NOTIFICATION

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:**  Bureau of Food and Drug Administration  Ministry of Health and Welfare  No.161-2, Kunyang Street  Nangang District, Taipei City 115-61, Taiwan  Tel: (886-2) 2787-7444  Fax: (886-2) 3322-9527  E-mail: [yhchan05@fda.gov.tw](mailto:yhchan05@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 |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft of Regulation for Patent Linkage of Drugs (1 page(s), in English; 12 page(s), in Chinese) |
| **6.** | **Description of content:** To protect the pharmaceutical 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 to implement the patent linkage under the regulation for Patent Linkage of Drugs. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of pharmaceutical intellectual property; Protection of human health or safety |
| **8.** | **Relevant documents:** Articles 40-20 and 40-22, 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 Standards, 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/2018/TBT/TPKM/18_4858_00_e.pdf>  <https://members.wto.org/crnattachments/2018/TBT/TPKM/18_4858_00_x.pdf> |