



1 February 2018

(18-0729)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION 臺灣 通知—原料藥

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 St, Nangang District, Taipei City 115-61, Taiwan Tel: (886-2) 27878000#7486 Fax: (886-2) 27877498 E-mail: chuyiyang@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 [X], 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): Active pharmaceutical ingredients (APIs)
5. Title, number of pages and language(s) of the notified document: Draft Amendment of "Regulations for the Inspection and Examination of Imported Medicaments" (1 page(s), in English; 1 page(s), in Chinese)
6. Description of content: To prevent active ingredients of narcotics from being imported as active pharmaceutical ingredient (API), Ministry of Health and Welfare proposes implementation of border inspections of active pharmaceutical ingredient under the "Regulations for the Inspection and Examination of Imported Medicaments". 為防止製毒原料假冒藥品原料藥進口，衛生福利部依據輸入藥物抽查檢驗辦法，建議實施輸入原料藥邊境查驗。
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Quality requirements
8. Relevant documents: Article 71-1 of the Pharmaceutical Affairs Act, Regulations for the Inspection and Examination of Imported Medicaments
9. Proposed date of adoption: To be determined Proposed date of entry into force: 1 May 2018
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_0631_00_e.pdf

https://members.wto.org/crnattachments/2018/TBT/TPKM/18_0631_00_x.pdf