WORLD TRADE ORGANIZATION

G/TBT/N/KOR/1309

18 September 2025

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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:** REPUBLIC OF KOREA **If applicable, name of local government involved (Articles 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Food and Drug Safety
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable):** (HS code(s): 30) Pharmaceuticals
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Proposed amendment to the "Regulations on Fees for Pharmaceutical Approval, etc."; (12 page(s), in Korean) **Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request:** https://members.wto.org/crnattachments/2025/TBT/KOR/25_06131_00_x.pdf Documents are available from the Ministry of Food and Drug Safety (MFDS) website: www.mfds.go.kr International Cooperation Office, Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564, Fax: (+82) 43-719-1550, Email: intmfds@korea.kr
6.	**Description of content:** The Ministry of Food and Drug Safety (MFDS) is amending the "Regulations on Fees for Pharmaceutical Approval, etc." as follows: A. Increase in application fees for biosimilar products approval and preliminary review (3 and 26 of Annex 1 in the Draft) • The fees that have been applied to new biologics are separately classified as biosimilar products. The fee for manufacturing authorization (MA) is increased from 8.03 million won (approximately $5,782) to 310 million won (approximately $223,246), and the fee for preliminary safety/efficacy review from 3.01 million won (approximately $2,167) to 155 million won (approximately $111,623), to reflect actual circumstances. B. Fee reduction for biosimilar products from small and medium-sized enterprises (newly established Article 2 (4) (c) in the Draft) • To reduce the fees for biosimilar products developed by small and medium-sized enterprises in Korea by 50%.

	C. Fee reduction of the second MA application for biosimilar products by the same applicant (3 and 26 of Annex 1 in the Draft) • When the same applicant files the second application for a different dosage or injection dosage form (including vial, ampule, Pen) for the newly established biosimilar product fee, the current fees for new biologics are applied from the second application.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Improvement of operational deficiencies in the current system.
8.	**Relevant documents:** MFDS NOTIFICATION No. 2025-393 (11 September 2025)
9.	**Proposed date of adoption:** 1 January 2026 **Proposed date of entry into force:** 1 January 2026
10.	**Provision of comments** **Final date for comments:** 17 November 2025 **[X] 60 days from notification** **Contact details of agency or authority designated to handle comments regarding the notification:** Korea WTO TBT Enquiry Point Technical Regulatory Policy Division Korean Agency for Technology and Standards (KATS) 93 Isu-ro Maengdong-myeon Eumseong-gun Chungchungbuk-do 27737 Tel: +(82) 43 870 5315 Fax: +(82) 43 870 5682 Email: tbt@korea.kr Website: https://www.knowtbt.kr