WORLD TRADE ORGANIZATION

G/TBT/N/CHN/1313

11 March 2019

(19-1455)

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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:** CHINA **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Justice, the People's Republic of China **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):** Medical devices (HS: 9001-9033); HEALTH CARE TECHNOLOGY (ICS 11)
5.	**Title, number of pages and language(s) of the notified document:** Amendments to Regulations for the Supervision and Administration of Medical Devices (Draft) (25 page(s), in Chinese)
6.	**Description of content:** The *Regulations for the Supervision and Administration of Medical Devices* makes the provisions on whoever engaging in the research and development, production, operation, use, the relevant supervision and administration of medical devices within the territory of China. The Amendment further clarifies the system of medical device marketing licensee, changes the approval of clinical trials to implied licensing, adds provisions including conditional approval and expanded clinic, and makes an explicit request on the establishment of professional inspector system. Meanwhile, for the prominent problems in regulation practice, it also adds the agent management of the overseas medical device marketing licensee, and requirements on the prohibition of the import and sales of used medical devices, etc., improves the systems of clinical evaluation, operation management of type II medical devices and re-examination, and adds the punishment provisions specific to person.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Prevention of deceptive practices and consumer protection; Protection of human health or safety
8.	**Relevant documents:** • Regulations for the Supervision and Administration of Medical Devices
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
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E-mail: tbt@aqsiq.gov.cn

https://members.wto.org/crnattachments/2019/TBT/CHN/19_1434_00_x.pdf