LCQ17: Cancer treatment

Following is a question by the Hon Elizabeth Quat and a written reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (January 13):

Question:

Some patient groups have relayed that it may take as long as five years for a new drug to go through the process from submission of an application for its registration in Hong Kong to the Pharmacy and Poisons Board (the Board), approval given for its registration, its being listed by the Hospital Authority (HA) on HA's Drug Formulary (HADF) as a Self-financed Item (SFI) with safety net coverage, to its being reclassified as a General Drug or a Special Drug on HADF. As a result, quite a number of patients with cancers are unable to receive in time treatments which make use of new drugs. Regarding cancer treatment, will the Government inform this Council:

(1) of the respective dates on which the various SFIs and Special Drugs under the category of "Malignant Disease and Immunosuppression" in HADF were (i) given approval for registration by the Board, (ii) listed as SFI, and (iii) reclassified as a Special Drug (if applicable);

(2) whether it has reviewed if the time taken for a new drug to go through the process from approval for its registration being given by the Board to its being listed as a Special Drug is reasonable and meets the public expectation; if it has reviewed and the outcome is in the negative, whether it will make improvements;

(3) since some patients with cancers have relayed that they cannot afford the expensive drugs used for cancer therapies, such as chemotherapy, targeted therapy, hormonal therapy and immunotherapy, whether the Government will consider further relaxing the threshold for applying for the Samaritan Fund and Community Care Fund Medical Assistance Programmes; if so, of the details; if not, the reasons for that;

(4) as some patient groups have indicated that tumour treating fields therapy and cell therapy are not covered by the Medical Assistance Programmes of the two aforesaid funds, of the Government's measures to assist patients receiving these two therapies in obtaining the support needed; whether it will expand the clinical application of these two therapies in public hospitals; if so, of the details and timetable; if not, the reasons for that; and

(5) given that Hong Kong currently adopts a "secondary review" approach in vetting and approving applications for registration of pharmaceutical products containing new chemicals or biological entities, under which applicants are required to submit to the Board documentary proof of registration and certificates of free sale issued by the drug regulatory

authorities of two or above of the recognised countries, whether the Government will study the relaxation of the relevant registration requirements by allowing applicants to submit the relevant documents issued by the drug regulatory authority of only one of the advanced countries, with a view to expediting the registration process; if so, of the details; if not, the reasons for that?

Reply:

President,

In consultation with the Department of Health (DH) and the Hospital Authority (HA), I provide a reply to the various parts of the question raised by Hon Elizabeth Quat as follows:

(1)&(2) The Government and the HA strive to provide all patients (including cancer patients) with sustainable, affordable and optimal treatments and care. The HA has put in place mechanisms to provide support for patients in various aspects, including clinical diagnosis and assessment, multi-disciplinary specialist care and rehabilitation services, introduction of new drugs, as well as drug subsidies.

On drug management, drugs listed on the HA Drug Formulary (HADF) are intended for corporate-wide use by the HA, the coverage of which is driven by clinical service needs. The HA has put in place a mechanism for regular evaluation of new drugs and review of drugs currently listed on the HADF with the support of expert panels. The process follows an evidence-based approach, taking into account the safety, efficacy and cost-effectiveness of the drugs. Other factors for consideration include international recommendations and practices, advance in technology, disease state, patient compliance, quality of life, actual experience in the use of drugs, as well as views of professionals and patient groups. Under the existing mechanism, clinicians would submit new drug applications, based on service needs, to the Drug Advisory Committee (DAC) for consideration of listing on the HADF. The DAC would review new drug applications every three months.

Besides, under the existing HADF mechanism, doctors may use non-HADF drugs under exceptional situations in order to manage urgent cases or meet the clinical needs of individual patients. To ensure that patients are provided with timely and appropriate clinical care, clinicians would prescribe appropriate drug treatments based on their professional judgment, taking into consideration the clinical conditions of individual patients.

Evaluation of new drugs is an on-going process driven by evolving medical evidence, the latest clinical development and market dynamics. Moreover, a drug may have different therapeutic applications and may fall into more than one category on the HADF. Hence, the HA does not maintain information regarding the dates on which the drugs were listed in respective categories. At present, the HADF covers 132 drugs for treatment of various types of cancer. The number of new cancer drugs reviewed by the DAC and listed on the HADF, and their percentage share in the total number of new

drugs listed on the HADF in the past three years are shown in the table below:

Year	2018-19	2019-20	2020-21*
Number of new cancer drugs listed on the HADF	9	8	11
Percentage share in the total number of new drugs listed on the HADF	41%	26%	44%

* As of December 31, 2020

As of December 2020, the Samaritan Fund (SF) covered 51 self-financed drugs, among which 22 are for treating cancers, while the Community Care Fund (CCF) Medical Assistance Programmes covered 34 cancer drugs. The types of cancer treated by these subsidised drugs under the above-mentioned Funds include lung cancer, breast cancer, prostate cancer, colorectal cancer, liver cancer, leukaemia, multiple myeloma, lymphoma and neuroblastoma, etc. The number of cancer drugs introduced into the SF and the CCF Medical Assistance Programmes in the past three years are shown in the table below:

Year	2018-19	2019-20	2020-21*
Number of cancer drugs introduced to the SF**	2	5	3
Number of cancer drugs introduced to the CCF Medical Assistance Programmes	9	3	11

* As of December 31, 2020
** Including new drugs repositioned from the CCF Medical Assistance Programmes to the SF, as well as new drugs originally covered by the SF or the CCF Medical Assistance Programmes and subsequently introduced to the other source of funding for different therapeutic application.

Since the implementation of the HADF, the HA has continued to refine its review mechanism in the light of medical technology development and rising public expectations. The HA will pay close attention to the latest scientific and clinical evidence of drugs and update the HADF as necessary, with a view to ensuring equitable access by patients to cost-effective drugs of proven safety and efficacy.

(3) At present, the HA includes drugs that are proven to be safe and of significant benefits in the HADF and the safety net of the SF under the established mechanism, while the CCF has rolled out medical assistance programmes for cancer drugs which have yet to accumulate further medical scientific evidence and ultra-expensive drugs (including those for treating uncommon disorders) respectively to facilitate early drug treatment of patients. Meanwhile, to alleviate the financial burden on cancer patients,

the HA has been in close liaison with pharmaceutical companies on the setting up of risk sharing programmes for specific cancer drugs. Under the programmes, the HA, patients and pharmaceutical companies will contribute to the drug costs in specific proportions within a defined period, or the drug treatment costs to be borne by patients will be capped. The aim is to facilitate patients' early access to drug treatments and provide the patients with sustainable, affordable and optimal drug treatments in the long term.

The HA understands the strong aspiration of some patients for listing certain drugs on the HADF and including them in the scope of subsidy under the safety net. To provide more timely support for patients with financial needs, the HA has increased the frequency of the relevant prioritisation exercise for including drugs in the safety net from once a year to twice a year. Moreover, the Commission on Poverty (CoP) has agreed to streamline the approval process for introducing new drugs to the CCF Medical Assistance Programmes, thereby providing more timely support to patients in need.

In addition, the Government and the HA have, since early 2019, relaxed the means test mechanism for the SF and the CCF Medical Assistance Programmes, including modifying the calculation of annual disposable financial resources (ADFR) in drug subsidy application by counting only 50 per cent of the patients' household net assets, thereby offering asset protection to their families; and refining the definition of "household" adopted in financial assessment to cover only core family members living under the same roof and having direct financial connection with the patient concerned. After reviewing the effectiveness of the measures, we plan to further refine the means test mechanism for drug subsidy with a view to easing the financial burden of patients requiring long-term medication. Specific measures include:

(i) modifying the calculation of the ADFR for recurrent applications, including deducting the drug expenses paid by the patient for the last treatment course (See Note 1) and calculating only 80 per cent of the patient's household disposable income;
(ii) including more allowable deduction items in the calculation of the ADFR (including school fees on tertiary education for full-time students aged 25 or below, and maintenance payments), and adjusting the calculation of income (See Note 2) for all applications; and
(iii) extending the validity period of the financial assessment of recurrent applicants (See Note 3).

The Government and the HA will continue to closely monitor the operation of the safety net and will explore from time to time the scope of further enhancement for providing sustainable and optimal care to patients.

(4) The HA has established Coordinating Committees and the Central Technology Office (CTO) to closely monitor the clinical services and medical technology development in public hospitals, and keeps on upgrading medical devices and introducing appropriate treatment options in a timely manner having regard to international guidelines and scientific research data, with a view to enhancing the detection, diagnosis and management of different diseases. The

HA has been keeping abreast of the latest international development in treating glioblastoma. In 2019, the CTO conducted a technology assessment on the safety and efficacy of tumor treating fields therapy for glioblastoma. The Coordinating Committee concerned also plans to launch a pilot programme in 2021-22 to subsidise certain eligible patients with glioblastoma to receive tumor treating fields therapy with the aim of accumulating local experience and further examining the efficacy of the treatment.

The HA has also kept in view the development in Chimeric Antigen Receptor-T cell (also known as "CAR-T cell") therapy, and will introduce the treatment into public hospitals under the existing mechanism. The HA is drawing up the service details with a view to commencing implementation in 2021.

The HA will continue to keep abreast of the latest development of clinical and scientific evidence, review and enhance the relevant mechanisms and healthcare services so as to enhance its support for patients suffering from different diseases.

(5) Under the Pharmacy and Poisons Ordinance (Chapter. 138) (the Ordinance), pharmaceutical products shall meet the criteria of safety, efficacy and quality for registration with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold or distributed in Hong Kong. For pharmaceutical products containing new chemical or biological entity (i.e. contain active ingredients which have not been registered in Hong Kong), applications should be submitted to the Board for approval. In such case, legislative amendments are required in order to incorporate the new chemical or biological entity into the relevant schedules of legislation and to impose necessary sales control.

For registration of pharmaceutical products containing new chemical or biological entity, a "secondary review" approach is adopted in Hong Kong, i.e. the approval of the product should make reference to the reviews conducted by drug regulatory authorities of two or more designated reference countries (See Note 4). When applying for registration of a pharmaceutical product containing new chemical or biological entity in Hong Kong, the applicant should provide supporting documents as set out in the "Guidance Notes on Registration of Pharmaceutical Products/Substances", including expert evaluation reports on the safety, efficacy and quality of the new product, and documentary proof of registration of the product (such as free sale certificates) issued by the drug regulatory authorities of two or more designated reference countries.

In order to facilitate timely registration of new pharmaceutical products for the treatment of patients in Hong Kong, the Government has introduced various measures in the past few years to expedite the registration of pharmaceutical products containing new chemical or biological entity. This included the amendment to the Ordinance in 2015 so that the legislative amendments relating to new entities could be made via the negative vetting procedure so as to expedite the time required for registration of new pharmaceutical products in Hong Kong. To further expedite

the processing of application for registration, the Board implemented the Enhanced Procedures for Registration of New Drugs (Enhanced Procedures) in 2018. Upon receipt of an application for registration of a new pharmaceutical product by a pharmaceutical company, or when a new pharmaceutical product is covered under "Expanded Access Programme" of the HA, or other relevant drug programmes subsidised by the Government, the Board will initiate the legislative procedures with a view to shortening the time required for registration of the pharmaceutical product. The time required for processing application for registration of pharmaceutical products is generally shortened by two to three months after the implementation of the Enhanced Procedures.

Moreover, the DH has attached importance on service efficiency and has pledged that no less than 90 per cent of applications for pharmaceutical product registration would be processed within five months upon the submission of all required documents by the applicants. According to the Board's information, the DH fulfilled the above performance pledge in the past five years, with about 95 per cent of applications processed within five months on average per year. The DH will continue to maintain close communication and liaison with the pharmaceutical industry, and review and enhance the registration mechanism of pharmaceutical products as appropriate.

Note 1: The expenses at public hospitals/clinics on the drug under application of the last 12 months.
Note 2: Double pay, year-end payment, bonus and gratuity, as well as monthly payout amount of reverse mortgage/policy reverse mortgage will be excluded from the calculation of income.
Note 3: The validity period of the financial assessment of the first application will be extended from 12 months to 18 months on the condition that the patient contribution is not more than $2,000. In addition, the HA will waive the requirement to submit financial documents if the patient has been referred second application within one to two months after the first application.
Note 4: There are a total of 32 reference countries, including Australia, Canada, European Union Member States, Japan, Switzerland and the United States.