



14 September 2018

(18-5674)

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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: 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 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. 為了保護研發產業的藥品智慧財產權，以及減少學名藥產業專利侵權的風險，衛生福利部提案依據西藥專利連結施行辦法，以利專利連結制度之施行。
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

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