "Freeze-dried Polyethylene Glycol-treated Normal Human Immunoglobulin" and "Freeze-dried Human Antithrombin III Concentrate" will be partially amended. In addition, the criterion and fee for "Human Haptoglobin" will be partially amended.</p>

G/TBT/N/J PN/792	Japan	Date of Distribution: 05 January 2024 Deadline for Comments: Not Applicable	Shitei Yakubutsu	Proposal for the additional designation of 1 substance group as Shitei Yakubutsu, and their proper uses under the Act.
G/TBT/N/C HN/1778	China	Date of Distribution: 05 January 2024 Deadline for Comments: 04 March 2024	Metallic materials : wrought titanium 6- aluminum 4- vanadium alloy	This document specifies the characteristics and corresponding test methods for the wrought titanium 6-aluminum 4-vanadium alloy (Ti-6Al-4V alloy) used in the manufacture of surgical implants. This document applies to the testing and evaluation of the performance of the wrought titanium 6-aluminum 4-vanadium alloy used in the manufacture of surgical implants
G/TBT/N/C HN/1779	China	Date of Distribution: 05 January 2024 Deadline for Comments: 04 March 2024	Unalloyed titanium used in the manufacture of surgical implants	This document specifies the characteristics and corresponding test methods for unalloyed titanium used in the manufacture of surgical implants. This document applies to the testing and evaluation of the performance of unalloyed titanium used in the manufacture of surgical implants.
G/TBT/N/C HN/1780	China	Date of Distribution: 05 January 2024 Deadline for Comments: 04 March 2024	Cobalt-chromium-nickel-molybdenum-iron alloy used in the manufacture of surgical implants	This document specifies the characteristics and corresponding test methods for forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy used in the manufacture of surgical implants. This document applies to the testing and evaluation of the performance of forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy used in the manufacture of surgical implants.
G/TBT/N/B RA/1458/A dd.1	Brazil	Date of Distribution: 04 January 2024 Deadline for Comments: Not Indicated	Medical devices - Addendum	Draft resolution number 1123, 27 October 2022 - previously notified through G/TBT/N/BRA/1458 - which contains provisions on the performance of clinical trials with medical devices in Brazil, was adopted as Resolution 837, 13 December 2023.

G/TBT/N/B RA/1512	Brazil	Date of Distribution: 04 January 2024 Deadline for Comments: 12 February 2024	Advanced therapy products	This normative instruction contains provisions on Good Manufacturing Practices Complementary to Advanced Therapy Products.
G/TBT/N/B RA/1517	Brazil	Date of Distribution: 05 January 2024 Deadline for Comments: 19 March 2024	Leaflets in digital format	This Draft Resolution is a proposal for a standard that deals with the availability of leaflets in digital format.

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