



29 November 2017

(17-6545)

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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 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 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Pharmaceutical, quasi-drug, cosmetic, medical device and regenerative medicine products (hereinafter referred to as "pharmaceuticals, etc.").
5. Title, number of pages and language(s) of the notified document: Partial amendment to the Standard for Biological Ingredients (1 page(s), in English)
6. Description of content: The Standard for Ruminant-Derived Ingredients in the Standard for Biological Ingredients (the notification No.210 of MHLW, 2003): To delete bovine-derived "placenta" and "spleen" from the list of the parts which must not be used as source materials for manufacturing pharmaceuticals, etc., in accordance with the revision of the Standard for Ruminant-Derived Ingredients.
7. Objective and rationale, including the nature of urgent problems where applicable: To provide guidance for necessary measures to be taken when a biological ingredient is used in manufacturing pharmaceuticals, etc.
8. Relevant documents: The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. This amendment will be published in "KAMPO" (Official Gazette) when adopted.
9. Proposed date of adoption: Late February, 2018 Proposed date of entry into force: Late February, 2018
10. Final date for comments: 60 days from notification
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 https://members.wto.org/crnattachments/2017/TBT/JPN/17_5326_00_e.pdf