

31 January 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 20 to 26 January 2024.

Relative thereto, we respectfully invite stakeholders to comment on the three (3) notified draft technical regulations from Japan and Viet Nam:

Document Symbol	Notifying Member	Relevant Dates	Products Covered	Summary
G/TBT/N/J PN/794	Japan	Date of Distribution: 22 January 2024 Deadline for Comments: Not Applicable	Shitei Yakubutsu	Proposal for the additional designation of 3 substances as Shitei Yakubutsu, and their proper uses under the Act.
G/TBT/N/J PN/795	Japan	Date of Distribution: 26 January 2024 Deadline for Comments: 24 February 2024	Regenerative medicine	Under the current Act on the Safety of Regenerative Medicine, when entrusting the manufacturing of processed cells used in regenerative medicine to a business which manufactures them in a foreign country, it is limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare prescribed in the Act. Gene therapy, etc. which does not use processed cells (medical care which uses nucleic acid, etc.) will be added to the scope of the Act, due to the partial amendment of the Act. Therefore, when entrusting the manufacturing of nucleic acid, etc. used for such medical care to a business which manufactures them in a foreign country, it is limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare prescribed in the Act as well as

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)

				processed cells used in regenerative medicine.
G/TBT/N/VNM/290	Viet Nam	<p>Date of Distribution: 24 January 2024</p> <p>Deadline for Comments: 22 March 2024</p>	Pharmaceutical products	<p>This draft Law amends and supplements a number of articles of Law No. 105/2016/QH13 on Pharmacy.</p> <p>These Articles include 2, 4, 6, 7, 8, 10, 17, 24, 28, 32, 33, 34, 35, 37, 42, 43, 44, 46, 47, 48, 49, 53, 54, 55, 56, 58, 59, 60, 61, 64, 65, 76, 78, 79, 87, 89, 107, 109, 110, 112, 113;</p> <p>This draft Law abolishes point c and d, clause 26, Article 2, point a, clause 10, Article 6, point b, clause 4, Article 7 of Law No. 105/2016/QH13 on Pharmacy.</p> <p>Transitional provisions:</p> <ol style="list-style-type: none"> 1. Certificates of drug information and advertising content issued under the provisions of Law No. 105/2016/QH13 on Pharmacy will continue to be used until the expiry of the Certificate's validity 2. Dossier submitted before the entry into force of this draft Law and requesting the issuance, extension, amendment or supplementation of the registration certificate for the circulation of drugs and medicinal ingredients shall be implemented in accordance with the provisions of Law No. 105/2016 /QH13 on Pharmacy, except in cases where the establishment requests to comply with the provisions of this draft Law. 3. For dossiers applying for a License to import toxic drugs and toxic medicinal ingredients; drugs and medicinal ingredients that are on the list of substances whose use is prohibited in a number of industries and fields used for testing, research, and manufacturing

				of drugs for export in accordance with the provisions of the 2016 Law on Pharmacy and its guiding Decrees. 4. Chain pharmacy businesses that have had a chain pharmacy system prior to the effective date of this Law shall complete procedures to apply for a certificate of authority to do business as a chain within 45 days of the effective date of this draft Law.
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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,



FERDINAND L. MANFOSTE
Officer-in-Charge