WORLD TRADE ORGANIZATION

G/TBT/N/KOR/1227

2 September 2024

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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 (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Food and Drug Safety (MFDS) **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 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 Safety of Pharmaceuticals, etc."; (11 page(s), in Korean)
6.	**Description of content:** The proposed amendments to the "Regulation on Safety of Pharmaceuticals, etc." are as follows: A. Specification of submission and follow up of Risk Management Plan (Article 4 and 8 of the draft) To specify the data including legal sources that the person, who already obtained marketing authorization for the product provided with its Risk Management Plan, is required to summit when applying for another marketing authorization for new product or change. B. Streamlined process of approval for change (Article 8) To provide a legal basis for addressing changes in the medical product item together with approval for or notification of change, in case an application for approval for change in pharmaceutical manufacturing business (import) is submitted due to the change of

	manufacturer (importer) name or business site. C. Specification of subject and items to be disclosed for data protection (newly established Article 21 bis) To specify the pharmaceuticals subject to data protection to be determined by Ordinance of Prime Minister under the Pharmaceutical Affairs Act and the items to be disclosed including product name, manufacturer name and protection period D. Specification of the subject for submission of a risk management plan (newly established Article 23 bis) To specify the product to establish a Risk Management Plan to be determined by Ordinance of Prime Minister under the Pharmaceutical Affairs Act
7.	**Objective and rationale, including the nature of urgent problems where applicable:** to compensate the inadequacies of the current operating system
8.	**Relevant documents:** MFDS NOTIFICATION No. 2024-403, 30 August 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 [X] 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, 27737, Republic of Korea Tel: (+82) 43-870-5521~8 Fax: (+82) 43-870-5682 Email: tbt@korea.kr https://members.wto.org/crnattachments/2024/TBT/KOR/24_05793_00_x.pdf