WORLD TRADE ORGANIZATION

G/TBT/N/KOR/1337

8 January 2026

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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:** 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 (MFDS)
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):** Pharmaceuticals
5.	**Details of notified document(s) (title, number of pages and languages, means of access):** Proposed revision of the "Korean Pharmacopoeia"; (4 page(s), in Korean), (8 page(s), in Korean), (15 page(s), in Korean), (1484 page(s), in Korean), (357 page(s), in Korean), (362 page(s), in Korean), (265 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/2026/TBT/KOR/26_00150_00_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_01_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_02_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_03_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_04_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_05_x.pdf https://members.wto.org/crnattachments/2026/TBT/KOR/26_00150_06_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 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) of the Republic of Korea intends to revise the following provisions of the Korean Pharmacopoeia:

To respond to changes in the international regulatory environment, the Korean Pharmacopoeia (KP) will be completely revised from the 12th to the 13th edition. This revision aims to ensure the distribution of quality-assured pharmaceuticals and secure competitive edge in global markets by reorganizing KP and harmonizing pharmaceutical standards and specifications internationally.

A. Revisions based on international harmonization of Pharmacopoeia Discussion Group (PDG) (Appendix 1, 5 and 6 of the draft)

- Replacement of "Korean Pharmacopoeia 12th edition" with "Korean Pharmacopoeia 13th edition" in Article 1.1 of General Notices (Appendix 1 of the draft)
- Harmonization of two methods (mass variation test for uniformity of dosage units and disintegration test for suppositories and vaginal tablets) with PDG standards (Appendix 5 of the draft)
- Reflection of the latest revisions to the PDG guidelines for international harmonization (Appendix 6 of the draft)

B. Revision of General Notices and General Requirements for Pharmaceutical Preparations of the Korean Pharmacopoeia (Appendix 1 and 2 of the draft)

C. Corrections of errors and reorganization of test methods and terminology in Monographs and General Tests (Appendix 3, 4 and 5 of the draft)

- Partial amendments to 28 specifications including application of a common assay to drug substances and drug products for "Cefotiam Hexetil Hydrochloride Tablets" in Part 1 Monographs (Appendix 3 of the draft)
- Additionof a new test method (Method2) utilizing state of the art analytical equipment for purity tests of "MumeFruit" and "Amomum Tsao-ko Fruit" to Part 2 of the Monographs (Appendix 4 of the draft)
- Partial amendments to 6 specifications including preparation of Ninhydrin Sodium Bisulfite solution for identification of Hydroxypropyl Starch in part 2 of the Monographs (Appendix 4 of the draft)
- Refinement of terminology in General Tests (Appendix 5 of the draft)

D. Addition of new test methods to General Tests (Appendix 5 of the draft)

- Addition of two test methods (Delivered Dose Uniformity (DDU) and Aerodynamic Particle Size Distribution (APSD) testing for inhalers) for quality control of bronchial and pulmonary preparations

E. Addition of new test methods to General Information(Appendix 6 of the draft)

- Addition of two test methods (nucleic acid-based method and rapid microbial detection method for advanced biopharmaceuticals) for R&D and quality assessment of advanced biopharmaceuticals including cell and gene therapy
- Provision of Information for the management of microbial limit tests (application of water activity measurement test to non-sterile drugs) and quality control of additive ethanol (Alcoholometric Table)
- Addition of two test methods (standardization method for crude drugs and genetic analysis method for herbal (crude) medicines) as reference for the quality control of herbal (crude) medicines

7. **Objective and rationale, including the nature of urgent problems where applicable:** Quality requirements; Harmonization

8. **Relevant documents:**

MFDS NOTIFICATION No.2025-538, 31 December 2025

9.	**Proposed date of adoption:** To be determined **Proposed date of entry into force:** To be determined
10.	**Provision of comments** **Final date for comments:** 9 March 2026 **[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 Agricultural products: Quarantine Policy Division Ministry of Agriculture, Food and Rural Affairs (MAFRA) 94, Dasom 2-ro, Sejong-si Sejong-si Sejong-si 339-012 Tel: +(82 44) 201-2080 Fax: +(82 44) 868-0449 Email: wtoagri@korea.kr