



12 September 2018

(18-5625)

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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

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| 1. Notifying Member: <u>CHINA</u> If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: China 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): Medical Device; Health Care Technology (ICS 11). |
| 5. Title, number of pages and language(s) of the notified document: Regulation for Supervision and Administration of Chinese Agent of Imported Medical Devices (9 page(s), in Chinese) |
| 6. Description of content: This measure is drafted in accordance with the Regulations on the Supervision and Administration of Medical Devices. It aims to strengthen the supervision and administration of imported medical devices, regulate imported medical device agents and ensure the safety and effectiveness of imported medical devices, The agents shall abide by the relevant provisions of the Regulations on the Supervision and Administration of Medical Devices and other laws and regulations, shall be responsible for the authenticity and legality of the related works and take legal responsibility for relevant acts of the agent products. Moreover, the agents shall also satisfy corresponding requirements and fulfill the relevant obligations. |
| 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: 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 National Notification and Enquiry Center of the People's Republic of China Tel.: +86 10 57954630/57954627 E-mail: tbt@aqsiq.gov.cn https://members.wto.org/crnattachments/2018/TBT/CHN/18_4847_00_x.pdf |