



13 February 2026

(26-1015)

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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: <u>JAPAN</u> 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; (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/2026/TBT/JPN/26_00895_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 standard for "Freeze-dried Human Fibrinogen", the article of "Labeling" will be partially amended owing to changing the description in the package insert for proper use.
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)
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: <ul style="list-style-type: none">• G/TBT/N/JPN/868
9. Proposed date of adoption: March 2026 Proposed date of entry into force: March 2026
10. Provision of comments Final date for comments: 15 March 2026 (30 days from notification) [] 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