



10 July 2024

(24-5034)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| 1. Notifying Member: <u>REPUBLIC OF KOREA</u> If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: Ministry of Food and Drug Safety (MFDS) 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 website (www.mfds.go.kr). Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: intmfds@korea.kr |
| 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other: |
| 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medicinal Products, Pharmaceuticals |
| 5. Title, number of pages and language(s) of the notified document: Proposed partial amendments to the "Regulation on Safety of Pharmaceuticals, etc."; (26 page(s), in Korean) |
| 6. Description of content: The proposed amendments to the "Regulation on Safety of Pharmaceuticals, etc." are as follows: A. Simplification of submission for Good Manufacturing Practice (GMP) conformity assessment (Article 4, 48-bis of the draft, and attached Form 4) - 11 GMP submission requirements for Marketing Authorization will be simplified into 4 requirements including site master file, and in particular, for an imported API (biological product is excluded), the submission can be replaced with an internationally harmonized GMP certificate. B. Simplification of API registration requirement (Article 15, 17 of the draft, attached Form 16 and 17) |

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| <p>- Existing API registration requirement, manufacturer 's certificate of origin or GMP conformity assessment, will be replaced with an internationally harmonized GMP certificate.</p> <p>C. Improvement of verification • inspection for extension of GMP certificate validity (Article 48-quarter of the draft)</p> <p>- A verification • inspection will be improved to extend the GMP certificate validity by verifying or inspecting by means other than on-site inspection, if the Minister of Food and Drug Safety recognizes that, for the reason including no history of significant change within the manufacturing site, as well as no natural disaster.</p> |
| <p>7. Objective and rationale, including the nature of urgent problems where applicable: Reducing trade barriers and facilitating trade</p> |
| <p>8. Relevant documents:</p> <p>MFDS NOTIFICATION No. 2024-322, 5 July 2024</p> |
| <p>9. Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: To be determined</p> |
| <p>10. Final date for comments: 60 days from notification</p> |
| <p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>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, 369-811 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: tbt@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2024/TBT/KOR/24_04457_00_x.pdf</p> |