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(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, Chengju-si, Chungcheongbuk-do, 28159 Republic of KoreaTel: (+82) 43 719-1564Fax: (+82) 43 719-1550Email: wtokfda@korea.kr |
| **3.** | **Notified under Article 2.9.2 [****X], 2.10.1 [****], 5.6.2 [****], 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):** Pharmaceutics (ICS 11.120). |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulation on Safety of Pharmaceuticals, etc. (63 pages, available in Korean) (63 page(s), in Korean)   |
| **6.** | **Description of content:** From Article 56-3 to 56-7: Develop a concrete procedure regarding the registration and inspection of foreign manufacturing site of imported pharmaceuticals, etc.The following regulation is newly established; where an obligation of registering a foreign manufacturing site is imposed on an importer and measures on the safety of pharmaceuticals are deemed necessary according to the revision of Pharmaceutical Affairs Act, the Minister of Ministry of Food and Drug Safety may ask to suspend the import and order the inspection of quality, etc. and request the correction with the onsite inspection.The purpose of this new regulation is to secure the integrity of the law by regulating mandated matters by the Ordinance of the Prime Minister in Pharmaceutical Affairs Act including a procedure of registering a foreign manufacturing site, a subject to register and notify of changes, a procedure and method of onsite inspection, measures on suspension of import, etc. and any related matter of dissolution, etc. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** MFDS NOTIFICATION No. 2019-088 (22 February 2019)  |
| **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 date of 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@kats.go.kr Website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_0998_00_x.pdf> |