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 Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159  Republic of Korea  Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: [wtokfda@korea.kr](mailto: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, quasi-drug |
| **5.** | **Title, number of pages and language(s) of the notified document:** Notification on Partial Amendment of 'Regulation for Pharmaceutical Approval, Notification and Reviews' (43 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety, Republic of Korea intends to revise the following matters in *Regulation for Pharmaceutical Approval, Notification and Reviews.*  1.Reinforcement of change control including manufacturing procedure for prescription drug  2. Abolishment of mandatory regulation on submission of manufacturing and Free Sales Certificate for imported new drug.  3. New Establishment on Example of indications of precaution for use by specifying package unit for disposable ophthalmic solutions at less than 0.5ml  4. Abolishment of foreign national drug formularies-based system to strengthen scientific evidence-based safety and validity review system |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Ensuring Pharmaceutical Safety Management; Protection of human health or safety; Other |
| **8.** | **Relevant documents:**  Notification No. 2020-590 by MFDS (Dec 29, 2020) |
| **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 Point Technical Barriers to Trade (TBT) Division Korean Agency for Technology and Standards (KATS) 93 Isu-ro Maengdong-myeon Eumseong-gun Chungchungbuk-do  27737 +(82) 43 870 5525 +(82) 43 870 5682 (Fax) [tbt@korea.kr](mailto:tbt@korea.kr) <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2021/TBT/KOR/21_7002_00_x.pdf> |