

27 April 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 15 to 21 April 2023.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulation from Canada:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/CAN/694	Canada	Date of Distribution: 19 April 2023 Deadline for Comments: 29 June 2023	Drugs and medical devices	The proposed amendments to the Food and Drug Regulations (FDR) would: <ul style="list-style-type: none"> · Establish a regulatory framework for recalls of drugs ordered by the Minister. Clarify reporting obligations for industry for voluntary (firm initiated) recalls. · Update the outdated references to foreign regulatory authorities who participate in mutual recognition agreements (MRA) with Canada and replace the outdated information with an ambulatory list of regulatory authorities incorporated by reference. · Offer conditional exemptions from requirements related to finished product testing for certain biologics (e.g., gene and cell therapies) and radiopharmaceuticals, as well as clarify that direct shipment to a person other than an importer

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)

				(typically a healthcare provider) is permitted for these products.
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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. CATAJAY
Director 