WORLD TRADE ORGANIZATION

G/TBT/N/JPN/804

10 April 2024

(24-3022)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** JAPAN **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Health, Labour and Welfare **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** PHARMACEUTICAL PRODUCTS (HS code(s): 30)
5.	**Title, number of pages and language(s) of the notified document:** Partial amendment to the Minimum Requirements for Biological Products Partial amendment to The Public Notice on National Release Testing.; (1 page(s), in English)
6.	**Description of content:** The Minimum Requirements for Biological Products will be amended as follows: ・GENERAL RULES Regarding the standard for "Nasally Live Attenuated Influenza Vaccine", the section of "Attenuation Assay" will be deleted. And the standard for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly approved will be added. ・STANDARDS The section of "Standard Antimeasles Serum" will be partially amended. The Public Notice on National Release Testing will be amended as follows: The criterion, fee, and quantity for "Purified Typhoid Vi Polysaccharide Vaccine" that is to be newly approved will be added. And the criterion, fee, and quantity for "Human Serum Albumin" and "Freeze-dried Human Blood Coagulation Factor Ⅷ Concentrate" will be partially amended. In addition, the criterion and fee for "Human Plasma Protein Fraction" will be partially amended.

7.	**Objective and rationale, including the nature of urgent problems where applicable:** To establish the standard for manufacturing process, properties, quality, storage, and others of pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation (Biological products). In addition, to stipulate the pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation as subject to National Release Testing, as well as fee, criterion, and quantity for the testing.
8.	**Relevant documents:** Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. https://www.japaneselawtranslation.go.jp/en/laws/view/3213 This amendment will be published in "*KAMPO*" (Official Gazette) when adopted.
9.	**Proposed date of adoption:** June 2024 **Proposed date of entry into force:** June 2024
10.	**Final date for comments:** 30 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Japan Enquiry Point International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs Fax: (+81 3) 5501 8343 E-mail: enquiry@mofa.go.jp https://members.wto.org/crnattachments/2024/TBT/JPN/24_02548_00_e.pdf