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:** Documents are available from the Ministry of Food and Drug safety (MFDS) website ([www.mfds.go.kr](http://www.mfds.go.kr)). Also available from: International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564Fax: (+82) 43-719-1550Email: wtokfda@korea.kr |
| **3.** | **Notified under Article 2.9.2 [ ],** **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):** Cell therapy and Gene therapy, Biopharmaceutics |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed Revision of the "Regulation on Approval and Review of Biological Products" (27 page(s), in Korean) |
| **6.** | **Description of content:** The main proposed amendments is as the following:- For the Biopharmaceutical's safety, Cell Therapy and Gene Therapy Product's manufacturer using the cell banking system should submit the cell consistency data (Short tandem repeat, etc) when establishing and running the cell banking for the approval. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human health and Safety |
| **8.** | **Relevant documents:** * MFDS NOTIFICATION No. 2019- 285 (7 June, 2019)
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| **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) DivisionKorean Agency for Technology and Standards (KATS) 93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, 27737 Republic of KoreaTel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682E-mail: tbt@korea.krWebsite: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_3405_00_x.pdf> |