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 [****],** **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):** Drug; Medicaments (ICS 11.120.10) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Key points for the Inspection of Drug Marketing Authorization Holders (draft for comments) (7 page(s), in Chinese) |
| **6.** | **Description of content:** These Key points for the Inspection is to provide guidance for the drug supervision and administration department in the supervision and inspection of the MAH. It mainly includes institutions and personnel, quality assurance system, pharmacovigilance management, risk management, post-marketing study, documents and record management, liability compensation, vaccine MAH. etc. |
| **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 57954631 / 57954627 Email: [tbt@customs.gov.cn](mailto:tbt@customs.gov.cn)  <https://members.wto.org/crnattachments/2020/TBT/CHN/20_4124_00_x.pdf> |