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 Agriculture, Forestry and Fisheries (MAFF)  **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):** Veterinary biologics except in vitro diagnostics |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Amendment of the Ministerial Ordinances "Regulatory Rules for Veterinary Medicinal Products" and "Manufacturing Quality and Quality Control of Veterinary Pharmaceutical Products" |
| **6.** | **Description of content:** The Ministerial Ordinances "Regulatory Rules for Veterinary Medicinal Products" and "Manufacturing Quality and Quality Controlof Veterinary Pharmaceutical Products" to introduce new quality control measures for veterinary biologics by the government. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** With the advancement of veterinary and scientific technology, to introduce review by the government on summary documents for manufacturing and quality control records of veterinary biologics, instead of laboratory testing. |
| **8.** | **Relevant documents:**   * Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (No. 145 of 10 August 1960)   (<http://www.japaneselawtranslation.go.jp/law/detail/?id=3213&vm=04&re=01&new=1>).  This amendment will be published in "KAMPO" (Official Gazette, Available in Japanese). |
| **9.** | **Proposed date of adoption:**March 2019  **Proposed date of entry into force:**3 years after the date of its publication in "KAMPO" |
| **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 TBT 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/2019/TBT/JPN/19_0328_00_e.pdf> |