Notification 20 March 4

Kanto Shinetsu Bureau of Health and Welfare Kinki Bureau of Health and Welfare Okinawa Narcotics Control Branch, Gonakakushu Health Bureau

> Department of Vigilance and Guidance and Narcotic Drugs, Pharmaceutical and Life Health Bureau, Ministry of Health, Labour and Welfare

Handling of certificates of drug supervision associated with outbreaks of new coronavirus infections

Currently, the increasing demand associated with the outbreak of new coronavirus infections has resulted in a shortage of supplies of disinfectant alcohol and other products.

Under these circumstances, pharmaceuticals and medical devices will be imported by the company to be used in-house from the perspective of preventing infection among its employees as shown below. Please respond to this situation.

Notation

- 1. When a company intends to import pharmaceuticals and medical devices (only those intended to be used by the general public as infection prevention measures) for the purpose of in-house use as countermeasures against new-type coronavirus infections in its employees, it may be used as an object for dispensing certificates of pharmacovigilance.
- 2. When issuing the pharmaceutical inspector certification, the importer shall be required to submit the following documents and carry out the necessary confirmation.
 - Import report
 - Product instruction/description for imported items
 - Purchase Form (Invoice)
 - Airway Bill (AWB) (copies) or Bill of Lading (B/L) (copies)
 - Written pledge

- 3. The following items shall be required to be included in the written pledge among the documents to be submitted.
 - Import due to lack of supplies and unable to procure products distributed in Japan
 - Being restricted to in-house use for countermeasures against new coronavirus infections
 - The use and storage management of imported products shall be appropriately carried out under the responsibility of the relevant company.
 - Provide appropriate guidance and oversight to employees in order to prevent the occurrence of misdistribution to the outside.

End of Notification