LCQ8: Introduction of drugs for use in Hong Kong

Following is a question by the Hon Joephy Chan and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (December 11):

Question:

It is learnt that a number of new oncology and cancer drugs from the Mainland have shown satisfactory efficacy, but their introduction into Hong Kong is subject to a complicated drug registration system. On the other hand, there are inadequacies in the Named Patient Program (the Program) introduced by the authorities, such as the need for individual applications to make full pre-payment to pharmaceutical companies, the cumbersome procedures for doctors' applications for drugs and the long lead time from the submission of applications to the granting of approval and the individual packaging and shipment of drugs. In this connection, will the Government inform this Council:

(1) of the following information about the Program in each of the past five years:

(i) the number of applications received;

(ii) the expenditure involved;

(iii) the top 10 drugs with the highest number of applications, the number of applications for and the fees of such drugs, and whether they were provided free of charge for use by patients in public hospitals and private hospitals;

(iv) the average time respectively between the receipt and approval of applications, and between the approval of applications and the use of the drugs; and

(v) how the final charges for the drugs are determined (for example, whether the charges only aim at recovering the cost);

(2) as it is learnt that the certification of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) is widely recognised as the most stringent pharmaceutical specification in the world, and there are views that the Government, as a member of PIC/S, may help facilitate the introduction of Mainland-made drugs overseas while the Mainland's application for joining PIC/S is pending approval, of the following in the past five years:

(i) the number of drugs by Mainland pharmaceutical companies which had lodged applications for Good Manufacturing Practice (GMP) for Medicinal Products certification by PIC/S in Hong Kong, and the number of applications involved;

(ii) the number of occasions on which the Department of Health (DH) had to

send GMP inspectors to the Mainland and overseas for conducting certification, and the expenditure involved; and

(iii) the average waiting time for GMP certification applications; and

(3) of the details of DH's total staff establishment responsible for handling PIC/S certification at present, and their duties; whether it will introduce express/priority handling arrangements or set up a dedicated team for urgently-needed drugs to expedite the certification and registration of the drugs?

Reply:

President,

"The Chief Executive's 2024 Policy Address" has proposed a number of initiatives to improve the drug approval mechanism so as to speed up registration and facilitate good drugs for use in Hong Kong. In particular, to enhance the drug regulatory regime, the Hong Kong Special Administrative Region (HKSAR) Government implemented a new mechanism for the approval of new drugs ("1+" mechanism) (Note 1) on November 1, 2023, which has been extended to all new drugs since November 1 this year, including vaccines and advanced therapy products. So far, the Department of Health (DH) has received more than 350 enquiries from over 90 pharmaceutical companies, and approved seven new drugs under the "1+" mechanism, bringing new hope for treatment to patients. The seven new drugs mentioned above include two new drugs for treating metastatic colorectal cancer which have been approved by the National Medical Products Administration and have been listed in the "Special Drug" category of the Hospital Authority (HA) Drug Formulary. Not only has the procurement cost of the drugs been reduced by nearly 30 per cent successful after price negotiation by the HA, patients are also only required to pay the standard fee of $15 if these two drugs are prescribed under specified clinical applications, greatly alleviating their financial burden. It is expected that nearly 300 cancer patients will benefit each year. Extending the "1+" mechanism could attract more new drugs from different parts of the world seeking approval for registration in Hong Kong, giving patients more choices and further strengthening the local capacity for drug evaluation while enhancing the development of relevant software, hardware and expertise with a view to progressing towards "primary evaluation". The Government will complement technological innovation with institutional innovation, developing Hong Kong into an international health and medical innovation hub.

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

(1) Under the Pharmacy and Poisons Regulations (Cap. 138A) (Regulations), pharmaceutical products must satisfy the criteria of safety, efficacy and quality and be registered with the Pharmacy and Poisons Board of Hong Kong (Board) before they can be sold or supplied in Hong Kong.

To address the needs of patients for the prevention and treatment of

life threatening and severely debilitating diseases (e.g. cancer and rare diseases), the law allows a registered medical practitioner or a registered dentist to possess or use of an unregistered drug for the purpose of treatment of a particular patient for which no registered drugs for effective treatment or prevention are available (Note 2). Importation of unregistered pharmaceutical products under the above situation needs to apply for an import licence from the DH under the authority of the Director-General of Trade and Industry in accordance with the Import and Export Ordinance (Cap. 60) and meeting the approval requirements for the issuance of the import licence. The performance pledge of the Drug Office of the DH in approving applications for import and export licence for pharmaceutical products is two working days. The relevant arrangement is to ensure that a registered medical practitioner or dentist will not be prevented from obtaining and administering a necessary drug to a local patient on the ground that an overseas pharmaceutical company has not applied for registration of the drug in Hong Kong.

The number of applications for import of unregistered drugs for particular patients (including applications from the HA) received and import licenses issued by the DH in the past five years are set out in the table below. The DH does not regulate or handle commercial transactions between importers and doctors/organisations or between doctors/organisations and patients, and thus, does not maintain information on the fees of relevant drugs. Meanwhile, the HA does not maintain statistics on the use of unregistered drugs for treatment under its Named Patient Scheme (Note 3).

Year	Number of applications for import of unregistered drugs for the treatment of particular patients received by the DH (Note 5)	Number of import licenses issued for import of unregistered drugs for the treatment of particular patients (Note 5) (Note 6)
2019 (Note 4)	–	6 269
2020 (Note 4)	–	6 061
2021 (Note 4)	–	7 101
2022	7 359	7 283
2023	7 268	7 195

Note 4: Before December 31, 2021, the DH adopted a paper-based approach in processing applications for import licenses and did not keep records on the number of applications.

Note 5: Multiple import licences may be applied for the same drug in accordance with the circumstances and conditions.

Note 6: The applicant may only partially or not import the drug concerned

after the issue of the import licence. Therefore, the actual number of drugs imported may be smaller.

The 10 drugs with the highest number of applications for import of unregistered drugs for the particular patients received by the DH between 2022 and 2023 are tabulated below. The DH does not maintain the actual expenditure involved for processing relevant applications.

	Drugs with the highest number of applications for import of unregistered drugs for the treatment of particular patients received by the DH	Number of applications for import of unregistered drugs for the treatment of particular patients (Note 7)
1	Selpercatinib capsule 80mg (Note 8)	214
2	Mobocertinib 40mg Cap	208
3	INDIUM-111 SOLUTION IN VIALS (Indium (In 111) Oxinate)	178
4	ORALTEK Spray	176
5	SLITone ULTRA Dermatophagoides pteronyssinus + Blomia Maintenance kit	152
6	SLITone ULTRA Dermatophagoides (HDM) mix Maintenance kit	145
7	ATROPINE EYE DROPS 0.01% (Note 8)	138
8	Mon.Tek Mo-99/Tc-99m Generator (Note 8)	129
9	MyoMIBG-I 123 Injection	122
10	FRUQUINTINIB (ELUNATE) CAP. 5MG (Note 8)	121

Note 7: The number of applications made by applicants for different drugs may vary depending on factors such as the nature of the drug and its expiry date. Hence, the number of applications for a drug may not fully reflect the demand for the drug.

Note 8: Relevant drugs have been registered in Hong Kong during 2023 and 2024.

The HKSAR Government encourages pharmaceutical products manufacturers or suppliers to apply for registration in Hong Kong of unregistered drugs with continued need for use. The DH will continue to proactively publicise the "1+" mechanism and liaise closely with the trade.

(2) and (3) The Pharmaceutical Inspection Co-operation Scheme (PIC/S) is an international organisation comprising pharmaceutical inspection authorities

from multiple countries and regions with a mission to lead the international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. As of December 2, 2024, there were 56 participating authorities in the PIC/S. Hong Kong has become a member of the PIC/S since 2016. The DH is responsible for GMP inspections to ensure compliance of manufacturers. Hong Kong's membership of the PIC/S signifies that it has been recognised by international drug regulatory bodies and its drug regulatory standards have reached international standards.

According to the Regulations, all local pharmaceutical products manufacturers must obtain a licence from the Board to manufacture pharmaceutical products. Since the Board has become the participating authority of the PIC/S on January 1, 2016, one of the key requirements for licensing a manufacturer for pharmaceutical products is the full compliance with the PIC/S GMP standards. The relevant standards covered requirements on drug manufacture including the pharmaceutical quality system, personnel, premises, equipment, documentation, production process, quality control, outsourced activities, complaint handling, product recall and self-inspection of manufacturer so as to ensure that high quality drugs were produced. At present, there are 22 licensed local pharmaceutical products manufacturers which they are all fully compliant with the PIC/S GMP standards.

At present, the Manufacturers Regulatory Unit (Unit) of the Drug Office of the DH is responsible for processing application of manufacturer licence (including applications for post-licensing changes), examining compliance with the licensing requirements laid down by the Board as well as the level and requirements of the PIC/S GMP, with a view to making a recommendation for approval of the application to the Board. The Drug Office is also responsible for conducting regular and ad hoc inspections on local licensed pharmaceutical manufacturers based on risks associated with their products and the track record of inspections, so as to ensure their continuous compliance with the Code of Practice for Licensed Manufacturers and Registered Authorized Persons released by the Board and the relevant PIC/S GMP requirements. Relevant licensing and inspection work includes meeting with manufacturers to discuss the commissioning or changing plan before processing the application, reviewing the documents and information submitted by the manufacturer including the quality management policies, activities of the site, the production and quality control of pharmaceutical manufacturing operations carried out therein and key personnel, as well as arranging and conducting PIC/S GMP inspections, preparing inspection reports and following up the corrective actions with the manufacturers as necessary. In addition, the Unit is also responsible for the update, amendment and implementation of PIC/S GMP standards, including the adoption of new version of PIC/S GMP Guide to enhance local GMP standards, participation in international exchanges and meetings with other PIC/S participating authorities, assisting in the development of PIC/S related guidelines, and the need to receive regular training related to PIC/S and GMP. The Unit currently comprises a senior pharmacist, pharmacists, and scientific officers. The Unit also handles tasks other than PIC/S GMP inspections, and some tasks related to PIC/S also involve other units. The DH does not maintain the breakdown of the staff

establishment responsible for handling PIC/S certification.

For applications of registration of pharmaceutical products with non-local manufacturers, the applicants for registration of those products should submit evidence of compliance with PIC/S GMPs. Applicants who do not successfully invite other PIC/S participating authorities to conduct inspection may consider inviting the Drug Office of the DH to conduct PIC/S GMP inspection outside Hong Kong by submitting the relevant invitation. After receiving the invitation and taking into account factors like risks arising from the inspection and whether the drug may address local healthcare medical needs, the Unit of the Drug Office will consider arranging PIC/S GMP inspection outside Hong Kong if the following conditions are fulfilled:

(i) The invitation has to be issued by the applicant of registration of pharmaceutical products, together with all the required information and supporting documents related to the manufacturer;
(ii) The concerned manufacturer is not located in country or region that is PIC/S member and the relevant facility has not yet been inspected by other PIC/S participating authority;
(iii) The applicant has to confirm that the drug regulatory authority of the country or region where the manufacturer is located has been informed or has no objection to the PIC/S GMP inspection of the manufacturer by the Drug Office;
(iv) The inspection outside Hong Kong will not affect the Drug Office's schedule for inspections of local manufacturers in Hong Kong; and
(v) The applicant pays the required inspection fees on the full cost-recovery principle.

Due to the COVID-19 epidemic, the DH has not conducted any PIC/S GMP inspections to manufacturers outside Hong Kong from 2020 to 2022. From 2023 to November 2024, the DH, as invited by applicants of registration, arranged three PIC/S GMP inspections to pharmaceutical manufacturers outside Hong Kong, which were in Jordan, the Philippines and Mainland China respectively.

Note 1: Under the "1+" mechanism, eligible holders of registration from one (instead of two in the past) of the recognised drug regulatory authorities for new drugs could apply for registration in Hong Kong, on the condition that they could provide local clinical data which complies with the requirements and recognised by local experts.

Note 2: Regulation 36(1A) of the Regulation stipulates that the prescribed requirement for registration of pharmaceutical products is not applicable to certain specified circumstances, including the possession or use of the pharmaceutical product for the purpose of treatment by a registered medical practitioner or registered dentist of a particular patient in accordance with Regulation 36(1A)(ab) of the Regulations.

Note 3: If doctors of public hospitals, based on their professional judgement and having regard to the clinical conditions of individual patients, consider that it is necessary to prescribe unregistered drugs, they may submit an application for import license to the DH through the suppliers via the HA Named Patient Scheme. Meanwhile, according to the charging guidelines for the

use of drugs not listed in the HA Drug Formulary (including both registered and unregistered drugs), if a hospital or a doctor needs to use a drug not listed in the HA Drug Formulary for treatment for an emergency situation (including immediate life threatening situations, for use as drugs for treating poisoning conditions and for treatment of infectious diseases that give rise to an imminent medical need), the HA will provide the necessary drug to the patient at standard fees. If such drugs are prescribed to meet the specific clinical needs of a particular patient, the patient has to bear the cost of the drugs.