LCQ8: Selling Hong Kong-registered proprietary Chinese medicines in Guangdong-Hong Kong-Macao Greater Bay Area

Following is a question by Professor the Hon Chan Wing-kwong and a written reply by the Secretary for Health, Professor Lo Chung-mau, in the Legislative Council today (January 24):

Question:

In August 2021, the Guangdong Provincial Medical Products Administration (GDMPA) promulgated the Notice regarding the streamlining of registration approval for traditional proprietary Chinese medicines (pCms) for external use that have been sold in Hong Kong and Macao (the Notice). Holders of traditional pCms for external use that have been registered with the Chinese Medicine Council of Hong Kong and in use in the city for more than five years may apply for registration with GDMPA through the streamlined procedures. Such pCms, upon successful approval, may be sold in the Guangdong-Hong Kong-Macao Greater Bay Area. In this connection, will the Government inform this Council:

(1) whether it knows, since the promulgation of the Notice, the total number of registration holders of traditional pCms for external use in Hong Kong who have applied for registration with GDMPA through the relevant measures, and the number of types of pCms involved;

(2) whether it knows, among the applications mentioned in (1), the respective numbers of those approved and rejected, as well as the main reasons for rejecting the applications;

(3) whether it knows the average time taken for vetting and approving each application after the application procedures have been streamlined under the relevant measures;

(4) how the authorities promote the relevant measures among the pCm sector, and whether they have taken measures to assist the sector in lodging applications; if so, of the details; and

(5) as GDMPA indicated in November 2023 that it had submitted the Implementation plan for streamlining registration approval for traditional oral pCms that have been sold in Hong Kong and Macao for the National Medical Products Administration's examination and approval, whether the Government knows the details of the relevant plan?

Reply:

President,

Having consulted the Department of Health (DH) and the Guangdong Provincial Medical Products Administration (GDMPA), the Health Bureau provide a consolidated reply to the various parts of Professor the Hon Chan Wing-kwong's question as follows:

(1) to (3) According to the information provided by the GDMPA, since the promulgation of the Notice regarding the streamlining of approval procedures for Hong Kong and Macao registered traditional proprietary Chinese medicines for external use (the Notice) on August 27, 2021, a total of 15 local proprietary Chinese medicines (pCm) registration holders have applied through the streamlined procedures to the GDMPA for registration and sale of 22 Hong Kong registered pCms in the Mainland. Among all applications, nine products have been approved for registration and sale in the Mainland, five products are undergoing technical reviews, and holders of eight products are submitting supplementary information and planning to make declaration subsequent to the pre-vetting service. So far, no applications accepted have been rejected for approval.

Furthermore, as indicated by the GDMPA, the total time limit for vetting and approving applications submitted through the streamlined procedures for registration and sale in the Mainland has reduced from 235 days to 115 days.

(4) To help the Chinese medicine (CM) sector stay timely informed of the relevant policy and registration requirements, the Chinese Medicine Regulatory Office of the DH has created on its website a dedicated Greater Bay Area (GBA) webpage to provide updates on the development of CM in the GBA. For enabling trade members to keep abreast of the latest regulatory situation in the Mainland, the DH also maintains regular exchange with the industry on the CM development in the GBA through monthly talks.

In parallel, the Government of Hong Kong Special Administrative Region (HKSAR Government) supports the overall development of the CM sector through the Chinese Medicine Development Fund (CMDF). A number of funding schemes have been put in place to assist local licensed pCm manufacturers or wholesalers in upgrading their production management, equipment and product quality. Funding is also provided for applicants of pCm registration to conduct necessary testing on their pCm products and obtain professional support. The Health Bureau, in conjunction with the Advisory Committee on CMDF, has all along been closely monitoring the latest development of CM, as well as maintaining close contact with the implementation agent of CMDF and relevant CM stakeholders to timely introduce enhancement measures. Among these measures, in order to further support the sector to leverage the opportunities brought by the Notice, the CMDF will launch a new scheme to fund local pCm registration holders to apply for registration of their products with the GDMPA for sale in the Mainland through the aforesaid streamlined procedures, so as to encourage more local CM traders to make good use of the relevant policy to explore the Mainland market and promote the development of the CM sector. With preparatory work underway, the funding scheme concerned is expected to be officially launched in the first quarter of 2024.

(5) The GDMPA has submitted the Implementation Plan for streamlining of

approval procedures for Hong Kong and Macao registered oral traditional proprietary Chinese medicines for the National Medical Products Administration's examination and approval, in response to the aspirations of the two places for a policy on streamlined registration approval for traditional oral pCms. The HKSAR Government has maintained close liaison with the GDMPA for optimising the relevant policy. The relevant decision, once received via notification, will be announced to the sector in due course.