



12 December 2025

(25-8452)

Page: 1/2

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 [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): 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_08878_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 1 substance 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

<p>When adopted, <i>Shitei Yakubutsu</i> and their proper uses will be publicized in the Official Gazette, <i>KAMPO</i>.</p> <p>Relevant notifications:</p> <ul style="list-style-type: none">• G/TBT/N/JPN/884
<p>9. Proposed date of adoption: February, 2026 (planned)</p> <p>Proposed date of entry into force: February, 2026 (planned)</p>
<p>10. Provision of comments</p> <p>Final date for comments: 10 February 2026</p> <p>[X] 60 days from notification</p> <p>Contact details of agency or authority designated to handle comments regarding the notification:</p> <p>Japan Enquiry Point International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs Fax: (+81 3) 5501 8343 E-mail: enquiry@mofa.go.jp</p>