28 November 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 16 to 22 November 2024.

Relative thereto, we respectfully invite stakeholders to comment on the notified draft technical regulations from: Brazil, Perú, Switzerland, Viet Nam, and Ukraine

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/955/Add.3	Brazil	**Date of Distribution:** 22 November 2024 **Deadline for Comments:** Not indicated	Pharmaceutical products - Addendum	Resolution 742, 10 August 2022 - previously notified through G/TBT/N/BRA/955/Add.1 - which establishes the minimal technical requirements for relative bioavailability and bioequivalence studies that supports dossier of consent for clinical research, market authorization or post-market authorization of medicines, in the terms of this resolution, was changed by Resolution 942, 18 November 2024.The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/3855414/RDC_942_2024_.pdf/bf46fb32-1ddb-4ba9-abf4-e6fac15966e2
G/TBT/N/BRA/1528/Add.1	Brazil	**Date of Distribution:** 22 November 2024 **Deadline for Comments:** Not indicated	Industrialized medicines for human use - Addendum	Draft resolution 1245, 20 March 2024 - previously notified through G/TBT/N/BRA/1528 - which contains provisions on the validation of bioanalytical methods and analysis of study samples for regulatory submissions of industrialized medicines for human use, was adopted as Resolution 641, 18 November 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/3855414/RDC_941_2024_.pdf/fd356c37-661b-4c84-8f20-8e582b4e2f3f
G/TBT/N/BRA/1544/Add.1	Brazil	**Date of Distribution:** 22 November 2024 **Deadline for Comments:** Not indicated	Health surveillance - Addendum	Draft resolution 1259, 29 May 2024 - previously notified through G/TBT/N/BRA/1544 - which contains provisions on Good Storage Practices and Certification of Good Storage Practices for goods and products subject to health surveillance in Bonded Warehouses, was adopted as Resolution 938, 14 November 2024 The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6764059/RDC_938_2024_.pdf/79429825-81d7-4d05-94b5-66ffe64ea6c3
G/TBT/N/BRA/1545/Add.1	Brazil	**Date of Distribution:** 22 November 2024	Health care technology - Addendum	Draft resolution 1260, 29 May 2024 - previously notified through G/TBT/N/BRA/1545 - which contains provisions on criteria for petitioning for Company Operating Authorization (AFE), Special Operating

BUREAU OF PHILIPPINE STANDARDS

3/F Trade and Industry Building
361 Sen. Gil Puyat Avenue, Makati City, 1200 Philippines
☎ Phone: (632) 7791.3125 / 7791.3126
✉ E-mail: bps@dti.gov.ph • Website: www.bps.dti.gov.ph

Membership:
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- International Electrotechnical Commission (IEC)
- World Trade Organization (WTO) Technical Barriers to Trade (TBT)
  - National Enquiry Point (NEP)
  - National Notification Authority (NNA)

		Deadline for Comments: Not indicated		Authorization (AE) for storage service providers of goods and products subject to health control and inspection in Bonded Warehouses, and Company Operating Authorization (AFE) for importers for the account and order of a third party or order of goods and products subject to health control and inspection and exemption from AFE, was adopted as Resolution 939, 14 November 2024. The final text is available only in Portuguese and can be downloaded at: https://antigo.anvisa.gov.br/documents/10181/6764059/RDC_939_2024_.pdf/f2c79c88-1c1d-4d21-9c1f-4ecf109a7585
G/TBT/N/PER/167	Perú	**Date of Distribution:** 22 November 2024 **Deadline for Comments:** 21 January 2025	Pharmaceuticals, medical devices and healthcare products	El presente Reglamento tiene por objeto establecer las disposiciones reglamentarias de la Ley N° 29459, Ley de los Productos Farmacéuticos, Dispositivos Médicos y Productos Sanitarios, regulando el registro y control y vigilancia sanitaria de los dispositivos médicos, incluyendo a sus accesorios, basados en el cumplimiento de la seguridad y desempeño de los mismos, a fin de asegurar la protección de la salud pública.
G/TBT/N/CHE/258/Add.2	Switzerland	**Date of Distribution:** 21 November 2024 **Deadline for Comments:** Not indicated	In vitro diagnostic medical devices - Addendum	Content of changed notified measures are summarized as follows: In order to improve the safety and quality of medical devices, Switzerland adapted its legislation on medical devices in line with developments in EU law (Medical Devices Regulation, MDR and In vitro Diagnostic Medical Devices Regulation, IVDR). The new legislations in Switzerland are applicable since May 2021 for medical devices (MedDO) and May 2022 for in vitro diagnostic medical devices (IvDO) like in the EU.Transitional measures were notified to the WTO (G/TBT/N/CHE/258/add.1). Additional flexibilities for labeling requirements to IVD products that are not intended to be self-diagnosis are currently a temporary rule. The proposal foresees to adopt these flexibilities for labeling requirements as a permanent rule. In addition, on 13 June 2024, Regulation (EU) 2024/1860 amending the EU-MDR and the EU-IVDR entered into force in the EU and provides in particular for an extension of the transitional periods in the EU provided for in the IVDR and a gradual roll-out of Eudamed. The extended transitional periods in the IVDR as well as the applicable conditions for their extensions are transposed into the corresponding Swiss legislation to maintain the equivalence with the European regulation as regards the transitional periods. The registration of Unique Device Identification (UDI) number with the Swiss authorities will become mandatory by July 1st 2026.
G/TBT/N/VNM/331	Viet Nam	**Date of Distribution:** 21 November 2024	Medicinal finished products and	1. This draft Circular specifies:a) Documentation requirements, procedures for the issuance, renewal, revision and revocation of marketing authorization for modern

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		Deadline for Comments: 20 January 2025	medicinal ingredients	medicines, vaccines, biologicals, herbal drugs and medicinal materials (including active ingredients, semi-finished herbal ingredients, excipients, and capsule shells) for human use in Vietnam;b) Required clinical data to ensure safety and efficacy in the application;c) Requirements for exemption from clinical trial or certain phases thereof in Vietnam; drugs to be subjected to Stage 4 clinical trial;d) Rules for the validation of marketing authorization applications (hereinafter referred to as "marketing application") for drugs/medicinal materials, their renewal and revision;dd) Rules for the validation of applications for license to import drugs that are yet to beapproved for marketing authorization (hereinafter referred to as "unapproved drugs") in the cases specified in Point a Clause 43 Article 5 of Decree No. 155/2018/ND-CP dated November 12, 2018 providing amendments to regulations on business conditions under state management of the Ministry of Health of Vietnam (hereinafter referred to as"Decree No. 155/2018/ND-CP");e) Organizing and operating principles of the Advisory Council for issuance of marketing authorization of drugs and pharmaceutical ingredients (hereinafter referred to as the Council);g) Procedures for the assessment of applications for the granting, extension, variation of marketing authorizations for finished medical products and medicinal ingredients; procedures for the assessment of applications for import licenses of drugs without marketing authorization.h) Dossier and procedures for granting certificates of circulation of drugs in the form of reference and recognition;i) Regulations on drugs that must undergo bioequivalence testing and requirements for dossiers reporting bioequivalence research data in drug circulation registration in Vietnam.2. This draft Circular does not apply to the cases specified in Point a, b, Clause 2, Article 54 of the Law on Pharmacy, excipients, capsule shells, and semi-finished medicinal products for the manufacture of drugs according to drug registration dossiers that have a Certificate of Drug Circulation Registration in Vietnam; capsule shells, excipients used for testing, research or manufacturing of exported drugs and semi-finished medicinal products produced by the manufacturing facility itself for the manufacture of finished drugs, except in cases where the registration facility voluntarily request it.
G/TBT/N/UKR/318	Ukraine	**Date of Distribution:** 19 November 2024 **Deadline for**	Medicines	The draft Resolution of the Cabinet of Ministers of Ukraine "On Approval of the Procedure for State Registration (Reregistration) of Medicines" has been developed to establish a unified mechanism for the state registration (reregistration) of

		Comments: 18 January 2025		medicines, including finished medicines, immunobiological medicinal products. The draft Resolution proposes to approve a new Procedure for the State Registration (Reregistration) of Medicines, which provides for: - the procedure for the state registration (reregistration) of medicines, including finished medicines, immunobiological medicinal products, and medicinal products under obligations; - the mechanism for amending the registration dossier materials; - the procedure for making decisions on suspension, cancellation and termination of state registration of a medicine and decisions to refuse state registration of a medicine; - the procedure for evaluating periodically updated safety reports on medicines and making appropriate decisions; - the amount of fees for state registration (reregistration) of medicines and the cost of services for the evaluation of registration dossier materials.
G/TBT/N/UKR/319	Ukraine	**Date of Distribution:** 19 November 2024 **Deadline for Comments:** 18 January 2025	Medicines	The draft Order has been developed to establish the procedure for issuing or refusing to issue permits for parallel imports of medicines, including amendments, suspension, renewal, cancellation or termination of such permits. It also aims to ensure the control and pharmacovigilance over medicines, including medical immunobiological products, imported into Ukraine for the purposes of parallel imports and in circulation during the term of validity of the parallel import permit.
G/TBT/N/UKR/320	Ukraine	**Date of Distribution:** 19 November 2024 **Deadline for Comments:** 18 January 2025	Medical devices	The draft Technical Regulation sets out rules for placing on the market, making available on the market or putting into operation of medical devices intended for human use and accessories for such devices. It also applies to clinical investigations concerning such medical devices and their accessories conducted in Ukraine. The draft Regulation aims to remove legal, administrative and technical barriers in the field of medical devices, while ensuring the safety and efficacy of medical devices on the Ukrainian market, implementing modern European approaches to monitoring the safety and efficacy of medical devices and preventing the entry of unsafe, ineffective and counterfeit medical devices into Ukraine.This draft Regulation has been developed based on Regulation (EU) No 2017/745 of the European Parliament and of the Council of 5 April 2017

				on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

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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3/F Trade and Industry Building
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