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:** Partial amendment to the Minimum Requirements for Biological Products (1 page(s), in English) |
| **6.** | **Description of content:** Amendment of the provisions for Potency test in the "Recombinant Adsorbed Hepatitis B Vaccine (Prepared from Yeast)".Amendment of the provisions for Final bulk and final product in the "Polyethylene Glycol-treated Human Anti-HBs Immunoglobulin", and for Test procedures in the "Test for Measuring the Potency of Human Anti-HBs Immunoglobulin". |
| **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); Other |
| **8.** | **Relevant documents:** Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. <http://www.japaneselawtranslation.go.jp/law/detail/?id=3213&vm=04&re=2&new=1>This amendment will be published in "*KAMPO*" (Official Gazette) when adopted. |
| **9.** | **Proposed date of adoption:** In November 2021**Proposed date of entry into force:** In November 2021 |
| **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 PointInternational 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/2021/TBT/JPN/21_6472_00_e.pdf> |