NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Japan  **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:** 1) Partial amendment to the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and 2) Partial amendment to the Public Notice on Designated Biological Products under Article 197, Paragraph 2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (1 page(s), in English) |
| **6.** | **Description of content:** The Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and the Public Notice on Designated Biological Products under Article 197, Paragraph 2 of the Regulation for Enforcement will be partially amended to reflect the World Health Organization (WHO) standard on Summary Lot Protocol (SLP). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** With regard to National Release Testing of biological pharmaceuticals such as vaccines and blood products by national regulatory authority, an international standard for assessment process of SLP has been provided by WHO. In Japan, the SLP dossiers to be submitted for application of National Release Testing are specified under Article 197, Paragraph 2 of the Regulation for Enforcement, for biological pharmaceuticals designated by the Minister of Health, Labour and Welfare. This partial amendment will extend the designated biological pharmaceuticals to any biological pharmaceuticals.; Other |
| **8.** | **Relevant documents:**  The Act 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:** June 2021.  **Proposed date of entry into force:** July 2021. |
| **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](mailto:enquiry@mofa.go.jp)  <https://members.wto.org/crnattachments/2021/TBT/JPN/21_2467_00_e.pdf> |