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, Chungcheongbukdo,28159Republic of KoreaTel: (+82) 43 719-1564Fax: (+82) 43-719-1550Email: intmfds@korea.kr |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****X],** **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:** Standard on Pharmaceutical Equivalence Study (9 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is issuing the proposed amendments to the regulation notified as MFDS Notice "Standard on Pharmaceutical Equivalence Study". The content of the amendments is as follows.1. In an aim to enhance the credibility for the quality of generic drugs, the acceptance criteria of bioequivalence study have been adjusted upwards to the level of advanced countries. Also, the standards on the selection of reference products in case of approval for change have been strengthened.2. Pharmaceutical equivalence study shall only be conducted with referenced products published by MFDS. In addition, the exemption criteria have been modified for bioequivalence tests between products that have been proved to be bioequivalent to its originals and the products that are also bioequivalent but have different strength with them. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** To harmonize with global regulations on generic medicines |
| **8.** | **Relevant documents:** * MFDS NOTIFICATION No. 2019-541 (27 November 2019)
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| **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:** Technical Barriers to Trade (TBT) DivisionKorean Agency for Technology and Standards (KATS)93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, 27737 Republic of KoreaTel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682E-mail: tbt@korea.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_7037_00_x.pdf> |