

07 November 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 28 October to 03 November 2023.

Relative thereto, we respectfully invite stakeholders to comment on the five (5) notified draft technical regulations from Brazil, Republic of Korea, and Ukraine:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/B RA/1455/A dd.1	Brazil	Date of Distribution: 1 November 2023 Deadline for Comments: Not Indicated	Influenza vaccines - Addendum	Normative Instruction 189, 26 October 2022 - previously notified through G/TBT/N/BRA/1455 - which contains provisions on the composition of influenza vaccines to be used in Brazil in the year 2023, was revoked by Normative Instruction 261, 25 October 2023.
G/TBT/N/B RA/1485/A dd.1	Brazil	Date of Distribution: 1 November 2023 Deadline for Comments: Not Indicated	Surgical gloves and gloves for non-surgical procedures - Addendum	The Draft Resolution number 1161, 18 May 2023 - previously notified through G/TBT/N/BRA/1485 - which establishes the minimum identity and quality requirements for surgical gloves and gloves for non surgical procedures made of natural rubber, synthetic rubber, mixture of natural and synthetic rubbers and polyvinyl chloride, under a health surveillance regime, was adopted as Resolution - RDC number 825, October 26th, 2023.

BUREAU OF PHILIPPINE STANDARDS

- 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)

<u>G/TBT/N/B</u> <u>RA/1507</u>	Brazil	Date of Distribution: 1 November 2023 Deadline for Comments: 2 January 2024	Medicaments	This Draft Resolution contains provisions on regulation for expanded access, compassionate use, and post-study drug supply programs.
<u>G/TBT/N/K</u> <u>OR/1179</u>	Republic of Korea	Date of Distribution: 30 October 2023 Deadline for Comments: 28 December 2023	Korean herbal pharmacopoeia	The Monistry of Food and Drug Safety (MFDS) is proposing to the "Korean Herbal Pharmacopoeia" as follows: - [Attached Table 3. Part 1 of Monograph] Revision of Identification test and Content assay method for 'Moschus' of M.m oschiferus, and Purity test method of 'Moschus' - [Attached Table 4. Part 2 of Monograph] Revision of Identification test method and Quantitative assay for 7 items such as 'Boshimhwan Pill'
G/TBT/N/U KR/256/Re v.1	Ukraine	Date of Distribution: 1 November 2023 Deadline for Comments: 30 December 2023	Biological safety - Revision	The draft Law is developed with the aim of gradual creation of a unified system of biological safety and biological protection based on "One Health" approach, to fulfil obligations to protect the life and health of people and animals, to prevent the spread of harmful infectious diseases in the country, and to respond in a timely manner to outbreaks of infectious diseases. The draft Law defines the legal, organizational, economic and social principles of biological safety and biological protection in Ukraine, in particular: Introduces a new conceptual framework for definitions, inter alia, biological safety; biosynthetic activity; biological hazard; biological protection; biological agents; microorganism depository;

biological agents, entity engaged in biosynthetic activities; determines the authorized body in the sphere of biological safety and biological protection, parties of legal relations in the sphere of		engaged in biosynthetic activities; determines the authorized body in the sphere of biological safety and biological protection, parties of legal relations in the sphere of biological safety and biological
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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. CATAJAYDirector