NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Macao, China **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Health Bureau**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:** Economic and Technological Development Bureau |
| **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):** Imported new pharmaceuticals containing new active pharmaceutical ingredients |
| **5.** | **Title, number of pages and language(s) of the notified document:** Technical Instruction on Documents Required for Importing New Pharmaceuticals (2 pages, in Chinese and Portuguese) |
| **6.** | **Description of content:** This Technical Instruction prescribes the documents that shall be submitted by pharmaceutical importers/exporters and wholesalers when applying for import of pharmaceuticals containing new active pharmaceutical ingredients |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety, Protection of consumers  |
| **8.** | **Relevant documents:** Macao Special Administrative Region Official Gazette No. 6 Series II, Health Bureau Director's Decision, No. 4/SS/2021 of 10 February 2021.<https://images.io.gov.mo/bo/ii/2021/06/avisosoficiais-6-2021.pdf>  pp119-121 |
| **9.** | **Proposed date of adoption:** 11 February 2021**Proposed date of entry into force:** 11 February 2021 |
| **10.** | **Final date for comments:** N/A |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  |