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 Food and Drug safety 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, Chungcheongbukdo,Republic of Korea 28159Tel: (+82) 43 719-1564Fax: (+82) 43-719-1550Email: intmfds@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):** Medical Devices |
| **5.** | **Title, number of pages and language(s) of the notified document:** Amendments to the "Enforcement Regulation of the Medical Devices Act" (28 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea is amending the "Enforcement Regulation of the Medical Devices Act" as stated below:1. When supply interruptions become predictable for essential medical devices for public healthcare, manufacturers and importers of the devices shall be mandated to report to the Minister of Food and Drug Safety.
2. An administrative disposition on false and misleading advertisement shall be introduced to regulate any actors engaging in marketing activities with exaggerated spoken language or performances trying to sell medical devices for purposes other than their original purposes, approved by the MFDS.
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| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The amendments aim to promote reliable supply and safe management of medical devices. |
| **8.** | **Relevant documents:** * MFDS NOTIFICATION No. 2019-406 (5 September 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, Republic of Korea, 27737Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682E-mail: tbt@korea.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_5309_00_x.pdf> |