



3 November 2014

(14-6344)

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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 (Article 3.2 and 7.2):
2. Agency responsible: Ministry of Health, Labour and Welfare (MHLW) 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 [], 2.10.1 [X], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Substances with probable effects on the central nervous system
5. Title, number of pages and language(s) of the notified document: Designation of "Shitei Yakubutsu" (designated substances), based on the provision of the Pharmaceutical Affairs Law (1960, Law No.145) (1 page, in English)
6. Description of content: Proposed "Shitei Yakubutsu" (designated substances), and their "proper uses" designated under the Pharmaceutical Affairs Law.
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 Pharmaceutical Affairs Law, the MHLW designates such substances as "Shitei Yakubutsu". Manufacture, import and sale, simple ownership and the use of "Shitei Yakubutsu" are banned except for the "proper uses" designated under the Law.
8. Relevant documents: When adopted, "Shitei Yakubutsu" (designated substances) and their proper uses will be publicized in the Official Gazette, "KAMPO"
9. Proposed date of adoption: 29 October 2014 Proposed date of entry into force: 8 November 2014
10. Final date for comments: Not applicable
11. Texts available from: National enquiry point [X] 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 http://members.wto.org/crnattachments/2014/tbt/jpn/14_4905_00_e.pdf

(Attachment)

Designation of “Shitei Yakubutsu” (designated substances) based on the provision of the Pharmaceutical Affairs Law (1960, Law No.145)

In order to clarify the regulation under the Pharmaceutical Affairs Law, the Minister of Health, Labour and Welfare of Japan proposes to designate the following substances as “Shitei Yakubutsu” (designated substances). Manufacture, import, sale, simple ownership and the use of “designated substances” are banned except for the “proper uses” (see below).

- The proposed substances as “Shitei Yakubutsu”
※Abbreviation is put in parentheses.
- 1. *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)-1*H*-indazole-3-carboxamide (5CI-AB-PINACA)
- 2. Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (NM2201)
- 3. Naphthalen-1-yl 1-pentyl-1*H*-indazole-3-carboxylate (SDB-005)
- 4. Naphthalen-1-yl(9-pentyl-9*H*-carbazol-3-yl)methanone (EG-018)
- 5. (4-Methylpiperazin-1-yl)(1-pentyl-1*H*-indol-3-yl)methanone (MEPIRAPIM)
- 6. Methyl 2-[1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido]-3-methylbutanoate (FUB-AMB)
- 7. Methyl 2-[1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide]-3,3-dimethylbutanoate (5F-ADB,MDMB2201 indazole analog)
- 8. Methyl 3-methyl-2-(1-pentyl-1*H*-indazole-3-carboxamido)butanoate (AMB)
- The “proper uses” for all “Shitei Yakubutsu”, designated based on the Law
 1. To be used for researches or tests at the government, the local governments, agencies thereof, technical colleges, inter-university research institutes, the independent administrative agencies and the local independent administrative agencies
 2. To be used for tests under the Pharmaceutical Affairs Law, and
 3. To be used for forensic use