



26 February 2016

(16-1183)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>CHINA</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: China Food and Drug Administration 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): Chemical drugs. Medicaments (ICS: 11.120.10)
5.	Title, number of pages and language(s) of the notified document: Work Program for the Reform of Chemical Drugs Registration Category (4 pages, in Chinese)
6.	Description of content: After adjustment, new registration category of chemical drugs includes Categories 1-5: Category 1 Innovative drugs not marketed in China and abroad, Category 2 New improved drugs that are not marketed in China and abroad, Category 3 Imitation of drugs that are marketed overseas but unavailable domestically, Category 4 Imitation of drugs that are marketed domestically, Category 5 Application for the domestic marketing authorisation of drugs marketed overseas.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8.	Relevant documents: –
9.	Proposed date of adoption: In the first half of 2016 Proposed date of entry into force: In the first half of 2016
10.	Final date for comments: 60 days after circulation by the WTO Secretariat
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: https://members.wto.org/crnattachments/2016/TBT/CHN/16_0779_00_x.pdf