



18 October 2018

(18-6523)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION 臺灣 通知－藥品

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</u> 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 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: 為避免不公平或限制競爭之協議，延遲其他學名藥之上市，影響病人用藥之可近性、公共衛生與市場交易秩序，衛生福利部食品藥物管理署依據藥事法第 42-19 條第 2 項規定，草擬「西藥專利連結協議通報辦法」。草案內容如下： <ol style="list-style-type: none">1. The method, content and starting date of reporting reverse payment interest agreements. 涉及逆向給付利益協議之通報方式、內容及通報起算日。2. Obligations of the parties that report the agreements. 協議通報當事人應遵行事項。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. 中央衛生主管機關得將所其認定違反公平交易之事項通報公平交易委員會處理。

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: <ul style="list-style-type: none">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 https://members.wto.org/crnattachments/2018/TBT/TPKM/18_5501_00_x.pdf