NOTIFICATION

Revision

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Food and Drug Administration  Ministry of Health and Welfare  No.161-2, Kunyang St,  Nangang District, Taipei City 115-61, Taiwan  Tel: (886-2) 2787-7819  Fax: (886-2)3322-9527  E-mail: [johnnylu1199@fda.gov.tw](mailto:johnnylu1199@fda.gov.tw)  **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:** |
| **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):** Pharmaceutical products; Pharmaceutics (ICS 11.120). |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations for the Patent Linkage of Drugs (Draft) (1 page(s), in English; 15 page(s), in Chinese) |
| **6.** | **Description of content:** To protect the intellectual property of invention industry, as well as reducing the risk of patent infringement of generic drug industry, the Ministry of Health and Welfare proposes a new draft of the Regulation for Patent Linkage of Drugs. Articles 3, 4, 5, 8, 9 and 16 are revised in this new draft. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of pharmaceutical intellectual property |
| **8.** | **Relevant documents:**   * Article 40-19, Pharmaceutical Affairs Act |
| **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:**  WTO/TBT Enquiry Point Bureau of Standard, Metrology and Inspection Ministry of Economic Affairs No.4 Sec 1, Jinan Rd. Zhongzheng Dist., Taipei City 100, Taiwan Tel.: (886-2) 2343-1813 Fax: (886-2) 2343-1804 E-mail: [tbtenq@bsmi.gov.tw](mailto:tbtenq@bsmi.gov.tw)  <https://members.wto.org/crnattachments/2019/TBT/TPKM/19_0604_00_e.pdf>  <https://members.wto.org/crnattachments/2019/TBT/TPKM/19_0604_00_x.pdf> |