

14 March 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 02 to 08 March 2024.

Relative thereto, we respectfully invite stakeholders to comment on the seven (7) notified draft technical regulation from six (6) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/NA/US/167	Australia	Date of Distribution: 04 March 2024 Deadline for Comments: 02 May 2024	Medicinal products	The Therapeutic Goods Administration (TGA) administers Australia's regulatory framework for the quality, safety, efficacy of therapeutic goods in Australia. There are provisions under the Therapeutic Goods Act 1989 (the Act) to establish Manufacturing Principles that are to be applied in the manufacture of therapeutic goods. The Therapeutic Goods (Manufacturing Principles) Determination 2020 (the Determination) is the legislative instrument that specifies the manufacture of therapeutic goods must comply with the applicable procedures and requirements in the Pharmaceutical Inspection Co-operation Scheme (PIC/s) Guide to GMP.
G/TBT/NE/GY/348/Add.1	Egypt	Date of Distribution: 04 March 2024 Deadline for Comments: Not Indicated	Medical electrical equipment : infant transport incubator equipment - Addendum	This addendum concerns the notification of the Ministerial Decree No. 499 /2023 (4 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 4941 for "Medical electrical equipment - Particular requirements for the basic safety and essential performance of infant transport incubators" (49 pages, in Arabic). It should be noted that the draft of this standard was formerly notified in G/TBT/NE/GY/348 dated 8 March 2023.
G/TBT/NE/GY/430	Egypt	Date of Distribution: 04 March 2024 Deadline for Comments: 02 May 2024	Dentistry operating lights	The Ministerial Decree No. 499 /2023 gives the producers and importers a six-month transitional period to abide by the Egyptian standard ES 4760 which specifies requirements and test methods for operating lights used in the dental office and intended for illuminating the oral cavity of patients. It also contains specifications on the instructions for use, marking and packaging.

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)

				This standard applies to operating lights, irrespective of the technology of the light source. This document excludes auxiliary light sources, for example, from dental hand pieces and dental headlamps and also operating lights which are specifically designed for use in oral surgery.
G/TBT/N/G BR/76	United Kingdom	Date of Distribution: 07 March 2024 Deadline for Comments: Not Applicable	Veterinary medicinal products	We are providing a transparency notification for minor amendments to the regulatory framework for the authorisation, manufacture, supply and use of veterinary medicinal products in Great Britain. These changes are not expected to have a significant impact on trade.
G/TBT/N/IS R/1241/Ad d.1	Israel	Date of Distribution: 04 March 2024 Deadline for Comments: Not Indicated	Tampons for menstruation - Addendum	The revision process of SI 1313, dealing with tampons was revoked on 3 March 2024.
G/TBT/N/J PN/800	Japan	Date of Distribution: 07 March 2024 Deadline for Comments: Not Applicable	Shitei Yakubutsu	Proposal for the additional designation of 3 substances as Shitei Yakubutsu, and their proper uses under the Act.
G/TBT/N/M EX/526/Ad d.1	Mexico	Date of Distribution: 04 March 2024 Deadline for Comments: Not Indicated	Medicaments - Addendum	The period of application of the emergency amendment to Mexican Official Standard NOM-059-SSA1-2015: Good manufacturing practices for medicinal products, published on 5 February 2016, which was published in the Official Journal on 23 August 2023, has been extended for six months from 24 February 2024.

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