

20 June 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 08 to 14 June 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Brazil, Egypt, Ukraine, Perú, and Egypt:

Document	Notifying	Relevant	Products	Summary
Symbol G/TBT/N/B RA/1505/A dd.1	Member Brazil	Dates Date of Distribution: 14 June 2024 Deadline for Comments: Not indicated	Biological products - Addendum	Draft resolution 1207, 02 October 2023 - previously notified through G/TBT/N/BRA/1505 - which contains provisions on post-market registration changes and cancellation of market registration of biological products in order to optimize the modification protocol process and its analysis by Anvisa, was adopted as Resolution - RDC number 876, 28 May 2024.
G/TBT/N/B RA/1544	Brazil	Date of Distribution: 14 June 2024 Deadline for Comments: 9 August 2024	Health surveillance	This Draft Resolution contains provisions on Good Storage Practices and Certification of Good Storage Practices for goods and products subject to health surveillance in Bonded Warehouses.
<u>G/TBT/N/B</u> <u>RA/1545</u>	Brazil	Date of Distribution: 14 June 2024 Deadline for Comments: 11 August 2024	Health control	This Draft Resolution contains provisions on criteria for petitioning for Company Operating Authorization (AFE), Special Operating Authorization (AE) for storage service providers of goods and products subject to health control and inspection in Bonded Warehouses, and Company Operating Authorization (AFE) for importers for the account and order of a third party or order of goods and products subject to health control and inspection and exemption from AFE
<u>G/TBT/N/B</u> <u>RA/1546</u>	Brazil	Date of Distribution: 14 June 2024 Deadline for Comments:	Mercury and non- encapsulated amalgam	This Resolution prohibits throughout the national territory the manufacture, import and sale, as well as the use in health services, of mercury and nonencapsulated amalgam alloy powder indicated for use in Dentistry.

BUREAU OF PHILIPPINE STANDARDS

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- 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)

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		13 August 2024		
G/TBT/N/E GY/479	Egypt	Date of Distribution: 14 June 2024 Deadline for Comments: 13 August 2024	Dental equipment	The Ministerial Decree No. 141/2024 cancels the Egyptian standard ES 4944 /2005 for " dental equipment connection for supply and waste "Worth mentioning is that this standard was replaced by ES 4761-1 for "dentistry - stationary dental units and dental patient chairs- part: 1 - general requirements" which was formerly notified in G/TBT/N/EGY/3/Add.75 dated 29 May 2024.
G/TBT/N/U KR/299	Ukraine	Date of Distribution: 14 June 2024 Deadline for Comments: 13 August 2024	Cosmetic products	The draft Order is developed to improve and clarify certain provisions of the Procedure for Notifying (Submitting Information) on Cosmetic Products, approved by the Order of the Ministry of Health of Ukraine No.1247 of 18 December 2023, concerning the maintenance and accounting of the status of product placement on the market, CMR substances and nanomaterials, administration of the Electronic Notification (Submitting Information) System for Cosmetic Products.
G/TBT/N/U KR/300	Ukraine	Date of Distribution: 14 June 2024 Deadline for Comments: 13 August 2024	Medicines	The Resolution amends the Procedure of State Registration (Re-registration) of Medicines, approved by the Resolution of the Cabinet of Ministers of Ukraine No. 376 of 26 May 2005, and ensures the implementation of a simplified state registration procedure of medicines purchased by a person authorised to carry out procurement in the sphere of healthcare, as well as those that are subject to procurement based on the results of a procurement procedure conducted by a specialised organisation carrying out procurement in accordance with a procurement agreement between the Ministry of Health and the relevant specialised procurement organisation;
G/TBT/N/P ER/161	Perú	Date of Distribution: 13 June 2024 Deadline for Comments: 12 August 2024	Pharmaceuti cal products for the diagnosis and/or treatment of rare or orphan diseases	The purpose of this Supreme Decree is to establish the provisions referring to the health registration of pharmaceutical products for the diagnosis and/or treatment of rare or orphan diseases and the health registration of pharmaceutical products for oncological treatments, within the framework of the provisions of article 9. of Law No. 29698, Law that declares the treatment of people suffering from rare or orphan diseases of national interest

				and preferential attention, incorporated by Law No. 31738
G/TBT/N/E GY/3/Add.8 1	Egypt	Date of Distribution: 12 June 2024 Deadline for Comments: Not indicated	Dental equipment - Addendum	Products covered: Dental Equipment (ICS code(s): 11.060.20)This addendum concerns the notification of the Ministerial Decree No. 141/2024 (2 pages, in Arabic) which cancels the Egyptian Standard ES 4759/2018" Dentistry-patient chair"(14 pages, in Arabic).It should be noted that this standard was replaced by ES 4761-1 for "dentistry - stationary dental units and dental patient chairs- part: 1 - general requirements" which was formerly notified in G/TBT/N/EGY/3/Add.75 dated 29 May 2024.
G/TBT/N/E GY/3/Add.8 2	Egypt	Date of Distribution: 12 June 2024 Deadline for Comments: Not indicated	Dental equipment - Addendum	Products covered: Dental Equipment (ICS code(s): 11.060.20)This addendum concerns the notification of the Ministerial Decree No. 141/2024 (2 pages, in Arabic) which cancels the Egyptian Standard ES 4761/2005 "Dental units "(37 pages, in English). It should be noted that this standard was replaced by ES 4761-1 for "dentistry - stationary dental units and dental patient chairs- part: 1 - general requirements " which was formerly notified in G/TBT/N/EGY/3/Add.75 dated 29 May 2024 and ES 4761-2 for" dentistry - stationary dental units and dental patient chairs- part: 2 - air, water, suction and wastewater systems " which was formerly notified in G/TBT/N/EGY/3/Add.76 dated 29 May 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,

FERDINAND L. MANFOSTE

Officer-in-Charge