



17 October 2025

(25-6710)

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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): Establishment of the Japanese Pharmacopoeia Nineteenth Edition; (7 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_06914_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: Ministry of Health, Labour and Welfare will abolish the Japanese Pharmacopoeia Eighteenth Edition and establish Nineteenth Edition based on Paragraph 1 of Article 41 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.
7. Objective and rationale, including the nature of urgent problems where applicable: To establish the Japanese Pharmacopoeia Nineteenth Edition for the purpose of maintaining proper properties and quality of pharmaceuticals.
8. Relevant documents: The 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/797

9.	Proposed date of adoption: At the beginning of April 2026 (planned) Proposed date of entry into force: At the beginning of April 2026 (planned)
10.	Provision of comments Final date for comments: 16 December 2025 [X] 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