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:**  Food and Drug Administration  Ministry of Health and Welfare  No.161-2, Kunyang Street  Nangang District, Taipei City 115-61, Taiwan  Tel: (886-2) 2787-7819  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 (HS 30) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulation for the Notification of Drug Patent Linkage Agreements (Draft) (3 page(s), in Chinese) |
| **6.** | **Description of content:** With a view to avoiding delays of registration of other generic drugs and negative impacts on patient's access to medicines resulted from unfair or restrictive competition agreements, the Food and Drug Administration of the Ministry of Health and Welfare drafted the "Regulation for Notification of Drug Patent Linkage Agreements” in accordance with Paragraph 2 of Article 42-19 of the Pharmaceutical Affairs Act to ensure public health and fair market transactions. The content of the draft Regulations includes:   1. The method, content and starting date of reporting reverse payment interest agreements. 2. Obligations of the parties that report the agreements. 3. Notification to the Fair Trade Commission by the central health competent authority of agreements that it considers is likely to violate the Fair Trade Act. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Reducing trade barriers and facilitating trade |
| **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, Section 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_5501_00_x.pdf> |