WORLD TRADE ORGANIZATION

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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 **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, 363-700 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: wtokfda@korea.kr
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Biological Products
5.	**Title, number of pages and language(s) of the notified document:** Proposed amendments to the "Regulation on Approval and Review of Biological Products." (31 page(s), in Korean)
6.	**Description of content:** • Whereas the products with the same strength of active ingredients, dosage form and route of administration for each unit dose are approved as one product, orphan drugs can be approved as separate products. • Domestic pharmaceutical companies may manufacture drugs using contract-manufacturing in overseas manufacturing facilities, which are established or whose shares are largely held by the domestic pharmaceutical companies. Importers of pharmaceuticals may also entrust part of the manufacturing process of import products to domestic manufacturers. • If pharmaceutical companies change strains of the approved influenza vaccines, the products should be reviewed in order to ensure safety and efficacy. • The approved pharmaceuticals described as "in-house packaging units" or

	"manufacturer's packaging units" did not indicate the specific packaging unit information under the current regulation. As a result, consumers couldn't check the dosage or the total number of drugs in circulation. Under the amended regulation, however, more detailed packaging unit information of approved drugs will be provided. • The amended regulation provides bases that can be used to subject orphan drugs to re-examination upon consent of the applicant company. • Please refer to the attached document for information on other revisions to the Regulation.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Protection of consumer health
8.	**Relevant documents:** MFDS Notification No. 2018-145 (6 April 2018)
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@korea.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2018/TBT/KOR/18_2134_00_x.pdf