29 September 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 09 to 15 September 2023.

Relative thereto, we respectfully invite stakeholders to comment on the eight (8) notified draft technical regulations from four (4) WTO Members:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/BRA/1499	Brazil	**Date of Distribution**: 11 September 2023 **Deadline for Comments**: 09 November 2023	Medical equipment	This Draft Resolution contains provisions on the criteria for acceptance of toxicological evaluations of Technical Products for registration purposes resulting from decisions by the Equivalent Foreign Regulatory Authority (AREE). For the purposes of adopting the optimized analysis procedure, the following will be considered following AREE: I - European Food Safety Authority – European Food Safety Authority (EFSA); II - North American Environmental Protection Agency - United States Environmental Protection Agency (EPA); III - Australian Pesticides and Veterinary Medicines Authority -Australian Pesticides and Veterinary Medicines Authority (APVMA); IV – Ministry of Health of Canada – Health Canada Pest Management Regulatory Agency (PMRA); V - Ministry of Health, Labor and Welfare of Japan - Ministry of Health, Labor and Welfare of Japan (MHLW) or Ministry of

				Agriculture, Forestry and Fisheries of Japan - Ministry of Agriculture, Forestry and Fisheries of Japan (JMAFF).
G/TBT/N/BRA/1500	Brazil	**Date of Distribution**: 11 September 2023 **Deadline for Comments**: 25 September 2023	Medical equipment	This Draft Resolution contains provisions on the establishment of an optimized procedure for the analysis and decision of requests for registration of medical devices, through the use of analyzes carried out by an Equivalent Foreign Regulatory Authority. For the purposes of adopting the optimized analysis procedure, the following AREE and respective proof of registration or authorization: I - Australia: Australia Therapeutic Goods Administration (TGA) – Australian Register of Therapeutic Goods (ARTG); II - Canada: Health Canada (HC) – Medical Device License; III - Japan: Japan Ministry of Health, Labor and Welfare (MHLW) – Pre-market approval (Shonin) from MHLW; It is IV - United States of America (USA): US Food and Drug Administration (US FDA) – 510KClearance or Premarket Approval (PMA).
G/TBT/N/BRA/1501	Brazil	**Date of Distribution**: 11 September 2023 **Deadline for Comments**: Not Applicable	Pharmaceutics	This Resolution contains provisions on substances and drugs subject to special control and Good Pharmaceutical Practices for the sanitary control of the functioning, dispensing and commercialization of products and the provision of pharmaceutical services in pharmacies and

				drugstores and other provisions.
G/TBT/N/EU/1006	European Union	**Date of Distribution**: 14 September 2023 **Deadline for Comments**: 12 December 2023	Medicinal products for human use and investigational medicinal products for human use	This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use. It repeals and replaces Directive 2001/83/EC and Directive 2009/35/EC and it incorporates relevant parts of Regulation (EC) No 1901/2006; The Directive contains both technical regulations and conformity assessment procedures. 1. Technical regulations: The Directive establishes standards of quality, safety and efficacy for the authorisation of medicinal products as it establishes the conditions for the marketing authorisation of medicinal products for human use at central (EU) and national (in different Member States) levels. The Directive also establishes the conditions for the manufacturing authorisation and wholesale distribution authorisation. It moreover establishes requirements on labelling and packaging. 2. Conformity assessment procedures: The Directive establishes the procedures for the authorisation of medicinal products for human use at central (EU) and national (in different Member States. It also establishes procedures for the manufacturing

				authorisation and wholesale distribution authorisation. The Directive moreove establishes procedures for controls, supervision and inspections.
G/TBT/N/EU/1008	European Union	**Date of Distribution**: 14 September 2023 **Deadline for Comments**: 12 December 2023	Medicinal products for human use and investigational medicinal products for human use	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts. It revises and replaces Regulation (EC) 726/2004 (general), Regulation (EC) 141/2000 (rare disease medicines) and Regulation (EC) 1901/2006 (paediatric medicines).
G/TBT/N/KOR/1169	Republic of Korea	**Date of Distribution**: 12 September 2023 **Deadline for Comments**: 10 November 2023	Medicinal products, pharmaceuticals	The Regulations on GMP for Medicinal Products defined detailed guidelines and principles of good manufacturing practice for medicinal products. The following is the proposed amendment to this Regulations : - Annex 1, Annex 2 and Annex 2of2 to this regulations are amended to be equivalent to Annex 1, Annex 2B and Annex 2A of the current PIC/S GMP Guide.

G/TBT/N/KOR/1170	Republic of Korea	**Date of Distribution**: 14 September 2023 **Deadline for Comments**: 05 October 2023	Medical devices	The Korean Ministry of Food and Drug Safety is proposing to amend the "Regulations on Renewal of Manufacturing Permission, etc." as follows: 1) Reorganizing the requirement attached documents considering the characteristics of each medical device product 2) Incorporating key review points for each renewal cycle, etc.
G/TBT/N/PHL/308/Add.1	Philippines	**Date of Distribution**: 13 September 2023 **Deadline for Comments**: Not Indicated	Vaccines and biotherapeutic products for human use - Addendum	Application Process and Requirements for Post-Approval Changes of Biological Products Adopting the World Health Organization Guidelines for Changes to Approved Vaccines and Biotherapeutic Products for Human Use

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,

Catajay Neil Pinuela

NEIL P. CATAJAY
Director