



18 January 2018

(18-0496)

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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

<b>1. Notifying Member:</b> CHINA <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> China Food and Drug Administration <b>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:</b>
<b>3. Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Drug (ICS: 11.120.10; HS: 30) Medical device (ICS: 11; HS: 9018, 9019, 9020, 9021, 9022)
<b>5. Title, number of pages and language(s) of the notified document:</b> Provisions for Overseas Inspection of Drugs and Medical Devices (Draft) (23 page(s), in Chinese)
<b>6. Description of content:</b> Provisions for Overseas Inspection of Drugs and Medical Devices is applicable to the overseas development and production inspection of drugs and medical devices which are already on the market or will be on the market in China. The provisions consist of 5 chapters and 35 articles. 5 Chapters including general provisions, determination of the inspection task, inspection, audit and processing, and supplementary articles. The provisions specify the initiation, inspection and follow-up treatment of overseas drug and medical device inspection.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health or safety
<b>8. Relevant documents:</b> -
<b>9. Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> To be determined
<b>10. Final date for comments:</b> 60 days from notification
<b>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  WTO/TBT National Notification and Enquiry Center of the People's Republic of China Tel.: +86 10 84603881/84603950 Fax: +86 10 84603811 E-mail: <a href="mailto:tbt@aqsiq.gov.cn">tbt@aqsiq.gov.cn</a>  <a href="https://members.wto.org/crnattachments/2018/TBT/CHN/18_0440_00_x.pdf">https://members.wto.org/crnattachments/2018/TBT/CHN/18_0440_00_x.pdf</a>