NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Republic of Korea **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Ministry of Food and Drug Safety**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:** Documents are available from the Ministry of Food and Drug safety website ([www.mfds.go.kr](http://www.mfds.go.kr)). Also available from: International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564Fax: (+82) 43-719-1550Email: wtokfda@korea.kr |
| **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):** Pharmaceuticals; PHARMACEUTICAL PRODUCTS (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** The Amendment to the "Regulation on Designation, and Approval Procedure and Method of Pharmaceutical Products for National Lot Release" (25 page(s), in Korean) |
| **6.** | **Description of content:** The Amendment to the Regulation on Designation, and Approval Procedure and Method of Pharmaceutical Products for National Lot Release: 1. Clarifies details, including quantity of samples, period for the procedure, etc., of SARS-CoV-2 viral vector vaccines and other newly authorized pharmaceutical products subject to national lot release;
2. Clarifies products subject to be classified as carrying risk level 3 (subject to summary protocol review and test on entire items) as products (A) which have received national lot release inappropriately, (B) of which master formula is not provided during on-site inspection, or (C) for which false test results were submitted; and
3. Modifies quantity for samples of items including anti-tetanus immunoglobulin.
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| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Quality requirements |
| **8.** | **Relevant documents:** Notification No. 2021-616 by MFDS (December 27, 2021) |
| **9.** | **Proposed date of adoption:** To be determined**Proposed date of entry into force:** To be determined |
| **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:** Korea WTO TBT Enquiry PointTechnical Barriers to Trade (TBT) DivisionKorean Agency for Technology and Standards (KATS)93 Isu-ro Maengdong-myeon Eumseong-gunChungchungbuk-do 27737+(82) 43 870 5525+(82) 43 870 5682 (Fax)tbt@korea.kr<http://www.knowtbt.kr><https://members.wto.org/crnattachments/2022/TBT/KOR/22_0275_00_x.pdf> |