LCQ15: Treatments and support for patients with cancers and rare diseases

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 (June 24):

Question:

Some patient groups have relayed that it often takes years for a new drug to go through the process from application for its registration in Hong Kong, 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 and rare diseases have missed the golden opportunity for receiving treatment with the use of a new drug. In addition, although the Government and HA implemented enhancement measures early last year for the means test mechanism for drug subsidies under the Samaritan Fund and the Community Care Fund (CCF) Medical Assistance Programmes, there are still quite a number of cases of "having no money for treatment despite the existence of a needed drug" at present. In this connection, will the Government inform this Council:

(1) of the top 10 deadliest cancers in Hong Kong at present and, in respect of each of them, (i) the number of new confirmed cases and (ii) the number and age distribution of those persons who died of the cancer, in each of the past three years (set out in a table);

(2) whether it knows the current average time taken from a public hospital patient being suspected by a doctor of having cancer to that patient receiving first treatment, and the respective numbers of persons queuing to receive the relevant treatments (with a tabulated breakdown by type of cancer);

(3) of the new drugs for treating rare diseases and cancers which were approved in the past three years for registration in Hong Kong, and the average time taken for vetting and approval of the applications for registration of these drugs;

(4) whether it will consider afresh introducing, for rare diseases, (i) a drug registration system and (ii) a list of drugs, as well as making rare disease patients, medical practitioners and pharmaceutical companies all being able to apply for the inclusion of new drugs in the said list of drugs for rare diseases;

(5) whether it will consider afresh establishing a policy committee on rare

diseases to advise on the strategic direction and policies in respect of rare diseases, as well as to coordinate and monitor the implementation of such policies by relevant government departments and bodies as well as to submit reports in this regard; if so, of the details; if not, the reasons for that;

(6) whether it will consider afresh laying down a definition of rare diseases applicable to Hong Kong (e.g. by defining a disease which affects no more than 1 in 10 000 individuals in Hong Kong's population and is clinically definable as a rare disease); if so, of the details; if not, the reasons for that;

(7) given that quite a number of patients with cancers and rare diseases as well as their family members experience pay cuts and unemployment amid the downturn of Hong Kong's economy due to social disturbances and the epidemic, which has resulted in their having difficulties in making contributions to drug expenses under the existing means test mechanism for drug subsidies, whether the Government will provide them with targeted financial support;

(8) of the (i) total number and (ii) names of those drugs added, in the past three years, to the respective lists of SFIs covered by the drug subsidies under the two aforesaid funds;

(9) as some medical professionals have pointed out that at present, various immunotherapy drugs which have specific curative effects on certain cancers are not yet covered by the lists of SFIs under the two aforesaid funds (e.g. Atezolizumab), or are only covered by the CCF Medical Assistance Programmes for use in very limited treatment purposes (e.g. Nivolumab and Pembrolizumab), whether the Government knows if HA will expeditiously include in HADF those immunotherapy drugs which have not yet been covered, and provide such drugs for patients who have tried different drugs but failed to get satisfactory treatment results; if HA will, of the details and timetable; if not, the reasons for that; and

(10) given that the Drug Advisory Committee under HA meets once every three months to assess applications for inclusion of new drugs in HADF, but some terminal cancer patients in critical condition are in urgent need of certain drugs which have not yet been included in HADF, whether the Government knows if HA will establish a mechanism for speedy processing of applications for inclusion of relevant drugs in HADF for such patients on a discretionary basis; if HA will, of the details; if not, the reasons for that?

Reply:

President,

My reply to the various parts of the question raised by Dr the Hon Elizabeth Quat is as follows:

(1) According to the latest statistics of the Hong Kong Cancer Registry of the Hospital Authority (HA), the top ten causes of cancer deaths in Hong Kong in 2017 in order were lung cancer, colorectal cancer, liver cancer, breast

cancer, pancreatic cancer, stomach cancer, prostate cancer, non-Hodgkin lymphoma, leukaemia and oesophageal cancer. The numbers of new cases and registered deaths of these ten types of cancers from 2015 to 2017 are set out at Annex 1.

(2) Among the common cancers in Hong Kong, colorectal, breast and nasopharyngeal cancers can be diagnosed by pathological examination. The HA reviews on a regular basis the waiting time for patients with colorectal, breast and nasopharyngeal cancers to receive their first treatment after diagnosis. During the period from July 2018 to June 2019, the 90th percentile waiting time (Note 1) for patients with colorectal, breast and nasopharyngeal cancers to receive their first treatment after diagnosis was 76 days, 76 days and 60 days (Note 2) respectively. The HA does not maintain statistics on the waiting time for patients with other types of cancers and the number of patients waiting for various types of cancer treatments.

Note 1: The 90th percentile waiting time refers to the number of days between the date when a patient is diagnosed with cancer after pathological examination and the date when the patient receives the first treatment. The waiting time of 90 per cent of such cases is shorter than the value indicated.
Note 2: The 90th percentile waiting time for patients with nasopharyngeal cancer is calculated based on data between January and December 2019.

(3) According to the Pharmacy and Poisons Ordinance (Cap. 138) and its subsidiary legislation, “pharmaceutical products” must satisfy the criteria of safety, efficacy and quality, and must be registered with the Pharmacy and Poisons Board of Hong Kong (the Board) before they can be sold in Hong Kong.

Over the past few years, the Government has introduced various measures to expedite the drug registration process. Since February 2015, legislative amendments relating to new chemicals or biological entities are made via the negative vetting procedure instead of the previous positive vetting procedure, thereby streamlining the drug registration process.

To further expedite the processing of applications for drug registration so that pharmaceutical products containing new chemicals or biological entities can be sold in the market as early as possible to benefit more patients in need, the Board has implemented the Enhanced Procedures for Registration of New Drugs (Enhanced Procedures) since June 2018. Upon receipt of an application for registration of a new drug from a pharmaceutical company, or when a new drug is covered under the HA’s Expanded Access Programme or other relevant government-subsidised drug programmes, the Board will initiate the legislative procedures of amending the Pharmacy and Poisons Regulations simultaneously with a view to shortening the time required for drug registration and expediting the introduction of the new drug. With the implementation of the Enhanced Procedures, the application time for registration of pharmaceutical products is generally shortened by two to three months.

As at May 2020, the Department of Health (DH) had handled 48

pharmaceutical products containing new chemicals or biological entities under the Enhanced Procedures. The DH processed over 96 per cent of the registration applications for pharmaceutical products within five months between 2017 and 2019, meeting the target in its performance pledge.

(4) and (5) The Government and the HA strive to provide all patients (including those with uncommon disorders) with sustainable, affordable and optimal treatments and care. Currently, mechanisms have been put in place to provide support for patients in various aspects, including clinical diagnosis and assessment, multi-disciplinary care and rehabilitation services, introduction of new drugs, as well as subsidising drug treatments. The HA's multi-disciplinary and cross-departmental medical and rehabilitation teams have adopted an integrated approach to provide holistic medical and rehabilitation services for patients with uncommon disorders.

The Government and the HA have been working closely to discuss, formulate and review the policy support for patients with uncommon disorders, while maintaining communication with relevant patient groups to keep reviewing and enhancing relevant mechanisms and measures. The Government considers that currently there is no need to separately establish a policy committee in addition to the various existing mechanisms supporting patients with uncommon disorders.

Regarding drug registration system, there is currently an established mechanism to evaluate new drugs. As mentioned above, the Government has rolled out various measures under the existing drug regulatory regime in recent years with the aim to expedite the drug registration process to allow early registration of new drugs for use by patients in need.

On drug subsidy, the HA has been making use of the recurrent funding from the Government, the Samaritan Fund (SF) and the Community Care Fund (CCF) Medical Assistance Programmes to support eligible and needy patients (including those with uncommon disorders) to receive medical treatment. After consideration of factors such as the development of treatments for uncommon disorders, drug prices and drug efficacy, the Government and the HA introduced the "Subsidy for Eligible Patients to Purchase Ultra-expensive Drugs (Including Those for Treating Uncommon Disorders)" Programme under the CCF in August 2017. The HA's expert panel will assess the clinical benefit of the drug treatment under relevant arrangement on a case-by-case basis according to the clinical conditon of individual patients and the established treatment guidelines. The Government and the HA will, having regard to clinical evidence, continue to review the coverage of the SF and the CCF Medical Assistance Programmes in accordance with the established mechanism with a view to including more suitable new drugs to benefit patients in need.

(6) At present, there is no common definition of rare diseases/uncommon disorders worldwide. The definition of such diseases varies among countries/regions, depending on the characteristics of individual healthcare systems and local situations. Each disease has its uniqueness and individual patients need different clinical attention and care. Regardless of rare or known diseases, the optimal treatment for a patient hinges on professional

judgement, the seriousness (not just rarity) of the disease, and the availability of expertise and resources, instead of whether to mark an arbitrary boundary for these diseases.

If we lay down a definition of rare diseases and specify that only patients with diseases falling under the definition could receive certain entitlements, the focus of our support would be diverted to how to draw the line and review the defined coverage, thereby deviating from addressing the specific clinical needs of individual patients. A definition based on the prevalence rate would result in other significant factors such as the severity of the disease and the availability of treatments being overlooked.

To further support patients with uncommon disorders, the Government and the HA plan to implement progressively a series of targeted measures. These measures include developing databases for individual uncommon disorders to facilitate clinical diagnosis and treatment, and to enhance public awareness of such disorders; strengthening support for patients with uncommon disorders through the safety net mechanism; reviewing manpower support and deploying resources to help meet the needs of patients and promote technological development and clinical research relating to uncommon disorders. The Government and the HA will maintain communication with relevant stakeholders (including patient groups) to review and strengthen support for patients with uncommon disorders.

(7) To alleviate the financial burden of drug expenses on patients' families, the Government and the HA introduced measures to enhance the means test mechanism for the SF and the CCF Medical Assistance Programmes in 2019. The enhancement measures include modifying the calculation of annual disposable financial resources in drug subsidy application by counting only 50 per cent of the patients' household net assets, thereby offering asset protection to patients' 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. The Government and the HA have been closely monitoring the implications of the enhancement measures on patients' applications, and will review the effectiveness of these measures in a timely manner with a view to effectively supporting patients in need.

(8) The lists of self-financed drugs currently covered by the SF and the CCF Medical Assistance Programmes are available at the HA's website (Note 3). The numbers of drugs introduced to the SF and the CCF Medical Assistance Programmes over the past three years are as follows:

Year	2017-18	2018-19	2019-20
Number of drugs introduced to the SF (Note 4)	3	6	10
Number of drugs introduced to the CCF Medical Assistance Programmes (Note 4)	4	10	4

The relevant drug lists are at Annex 2.

Note 3: The list of self-financed drugs currently covered by the SF: https://www.ha.org.hk/haho/ho/sf/SF_Items_EN.pdf
The list of self-financed drugs currently covered by the CCF Medical Assistance Programmes: https://www.ha.org.hk/haho/ho/ccf/CCF_items_en.pdf
Note 4: 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.

(9) and (10) As the major provider of publicly-funded public healthcare services, the HA attaches great importance to providing optimal care for all patients (including cancer patients) while ensuring patients an equitable access to cost-effective drugs of proven safety and efficacy under the highly subsidised public healthcare system.

On drug management, the HA has an established mechanism for regular evaluation of new drugs and review of its Drug Formulary (HADF) and coverage of the safety net, including formulation of clinical criteria for drugs to be included in the HADF and the safety net. The process follows the principles of evidence-based practice, rational use of public resources, targeted subsidy, opportunity cost consideration and facilitation of patients' choice, taking into account the safety, efficacy and cost-effectiveness of drugs and other relevant considerations, including international recommendations and practices as well as views of professionals and patient groups.

In accordance with the above principles and mechanisms, Nivolumab, Pembrolizumab and Durvalumab, which are immunotherapy drugs, have been included in the subsidy coverage of the CCF Medical Assistance Programmes (First Phase Programme) (Note 5) since August 2018 and May 2020 respectively.

Since 2018, the HA has increased the frequency of review for including self-financed drugs in the safety net from once a year to twice a year, in order to shorten the lead time for introducing suitable new drugs to the safety net. As for the CCF Medical Assistance Programmes, the Commission on Poverty agreed in October 2019 to streamline the approval process for introducing new drugs/medical devices to the CCF Medical Assistance Programmes starting from 2020-21, thereby providing more timely support to patients in need.

Drugs listed on the HADF are intended for corporate-wide use by the HA to meet the healthcare needs of the general public. The HA has also put in place a mechanism to allow doctors to use non-HADF drugs under special circumstances in the light of the clinical needs of individual patients so as to meet indivdual needs, manage urgent or special cases and ensure that patients are provided with appropriate clinical care.

Evaluation of drugs is an on-going process driven by evolving medical evidence, the latest clinical developments and market dynamics. The HA will

continue to keep abreast of the latest development of clinical and scientific evidence of different cancer drugs and immunotherapy, listen to the views and suggestions of patient groups, and review the HADF and coverage of the safety net under the principle of rational use of limited public resources while providing adequate medical care to the largest number of patients in need.

Note 5: Under the coverage of the CCF Medical Assistance Programmes (First Phase Programme), the designated type of cancer treatment of Nivolumab (introduced in August 2018) is skin cancer, and the designated type of cancer treatment of Pembrolizumab and Durvalumab (introduced in May 2020) is lung cancer.