WORLD TRADE ORGANIZATION

G/TBT/N/JPN/868

3 July 2025

(25-4289)

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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 (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Health, Labour and Welfare
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** Pharmaceutical products (HS: 30)
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Partial amendment to the Minimum Requirements for Biological Products Partial amendment to the Public Notice on National Release Testing; (1 page(s), in English) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2025/TBT/JPN/25_04293_00_e.pdf Japan Enquiry Point International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs Fax: (+81 3) 5501 8343 E-mail: enquiry@mofa.go.jp
6.	**Description of content:** The Minimum Requirements for Biological Products will be amended as follows: Regarding the article of "Inactivation test" in the section of "Tests on final product" of the monograph for "High dose Influenza HA Vaccine", the rule of inoculating with the allantoic fluid into allantoic cavities of eggs in case there are positive hemagglutination test results will be partially amended. And regarding the standard for "Pneumococcal Polyvalent Vaccine", the section of "Serological identification test" will be deleted. In addition, the standard for "21-valent Pneumococcal Conjugate Vaccine" that is to be newly approved will be added. The Public Notice on National Release Testing will be amended as follows: The criterion, fee, quantity and Institution for National Release Testing for "21-valent Pneumococcal Conjugate Vaccine" that is to be newly approved will be added.
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, quantity and institution 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. **Relevant notifications:** • G/TBT/N/JPN/866
9.	**Proposed date of adoption:** August 2025 **Proposed date of entry into force:** August 2025
10.	**Provision of comments** **Final date for comments:** 30 days from notification (2 August 2025) **[ ] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** Japan Enquiry Point International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs Fax: (+81 3) 5501 8343 E-mail: enquiry@mofa.go.jp