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, 363-700 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 |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulation on Safety of Pharmaceuticals, etc. (46 page(s), in Korean) |
| **6.** | **Description of content:** This is to determine the matters entrusted by the law and the details necessary for its implementation including monitoring the implementation of procedures and conditions necessary for Conditional Marketing Authorization (CMA) and establishing Standard Operation Procedure (SOP) for Site Management Organization (SMO) and the Central Institution Review Board (IRB), following the revision of 'Pharmaceutical Affairs Act' (Act No.18307, Promulgation Date, 20 Jul, 2021, Enforcement Date, 21 Jan, 2022), which aims to provide legal basis on CMA which authorizes marketing under the condition that clinical trials result for the medicine user should be submitted and clinical trials consigned and conducted by IRB. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** To compensate the inadequacies of the current operating system; Other |
| **8.** | **Relevant documents:** Notification No. 2021-505 by MFDS (19 OCT, 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/2021/TBT/KOR/21_6959_00_x.pdf> |