



3 April 2018

(18-1978)

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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 products (HS 30)
5. Title, number of pages and language(s) of the notified document: Partial amendment to the Minimum Requirements for Biological Products. (1 page(s), in English)
6. Description of content: The Minimum Requirements for Biological Products shall be partially amended to revise the standard for the "Rotavirus live attenuated, Oral, Pentavalent vaccine".
7. Objective and rationale, including the nature of urgent problems where applicable: To establish the standard for manufacturing process, properties, quality, storage and others of pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation (Biological products)
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: The same day as the approval of the said vaccine. Proposed date of entry into force: The same day as the approval of the said vaccine.
10. Final date for comments: 30 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/2018/TBT/JPN/18_1806_00_e.pdf