LCQ9: COVID-19 oral drugs

Following is a question by the Hon Judy Chan and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (February 12):

Question:

In 2022, in consultation with experts, the Government introduced the COVID-19 oral drugs Paxlovid and Molnupiravir through the Hospital Authority (HA), and prescribed the two drugs to suitable patients through various channels such as public hospitals, designated clinics and residential care homes for the elderly. The Government has indicated that the fee for each course of treatment in respect of the two drugs is over $6,000. There are views that the fees for the two drugs are excessively high, and the Government should expeditiously introduce other less expensive drugs with similar efficacy. In this connection, will the Government inform this Council:

(1) of the details of the vetting and approval process for introducing the two drugs by the Government in consultation with experts at that time, and whether such vetting and approval process was different from the general approval process for introducing new drugs; if so, of the reasons for and details of that;

(2) of the current clinical guidelines for prescribing the two drugs, and the number of revisions made in the past;

(3) whether it knows the following information on the use of each of the two drugs by HA in each of the past three years: (i) the quantity purchased and expenditure incurred, (ii) the quantity used (with a breakdown by the channels through which they were used), and (iii) the quantity discarded due to expiry or other reasons;

(4) whether there has been any change to the approved shelf life of the two drugs since their introduction, and of the current respective shelf life; whether it knows the respective stock of the two drugs currently kept by HA; and

(5) whether the authorities have plans to introduce other drugs with efficacy similar to that of the two drugs; if so, of the progress and timetable; if not, the reasons for that?

Reply:

President,

With the ever evolvement of the SARS-CoV-2 virus, the prevention and treatment capacities of the local healthcare system and the handling capacity of society as a whole have been enhanced significantly. COVID-19 has been managed as an upper respiratory tract illness by the Government since early

2023. Despite this, the World Health Organization still highlights the importance of ensuring access to appropriate treatments for patients with COVID-19, including providing oral antiviral drugs to high-risk patients on a need basis taking the local situation into account. High-risk persons concerned include the elderly, immunocompromised individuals or persons with chronic illnesses.

The Health Bureau, together with the Department of Health (DH) and the Hospital Authority (HA), have been keeping abreast of the latest development of clinical treatment and scientific evidence-based research relating to SARS-CoV-2 virus, while making reference to the latest data from drug regulatory authorities and drug manufacturers globally so as to provide appropriate treatment for COVID-19 patients.

In consultation with the DH and the HA, the reply to the question raised by the Hon Judy Chan is as follows:

(1) According to the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong (Board) before they can be sold or supplied in Hong Kong.

During the COVID-19 pandemic, the then Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (Committee) established under the Board considered that, in view of the public health emergency and the local medical need at the time, together with the relevant scientific evidence, the benefits of the use of COVID-19 oral antiviral drugs, namely Paxlovid and Molnupiravir, in the treatment of mild-to-moderate COVID-19 outweighed the risks and hence conditionally approved the applications of the relevant drugs for registration in February and March 2022 respectively. As part of the conditional approval of registration, the corresponding drug registration certificate holders were required to submit additional data through clinical studies and post-marketing report to the Board according to the conditions imposed by the Committee (including that the concerned products can only be supplied to doctors or medical institutions). The certificate holders of the drugs have been continuously providing relevant reports and data to substantiate their products' safety, efficacy and quality. In this connection, Paxlovid was granted full registration in February 2024.

(2) According to the existing mechanism, the expert panel formed by the DH and the HA closely monitors the efficacy and possible side-effects of the relevant drugs in light of the evolving scientific evidence, and also evaluates various drugs treating COVID-19 while reviewing and updating the clinical guidelines in a timely manner with reference to the latest clinical development and research data in the Mainland and overseas, with a view to providing patients with appropriate treatments to reduce their risk of severe complications and death.

Based on the above principle, the relevant clinical guidelines have been updated for 27 times so far. Under the current guidelines, healthcare professionals will consider prescribing relevant drugs to patients aged 70 or

above, and patients aged below 70 with high-risk conditions or chronic diseases according to their clinical needs.

(3) Apart from providing antiviral drugs for treating COVID-19 at public hospitals/clinics under the HA, the Government has been providing private doctors with the two aforementioned COVID-19 oral drugs procured by the HA for free prescription to eligible COVID-19 confirmed 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. Private doctors must follow the aforementioned treatment guidelines set out by the HA. Besides, the DH's clinic dispensaries also distributed a small amount of treatment courses.

From 2022 to 2024, the HA has prescribed the two COVID-19 oral drugs to about 471 300 HA patients (a single patient may be prescribed with COVID-19 oral antivirals for more than once), including about 314 600 patients prescribed with Paxlovid and about 156 700 with Molnupiravir. Separately, about 181 700 treatment courses were prescribed by private doctors to eligible COVID-19 confirmed patients for free, in which about 104 000 Paxlovid treatment courses and about 77 700 Molnupiravir treatment courses were prescribed. About 1 500 treatment courses were prescribed by clinics under the DH (including Families Clinics and Elderly Health Centres).

Detailed figures on the quantity and expenditure incurred by the HA in purchasing the two COVID-19 oral drugs are tabulated below:

	2021/22	2022/23	2023/24
Total number of purchase* (Each treatment course)	356 000	342 000	85 000
Total expenditure ($ million)	2,051	1,968	503

* Figures adjusted to the nearest thousands

Following the prevailing practice, the HA dispenses drugs before the expiration dates based on the "first-expired, first-out" principle. For those drugs requiring disposal, including unserviceable ones, the HA will dispose of them in accordance with the established procedures. There has not been any disposal of COVID-19 oral drugs so far.

(4) The shelf-life of the two COVID-19 oral antiviral drugs, namely Paxlovid and Molnupiravir, are 24 and 30 months respectively. The HA has sufficient stock of drugs for prescription to COVID-19 patients, and will continue to closely monitor the supply and utilisation of the relevant drugs in order to cater for the needs of patients.

(5) The DH and the HA will continue to keep in view the latest data from drug regulatory authorities and drug manufacturers globally (including the Mainland) and introduce suitable drugs in a timely manner based on the available scientific evidence to ensure that patients are prescribed with

drugs of proven safety and efficacy.

Apart from Paxlovid and Molnupiravir, no other COVID-19 oral antivirals drugs are currently registered in Hong Kong. Based on the latest scientific evidence, there are no other COVID-19 oral antiviral drugs in the market that can provide the same level of appropriate treatment especially for high-risk patients.