Government’s response on arrangement of extending shelf life of COVID-19 oral drugs

â€‹In response to media enquiries on the arrangement of extending the shelf life of COVID-19 oral drugs, a Government spokesman today (May 12) stressed that all COVID-19 oral drugs currently prescribed to confirmed COVID-19 patients in Hong Kong have been tested and confirmed by the drug manufacturers as effective and safe, and comply with the relevant drug safety regulation. The practice of shelf life extension of the two COVID-19 oral drugs is also an established practice in the global pharmaceutical industry. The spokesman reiterated that the COVID-19 oral drugs is safe and effective while the local supply is sufficient. The Government will ensure that there are sufficient medical resources to meet local needs.

The Government has started providing private doctors with two COVID-19 oral drugs, Paxlovid and Molnupiravir, procured by the Hospital Authority (HA), for free prescription to "Eligible Persons" who are confirmed COVID-19 patients, since April 2022. Private doctors who have registered under the Electronic Health Record Sharing System (eHRSS) can make requests for provision of the two COVID-19 oral drugs via the dedicated online platform. The drug distributor will distribute the drugs concerned to their selected practice address among those they have registered with the eHRSS.

Generally speaking, subsequent to the launch of a pharmaceutical product, stability testing will continue in order to ensure that it meets the product specification requirement (including the shelf life) set by the manufacturers. Manufacturers can make application to the Pharmacy and Poisons Board of Hong Kong (the Board) for an extension of the shelf life once relevant supporting data is obtained, but relevant report and information (including the data on stability tests) requested by the Board must be submitted for reviewing its safety, efficacy and quality. Relevant procedures can be found at "Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances" stipulated by the Board.

The two COVID-19 oral drugs supplied in Hong Kong, Paxlovid (registration number: HK67360 and HK67683) and Molnupiravir (registration number: HK67385), have been approved as registered pharmaceutical products by the Board. They could only be supplied to healthcare institutions and doctors in public and private sectors. Registration holders of both COVID-19 oral drugs have submitted supporting reports and information on extension of product shelf life after the drugs were marketed. At present, Paxlovid is approved for a shelf life of 24 months while that for Molnupiravir is 30 months.

Take the COVID-19 oral drug Paxlovid as an example, the HA earlier received notification from the relevant manufacturer that the U.S. Food and Drug Administration and the Boardhad approved the extension of shelf life of

Paxlovid. Based on the relevant information, the HA has arranged for the contractor to affix the label indicating the latest expiry date to the drug packaging box. This arrangement does not affect the efficacy and safety of the drugs. The HA has also notified the medical staff of public hospitals about the relevant arrangement. In this connection, the Department of Health (DH) has also issued letters in December last year and January this year to private doctors who have requested the Government to provide Paxlovid via the online platform, informing them of the extension of shelf life of Paxlovid, and the procedures for the drug distributor to replace the label with an extended shelf life. The DH reminded private doctors yesterday (May 11) to pay attention to the label on the packaging box showing the correct expiry date when prescribing drugs, and they should dispense the medicine according to the established "first-expired, first-out" principle.

The spokesman emphasised that both types of COVID-19 oral drugs are new and were developed within a short period of time. Applications for shelf life extension were submitted by relevant registration holders with scientific evidence and test data to confirm the effectiveness of the relevant drugs, which is also an established practice in the global pharmaceutical industry.

According to the Pharmacy and Poisons Ordinance (Chapter 138), all pharmaceutical products must satisfy the criteria of safety, efficacy and quality and be registered with the Pharmacy and Poisons Board (the Board) before they can be sold in Hong Kong. However, the Ordinance allows the import of unregistered pharmaceutical product to be possessed or used for the purpose of treatment of a particular patient by a registered medical practitioner or conduct clinical trials. The DH provides administrative and professional support in respect of registration of pharmaceutical product for the Board and its subsidiary committees. Guidelines, fact sheets on the use of the COVID-19 oral drugs as well as other points to note formulated by the HA are available for download on the online platform. Private doctors must follow the treatment guidelines set out by the HA to prescribe the COVID-19 oral drugs to suitable patients. Besides, registered medical practitioners should abide by the relevant laws and the Code of Professional Conduct for the Guidance of Registered Medical Practitioners at all times when prescribing drugs, including COVID-19 oral drugs.

â€‹The spokesman reiterated that there is currently sufficient stock of drugs in the public healthcare system for prescription to COVID-19 patients, and the Government will ensure that there are sufficient medical resources to meet local needs. The Government has also procured and stockpiled sufficient oral drugs and adjusted, in a timely manner and according to actual needs, the number of courses that private doctors can request each time through the online platform set up by the Government, so as to cope with the changing situation of the COVID-19 epidemic.