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). Also available from:  International Cooperation Office  Ministry of Food and Drug Safety (MFDS)  187 Osongsaengmyeong 2-ro, Osong-eup, Heungdoek-gu Cheongju-si,  Chungcheongbuk-do, 28159  Republic of Korea  Tel: (+82) 43-719-1564  Fax: (+82) 43-719-1550  Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **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):** Medicinal Products, Pharmaceuticals |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed amendments to the Regulations on GMP for Medicinal Products; (161 page(s), in Korean) |
| **6.** | **Description of content:** The Regulations on GMP for Medicinal Products defined detailed guidelines and principles of good manufacturing practice for medicinal products. The following is the proposed amendment to this Regulations :  - Annex 1, Annex 2 and Annex 2of2 to this regulations are amended to be equivalent to Annex 1, Annex 2B and Annex 2A of the current PIC/S GMP Guide. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**  MFDS Public Notice No. 2023-453, (8 September 2023) |
| **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 [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Technical Barriers to Trade (TBT) Division  Korean Agency for Technology and Standards (KATS)  93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, 27737, Republic of Korea  Tel.: (+82) 43-870-5315  Fax: (+82) 43-870-5682  E-mail: [tbt@korea.kr](mailto:tbt@korea.kr)  Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2023/TBT/KOR/23_12279_00_x.pdf> |