

5 February 2024

Original: English

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## **Committee on Technical Barriers to Trade**

## 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:30)
- **5. Title, number of pages and language(s) of the notified document:** Partial revision of the Japanese Pharmacopoeia Eighteenth edition; (5 page(s), in English)
- **6. Description of content:** Under Paragraph 1 of Article 41 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Japanese Pharmacopoeia, Eighteenth edition are to be revised.
- **7. Objective and rationale, including the nature of urgent problems where applicable:** To maintain proper description 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.

**9. Proposed date of adoption:** June 2024 (planned)

Proposed date of entry into force: June 2024 (planned)

**10. Final date for comments:** 60 days from notification

11. Texts available from: National enquiry point [ ] 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 01013 00 e.pdf