



27 February 2025

(25-1425)

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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: CHINA If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: National Medical Products 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 [], 3.2 [], 7.2 [], other: |
| 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): drug (HS code(s): 30); (ICS code(s): 11.120.10) |
| 5. Title, number of pages and language(s) of the notified document: Regulations on the Supervision and Administration of Drug Production for Export; (34 page(s), in Chinese) |
| 6. Description of content: The purpose of the "Regulations on the Supervision and Administration of Drug Production for Export" is to regulate the drug manufacturing activities of Chinese manufacturers exporting drugs to other countries or regions, and to require the implementation of GMP. It mainly includes the following contents: general provisions, basic requirements, entrusted manufacturing for export, export drug archives, export certification documents (general requirements for export certification documents, Certificate of a Pharmaceutical product, Written confirmation for active substances exported to EU), supervision and management, and supplementary provisions. |
| 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 57954633/ 57954627

E_mail: tbt@customs.gov.cn

https://members.wto.org/crnattachments/2025/TBT/CHN/25_01711_00_x.pdf