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:**  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 Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) Website: [www.mfds.go.kr](http://www.mfds.go.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):** Pharmaceuticals |
| **5.** | **Title, number of pages and language(s) of the notified document:** The draft regulation of the "Act on pharmaceutical development and support for Public Health Crisis Response" (15 page(s), in Korean) |
| **6.** | **Description of content:** The Ministry of Food and Drug Safety of the Republic of Korea is proposing the draft regulation on the "Act on pharmaceutical development and support for Public Health Crisis Response". The main contents are:  1) Introduction of pharmaceutical designation system for Public Health Crisis Response to effectively develop and supply medicines for treatment diseases that pose a threat to public health (Article 5 of the proposal).  2) The Minister of Food and Drug Safety will provide administrative support to those who intends to develop medicines for public health crisis response, international exchange of technology and human resources, international joint research and development, and implementation of international joint clinical trials (Article 6 and Article 7 of the Proposal).  3)  In order to shorten the review period for marketing approval item of pharmaceutical for public health crisis response, clinical trials data shall be submitted at each development process and a frequent accompanying review system will be introduced to review the result in advance (Article 8 of the Proposal).  4) Where the application for marketing approval item of pharmaceutical for public health crisis response is filed, review for the application shall be taken precedence over the review for the other medicines (Article 9 of the Proposal)  5) The conditional permission of marketing approval item will be introduced, the permission enables to grant marketing approval item with condition that specific medicinal process is implemented to the patient for the pharmaceutical for public health crisis response, if the process is not implemented, the marketing approval will be revokes (Article 10 of the proposal).  6) The Minister of Food and Drug Safety assesses the overall therapeutic value and notify the result by taking into account the safety and efficacy of pharmaceutical for public health crisis response, and the person who has granted marketing approval item shall explore safety precaution for said pharmaceutical for public health crisis response and report it to the minister (Article 11 and Article 12 of the proposal).  7) A person who has granted marketing approval item can support the patient treatment such as providing the patient in need with pharmaceutical free of charge (Article 13 of the proposal).  8) A person who intends to obtain permission for manufacturing a medical device, which is composed of a combination of pharmaceutical for public health crisis response, under the Medical Device Act, shall request the Minister of Food and Drug Safety to use the materials submitted to obtain permission for review the medical device to grant marketing approval item by getting consent for said pharmaceutical from the person who has obtained the permission for pharmaceutical (Article 14 of the proposal). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** To effectively handle public health crisis by ensuring access to effective care and treatment for the patients who have suffered from critical illness through the promotion and support of development and by designating the pharmaceuticals which counteract public health crisis as public health crisis response medical product.; Protection of human health or safety |
| **8.** | **Relevant documents:**  The National Assembly Bill No.2100166 (4 June 2020) |
| **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:**  Korea WTO TBT Enquiry Point Technical Barriers to Trade (TBT) Division Korean Agency for Technology and Standards (KATS) 93 Isu-ro Maengdong-myeon Eumseong-gun Chungchungbuk-do  27737 +(82) 43 870 5525 +(82) 43 870 5682 (Fax) [tbt@korea.kr](mailto:tbt@korea.kr) <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_6263_00_x.pdf> |