



14 December 2023

(23-8574)

Page: 1/2

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): Pharmaceuticals |
| 5. Title, number of pages and language(s) of the notified document: Proposed amendments to the "ENFORCEMENT DECREE OF THE PHARMACEUTICAL AFFAIRS ACT"; (3 page(s), in Korean) |
| 6. Description of content: To implement the revision of the Act without difficulties by establishing specific criteria for the fine in the case of failure to report the reason for expiration of priority marketing authorization, which is responsible by the law, with the revision of [Pharmaceutical Affairs Act] (Act No, 19652, promulgation Date 16 Aug,2023, Enforcement Date 17, Feb,2024,), which includes that a person who obtained a priority marketing authorization that can market a medicine in priority to the identical medicine by receiving judgement or decision that means the medicine doesn't fall within the invalidity or the scope of patent right shall report it to the Minister of Ministry of Food and Drug Safety when a reason arises to the patent to expire. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: to complement the shortcomings of the current operating system |

| |
|--|
| 8. Relevant documents: MFDS NOTIFICATION No. 2023-571, 12 December 2023 |
| 9. Proposed date of adoption: To be determined Proposed date of entry into force: To be determined |
| 10. Final date for comments: 40 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 5315 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2023/TBT/KOR/23_14529_00_x.pdf |