



9 June 2023

(23-3948)

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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 [], 3.2 [], 7.2 [], 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. Partial amendment to The Public Notice on National Release Testing.; (1 page(s), in English)
6. Description of content: The Minimum Requirements for Biological Products will be amended as follows ; The standard name of "nucleoside modified coronavirus RNA Vaccine (SARS-CoV-2)" will be amended to "coronavirus (SARS-CoV-2) RNA Vaccine". Accordingly, the test for pH, storage and expiry date will be deleted and partially amended for the above-mentioned vaccine. The Public Notice on National Release Testing will be amended as follows ; The standard name of "nucleoside modified coronavirus RNA Vaccine (SARS-CoV-2)" will be amended to "coronavirus (SARS-CoV-2) RNA Vaccine". In addition, the criterion of "Adsorbed Diphtheria-purified Pertussis-tetanus-inactivated polio Haemophilus TYPE b Combined Vaccine" will be partially amended. Accordingly, the fee, criterion, and quantity for National Release Testing of the above-mentioned vaccine will be partially amended.
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). In addition, to stipulate the pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation as subject to National Release Testing, as well as fee, criterion and quantity for the testing.

8. Relevant documents: Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. https://www.japaneselawtranslation.go.jp/en/laws/view/3213 This amendment will be published in "KAMPO" (Official Gazette) when adopted.
9. Proposed date of adoption: August 2023 Proposed date of entry into force: August 2023
10. Final date for comments: 30 days from notification
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 https://members.wto.org/crnattachments/2023/TBT/JPN/23_10142_00_e.pdf