07 March 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 18 to 24 February 2023.

Relative thereto, we respectfully invite stakeholders to comment on the 11 notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/CAN/692	Canada	**Date of Distribution**: 21 February 2023 **Deadline for Comments**: Not Applicable	Medical devices	Regulatory amendments to the Medical Devices Regulations (MDR) will create a new permanent regulatory framework for COVID-19 medical devices. The amendments will allow for the continued importation and sale of over 800 COVID-19 medical devices authorized under Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 (the third interim order). As well, the amendments will maintain the regulatory flexibilities set out under the third interim order. The amendments will also permanently incorporate from the third interim order the expedited authorization pathways and certain flexibilities for COVID-19 medical devices that meet an urgent public health need.
G/TBT/N/CAN/624	Chile	**Date of Distribution**: 23 February 2023 **Deadline for Comments**: 23 April 2023	Medical devices : immunohematological reagents	Join the control system established in the article 111 of the Sanitary Code and its regulations, approved by Decree No. 825 of 1998, of Ministry of Health, the medical devices indicated.

BUREAU OF PHILIPPINE STANDARDS

3F Trade and Industry Building, 361 Sen. Gil Puyat Avenue
1200 Makati City, Philippines
(+632) 791.3124, 751.3126
(+632) 751.4700
bps@dti.gov.ph
www.bps.dti.gov.ph

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/EGY/344	Egypt	**Date of Distribution**: 21 February 2023 **Deadline for Comments**: 21 April 2023	Menstrual tampons	This draft of the Egyptian standard specifies the requirements of tampons. Worth mentioning is that this draft standard complies with the following: • ISO 17516/ 2014 • 2014/391/EU "Eco- label for bed mattresses" • Edana Code of practice for tampons Version 3: September 2020 • CFR - code of federal regulations Title 21 Volume 8 Sec 801.430: 20 Jul 2022 for user labelling for menstrual tampons • AS 2869 /2008 for tampons - Menstrual
G/TBT/N/RWA/811	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 23 April 2023	Pharmaceutical products and medical devices	The purpose of these Regulations is to provide a legal framework for the effective and efficient control of importation and exportation of pharmaceutical products, medical devices, and their respective raw materials in a transparent, non-discriminatory manner.
G/TBT/N/RWA/812	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 22 April 2023	Food and pharmaceutical products	This Law relates to the regulation and inspection of food and pharmaceutical products.
G/TBT/N/RWA/818	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 22 April 2023	Medical devices including in vitro giagnostics	The purpose of these regulations is to enforce the legal framework to ensure effective and efficient registration of human and veterinary Medical Devices including In Vitro Diagnostics, and to provide an open, transparent and nondiscriminatory process for the registration of Medical Devices including In Vitro Diagnostics.

G/TBT/N/RWA/819	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 22 April 2023	Medical products	These Regulations apply to public, and private manufacturers, distributors, wholesalers and retailers of medical products involved in the manufacture, storage, sale, distribution, and dispensing of medical products.
G/TBT/N/RWA/820	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 21 April 2023	Medical products	These Regulations enforce the legal framework for application, inspection, storage, distribution, and licensing of public and private manufacturers, distributors, wholesalers and retailers of Medical Products. These Regulations apply to public, and private manufacturers, distributors, wholesalers and retailers of medical products involved in the manufacture, storage, sale, distribution, and dispensing of medical products.
G/TBT/N/RWA/821	Rwanda	**Date of Distribution**: 22 February 2023 **Deadline for Comments**: 22 April 2023	Medical products	The purpose of these Regulations is to put in place a legal framework to ensure effective and efficient registration of medicinal products, and to provide an open, transparent and nondiscriminatory process for the registration of all medicinal products regulated by Rwanda Food and Drugs authority. These regulations cover human and veterinary medicinal products, vaccines and biological products for human and animal use, herbal medicinal products, disinfectant and antiseptics excluding cosmetics as well as laboratory and household chemicals. The regulations apply to all medicinal products to be registered in Rwanda.
G/TBT/N/RWA/828	Rwanda	**Date of Distribution**: 23 February 2023	Pharmaceutical products	These regulations shall apply to all activities related to the advertisements or promotion and marketing of regulated products that are manufactured,

		Deadline for Comments: 23 April 2023		imported, distributed, stored, sold or used in Rwanda.
G/TBT/N/RWA/829	Rwanda	**Date of Distribution**: 24 February 2023 **Deadline for Comments**: 24 April 2023	Medical products	These regulations shall apply to GMP inspections of active pharmaceutical ingredients and finished pharmaceutical products sites that manufacture, import, export, distribute, store, sell, and that are used within and outside Rwanda for medical products.

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