



1 September 2025

(25-5445)

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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 (MHLW)
3.	Notified under Article 2.9.2 [], 2.10.1 [X], 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): Substances with probable effects on the central nervous system
5.	Details of notified document(s) (title, number of pages and languages, means of access): Designation of <i>Shitei Yakubutsu</i> (designated substances), based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter referred to as the Act). (1960, Law No.145); (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_05765_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: Proposal for the additional designation of 3 substances as <i>Shitei Yakubutsu</i> , and their proper uses under the Act.
7.	Objective and rationale, including the nature of urgent problems where applicable: In order to prevent the abuse of substances with probable effects on the central nervous system and to clarify the regulation under the Act, the MHLW designates such substances as <i>Shitei Yakubutsu</i> . Manufacture, import, sale, simple ownership and the use of <i>Shitei Yakubutsu</i> are banned except for the proper uses designated under the Act.

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>

When adopted, *Shitei Yakubutsu* (designated substances) and their proper uses will be publicized in the Official Gazette, *KAMPO*.

Relevant notifications:

- [G/TBT/N/JPN/870](#)

9. Proposed date of adoption: 29 August 2025

Proposed date of entry into force: 8 September 2025

10. Provision of comments

Final date for comments: Not Applicable

[] 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