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 [****], 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 code(s): 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Partial amendment to the Minimum Requirements for Biological Products (1 page, available in English)  Partial amendment to The Public Notice on National Release Testing. |
| **6.** | **Description of content:** The Minimum Requirements for Biological Products will be amended as follows；To add the standard, criterion, fee and quantity for a vaccine product to be newly approved; "Meningococcal tetravalent polysaccharide tetanus toxoid conjugate vaccine", "Pneumococcal 15-valent conjugate vaccine". Partially amended to "Meningococcal tetravalent polysaccharide diphtheria toxoid conjugate vaccine", "Pneumococcal Vaccine Polyvalent", "Pneumococcal 13-valent conjugate vaccine", "Smallpox Vaccine Prepared in Cell Culture", "Freeze-dried Smallpox Vaccine Prepared in Cell Culture". To delete "Pneumococcal 10-valent conjugate vaccine", "Smallpox Vaccine", "Freeze-dried Smallpox Vaccine".  The Public Notice on National Release Testing will be amended as follows； To add the criterion, fee and quantity for a vaccine product to be newly approved; "Meningococcal tetravalent polysaccharide tetanus toxoid conjugate vaccine", "Pneumococcal 15-valent conjugate vaccine". Partially amended to "Meningococcal tetravalent polysaccharide diphtheria toxoid conjugate vaccine", "Pneumococcal Vaccine Polyvalent", "Pneumococcal 13-valent conjugate vaccine", "Smallpox Vaccine Prepared in Cell Culture", "Freeze-dried Smallpox Vaccine Prepared in Cell Culture". To delete "Pneumococcal 10-valent conjugate vaccine", "Smallpox Vaccine", "Freeze-dried Smallpox 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). 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:** September 2022  **Proposed date of entry into force:** September 2022 |
| **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](mailto:enquiry@mofa.go.jp)  <https://members.wto.org/crnattachments/2022/TBT/JPN/22_4626_00_e.pdf> |