ANGAT Negosyo
ASENSO Trabaho
ALAGANG Konsyumer
Para Sa Bagong Pilipinas

BAGONG PILIPINAS

08 July 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 29 June to 05 July 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from Brazil, United States and Indonesia :

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1297/Add.2/Corr.1	Brazil	**Date of Distribution:** 4 July 2024 **Deadline for Comments:** Not indicated	Medical devices - Corrigendum	The Resolution 886, 26 Junho 2024 - previously notified through G/TBT/N/BRA/1297/Add.2 - which contains provisions on the identification of regularized medical devices at Anvisa, through the Unique Device Identification (UDI) system, was rectified. Where it reads: "Resolution 886, 26 June 2024"; Read: "Resolution 884, 26 June 26 2024".The republished text is available only in Portuguese and can be downloaded at: https://www.in.gov.br/en/web/dou/-/retificacao-569312444
G/TBT/N/BRA/1297/Add.2	Brazil	**Date of Distribution:** 2 July 2024 **Deadline for Comments:** Not indicated	Medical devices - Addendum	Resolution 591, 21 December 2021 - previously notified through G/TBT/N/BRA/1297 - which contains provisions on the identification of regularized medical devices at Anvisa, through the Unique Device Identification (UDI) system, was changed by Resolution 886, 26 June 2024 The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6292482/RDC_886_2024_.pdf/1ace4521-50f9-4f7c-9950-8e93eb9745a9
G/TBT/N/USA/2054/Add.2	United States	**Date of Distribution:** 2 July 2024 **Deadline for Comments:** Not indicated	In vitro diagnostic test systems - Addendum	The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Laboratory Developed Tests: Small Entity Compliance Guide." The laboratory developed tests (LDT) final rule (notified as G/TBT/N/USA/2054/Add.1) amended FDA's regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory.

BUREAU OF PHILIPPINE STANDARDS

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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/IDN/166	Indonesia	**Date of Distribution:** 1 July 2024 **Deadline for Comments:** 30 August 2024	Quasi drugs	This regulation states that quasi-drugs produced, imported, and distributed in Indonesia must be registered with the Indonesian FDA. The requirement of quasi-drugs to be registered in Indonesia must fulfill the safety, efficacy, and quality aspects.

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,

Digitally signed by
Catajay Neil Pinuela

NEIL P. CATAJAY
Director

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