

12 September 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 31 August to 06 September 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from European Union and Republic of Korea:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/NEU/1084	European Union	Date of Distribution: 2 September 2024 Deadline for Comments: 1 November 2024	In vitro diagnostic medical devices	This draft Commission Implementing Regulation adds common specifications for some high-risk in vitro diagnostic medical devices in accordance with Art. 9 of Regulation (EU) 2017/746, notably in relation to their performance evaluation. It also makes a number of editorial corrections to existing specifications.
G/TBT/NKOR/1227	Republic of Korea	Date of Distribution: 2 September 2024 Deadline for Comments: 1 November 2024	Regulation on safety of pharmaceuticals	The proposed amendments to the "Regulation on Safety of Pharmaceuticals, etc." are as follows: A. Specification of submission and follow up of Risk Management Plan (Article 4 and 8 of the draft) B. Streamlined process of approval for change (Article 8) C. Specification of subject and items to be disclosed for data protection (newly established Article 21 bis) D. Specification of the subject for submission of a risk management plan (newly established Article 23 bis)

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

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)