

9 April 2018

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(18-2137)

Original: English

**Committee on Technical Barriers to Trade** 

## NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: CHINA

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 [ ], 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): Drugs

Medicaments (ICS 11.120.10).

- **5. Title, number of pages and language(s) of the notified document:** "Provisions for Inspection of Drugs (Draft)" (13 page(s), in Chinese)
- **6. Description of content:** The Provisions regulates on the inspections carried out by food and drug supervision and administration authorities, on MAH's drug development and producing processes. The provisions are consisted of 6 chapters and 55 articles including general provisions, basic requirements, inspection and implementation, follow-up treatment, management responsibility and supplementary articles. The provisions will play an important role in standardizing and ensuring the quality of drug inspections.
- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
- 8. Relevant documents: None
- 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 [] or address, telephone and fax numbers and email and website addresses, if available, of other body: WTO/TBT National Notification and Enquiry Center of the People's Republic of China Tel.: +86 10 84603886/84603950

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