



10 July 2024

(24-5037)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>REPUBLIC OF KOREA</u> 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 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: intmfds@korea.kr
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 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 partial amendments to the "Regulation on the Registration of Drug Substance; (11 page(s), in Korean)
6. Description of content: The proposed amendments to the "Regulation on the Registration of Drug Substance" are as follows: A. to clarify the expert in the medicine and pharmacy who reviewed translated documents for registration of drug substance and allow English translation of submitted documents written in other foreign languages. (Article 3 of the draft) B. to simplify the requirement for registration of drug substance by replacing Good Manufacturing Practice (GMP) inspection with submission of a GMP certificate and modify the relevant provisions (Article 4 and 5 of the draft and Annex 2)
7. Objective and rationale, including the nature of urgent problems where applicable: Cost saving and productivity enhancement

8. Relevant documents: MFDS NOTIFICATION No. 2024-323, 5 July 2024
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, Republic of Korea, 369-811 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2024/TBT/KOR/24_04453_00_x.pdf