

09 January 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 17 to 23 December 2022.

Relative thereto, we respectfully invite stakeholders to comment on the ten (10) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/784/Add.2	Brazil	Date of Distribution: 19 December 2022 Deadline for Comments: Not Indicated	Medicines - Addendum	The RDC N ^o 205, 28 December 2017 - previously notified through G/TBT/N/BRA/784 - which establishes special procedure for approval of clinical trials, good manufacturing practices certification and registration of new medicines for treatment, diagnosis or prevention of rare diseases, was changed by Resolution - Resolution - RDC number 763, 25 November 2022
G/TBT/N/BRA/1024/Add.1	Brazil	Date of Distribution: 19 December 2022 Deadline for Comments: Not Indicated	Labelling of medicines - Addendum	The Draft Resolution no. 815, 01 June 2020 - previously notified through G/TBT/N/BRA/1024 - which establishes technical requirements for the labelling of medicines, was adopted as the Resolution - RDC number 768, 12 December 2022.
G/TBT/N/BRA/1030/Add.1	Brazil	Date of Distribution: 19 December 2022 Deadline for Comments: Not Indicated	Large-volume parenteral solutions, solutions for irrigation, dialysis, plasma expanders and small-volume parenteral	The Draft Normative Instruction no. 816, 01 June 2020 - previously notified through G/TBT/N/BRA/1030 - which establishes technical requirements for labelling of large-volume parenteral solutions, solutions for irrigation, dialysis, plasma expanders and small-volume parenteral solutions, was

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)

			solutions - Addendum	adopted as the Normative Instruction number 198, 12 December 2022.
G/TBT/N/BRA/1031/Add.1	Brazil	Date of Distribution: 19 December 2022 Deadline for Comments: Not Indicated	Warning phrases for substances and or therapeutic classes in leaflets and packaging of medicines - Addendum	The Draft Resolution no. 817, 01 June 2020 - previously notified through G/TBT/N/BRA/1031 - which establishes warning phrases for substances and or therapeutic classes in leaflets and packaging of medicines, was adopted as the Normative Instruction number 200, 12 December 2022, and the Resolution - RDC number 770, 12 December 2022.
G/TBT/N/BRA/1118/Add.2	Brazil	Date of Distribution: 19 December 2022 Deadline for Comments: Not Indicated	Medicine leaflets - Addendum	The Draft Resolution number 989, 15 December 2020 - previously notified through G/TBT/N/BRA/1118 - which establishes technical requirements for the development, harmonization, updating, publication, and provision of medicine leaflets to patients and healthcare professionals, was adopted as Resolution - RDC number 769, 12 December 2022.
G/TBT/N/CAN/685	Canada	Date of Distribution: 21 December 2022 Deadline for Comments: 27 March 2023	Drugs and medical devices	Health Canada is proposing new targeted provisions and regulatory amendments to the Food and Drug Regulations and Medical Devices Regulations that would deliver on the Department's modernization commitments and leverage long-standing policies and practices. The proposal would take into account recent experience with regulatory agilities successfully piloted through the COVID-19 interim orders and their transition to regulations.
G/TBT/N/EGY/263/Add.1	Egypt	Date of Distribution: 20 December 2022	Intravascular catheters, supplied in the sterile condition and intended for	This addendum concerns the notification of the Ministerial Decree No. 561/2022 (2 pages, in Arabic) that gives the producers and importers a six-month transitional period to

		Deadline for Comments: 29 December 2022	single use, for any application - Addendum	abide by the Egyptian Standard ES 6788-1 for "Intravascular Catheters — Sterile And Single-Use Catheters- Part 1: General Requirements" (33 page(s), in Arabic).
G/TBT/N/EGY/264/Add.1	Egypt	Date of Distribution: 20 December 2022 Deadline for Comments: Not Indicated	Central venous catheters supplied in the sterile condition, and intended for single use - Addendum	This addendum concerns the notification of the Ministerial Decree No. 561/2022 (2 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6788-3 for "Intravascular Catheters — Sterile and Single-Use Catheters — Part 3: Central venous catheters" (8 page(s), in Arabic)
G/TBT/N/EGY/265/Add.1	Egypt	Date of Distribution: 20 December 2022 Deadline for Comments: Not Indicated	Balloon dilatation catheters supplied in the sterile condition, and intended for single use - Addendum	This addendum concerns the notification of the Ministerial Decree No. 561/2022 (2 pages, in Arabic) that gives the producers and importers a six-month transitional period to abide by the Egyptian Standard ES 6788-4 "Intravascular Catheters — Sterile And Single-Use Catheters Part 4: Balloon Dilatation Catheters" (17 page(s), in Arabic).
G/TBT/N/JPN/758	Japan	Date of Distribution: 19 December 2022 Deadline for Comments: Not Applicable	Shitei Yakubutsu	Proposal for the additional designation of 5 substances as Shitei Yakubutsu, and their proper uses under the Act.

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