



5 January 2024

(24-0080)

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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

<b>1. Notifying Member:</b> <u>JAPAN</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Ministry of Health, Labour and Welfare (MHLW) <b>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:</b>
<b>3. Notified under Article 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Substances with probable effects on the central nervous system
<b>5. Title, number of pages and language(s) of the notified document:</b> 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)
<b>6. Description of content:</b> Proposal for the additional designation of 1 substance group as <i>Shitei Yakubutsu</i> , and their proper uses under the Act.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> 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.
<b>8. Relevant documents:</b> The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. <a href="https://www.japaneselawtranslation.go.jp/en/laws/view/3213">https://www.japaneselawtranslation.go.jp/en/laws/view/3213</a> When adopted, <i>Shitei Yakubutsu</i> (designated substances) and their proper uses will be publicized in the Official Gazette, <i>KAMPO</i> .
<b>9. Proposed date of adoption:</b> 27 December 2023 <b>Proposed date of entry into force:</b> 6 January 2024

**10. Final date for comments:** Not Applicable

**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](mailto:enquiry@mofa.go.jp)

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