NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **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:**  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 E-mail: [intmfds@korea.kr](mailto:intmfds@korea.kr) Website: [www.mfds.go.kr](http://www.mfds.go.kr) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****X],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Advanced Biological Products (HS: 3004-90-9900); Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packings for retail sale (excl. medicaments containing antibiotics, medicaments containing hormones or steroids used as hormones, but not containing antibiotics, medicaments containing alkaloids or derivates thereof but not containing hormones or antibiotics and medicaments containing provitamins, vitamins or derivates thereof used as vitamins) (HS 300490) |
| **5.** | **Title, number of pages and language(s) of the notified document:** The draft regulation on the "Review and Approval of Advanced Biological Products" (94 page(s), in Korean) |
| **6.** | **Description of content:** As the Act on the Safety and Support of Advanced Biological Products was established, the Regulations on the Review and Approval of Advanced Biological Products was enacted to stipulate document requirements and evaluation criteria for the approval of advanced biological products. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Adoption of Domestic Law; Protection of human health or safety; Other |
| **8.** | **Relevant documents:**   * MFDS NOTIFICATION No. 2020-282 (3 July 2020); * G/TBT/N/KOR/891 - The enactment of enforcement rules for advanced biological products regarding safety and support (27 April 2020). |
| **9.** | **Proposed date of adoption:** 28 August 2020  **Proposed date of entry into force:** 28 August 2020 |
| **10.** | **Final date for comments:** 20 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, Republic of Korea, 27737 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: [tbt@korea.kr](mailto:tbt@korea.kr)  Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_4173_00_x.pdf> |