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Panel on Health Services
Subcommittee on Issues Relating
to the Development of Chinese Medicine

Regulatory regime for Chinese herbal medicines and proprietary Chinese medicines and development of the industry

Purpose

This paper briefs Members on the regulatory regime for Chinese medicine (CM) drugs and reports other related issues.

Background

2. The Chinese Medicine Council of Hong Kong (CMCHK) is an independent statutory body established in 1999 under the Chinese Medicine Ordinance (Cap. 549) (CMO). Under the CMCHK, the Chinese Medicines Board (CMB) is responsible for formulating and implementing the regulatory measures for CM drugs in accordance with the CMO. The Department of Health (DH) is responsible for providing professional support to the CMCHK and implementing regulatory measures in respect of CM drugs.

Regulatory Regime for Chinese Herbal Medicines

3. Currently, a stringent regime for the regulation of Chinese herbal medicines (Chm) and CM drug traders has been put in place under the CMO. For Chm, given the wide variety of Chm, they have been classified into different categories for regulatory control according to their toxicity and degree of popularity in Hong Kong. Having regard to the need of regulatory control, 605 types of Chm have been listed as Schedule 1 Chm (31 types) and Schedule 2 Chm (574 types) respectively under the CMO. Schedules 1 and 2 have clearly stated the origin of each Chm such as the scientific name of the plant or animal origin (including family, genus and species) and information on the medicinal parts to facilitate identification. The Chm specified in Schedules 1 and 2 of the CMO shall apply to the dried or processed form of such medicines and the following regulatory controls have been imposed –

Regulation on Sale of Chm

(i) The 605 types of Chm listed in the CMO (including 31 types of Schedule 1 Chm and 574 types of Schedule 2 Chm) can only be sold by licensed retailers or licensed wholesalers of Chm in the premises specified in the licences;

(ii) Control for the 31 types of Chm listed in Schedule 1 is more stringent as these are toxic Chm and the regulatory controls are set out as follows-

(a) Chm listed in Schedule 1 must be dispensed in accordance with a prescription given by a registered CM practitioner and cannot be sold at the retail level;

(b) No medicine traders shall possess, wholesale or dispense the Chm listed in Schedule 1 unless specified in their licences; and

(c) To fulfil the requirements on recording in respect of Chm listed in Schedule 1, licensed retailers of Chm have to keep the dispensing record and licensed wholesalers of Chm have to keep the related purchase and sales record.

Registration System of Proprietary Chinese Medicines (pCm)

4. All products fulfilling the definition of pCm as stipulated in the CMO must be registered by the CMB before they can be imported, manufactured or sold in Hong Kong. To be registered in Hong Kong, all pCm must meet the registration requirements in respect of safety, quality and efficacy prescribed by the CMB.

5. A transitional registration arrangement was provided under the CMO to allow the continuation of sale and manufacture of those pCm fulfilling the eligibility criteria of transitional registration. Provided that an application was made within the specified period, a "Notice of confirmation of transition registration of pCm" (HKP) would be issued subject to the assessment of the eligibility of the application for transitional registration. Such registration shall be effective until the issue of a "Certificate of registration" (HKC) or the refusal of an application in respect of the pCm or such date as specified and promulgated by the Secretary for Food and Health by notice published in the gazette, whichever is the earliest. As at 31 March 2020, there were 2 383 HKC and 5 863 HKP issued.

6. In order to assist the industry to fulfill the requirements concerning reports and other materials for the purpose of completing the move from transition registration of pCm to formal registration, with the support of CMB, DH has implemented different measures since 2014, such as a pilot project for provision of consultation services, adjustments to the technical requirements and expanding the list of recognised testing institutions.

7. The number of HKP cases reduced from 7 883 in December 2015 to 5 863 in March 2020. Among the 5 863 HKP cases being processed, 356 cases (about 6%) have been approved by the Chinese Medicines Committee as HKC and the "Certificate of registration of pCm" will be issued subject to payment of relevant fees from the applicants. Moreover, 2 167 HKP cases (about 37%) will be approved as HKC upon the completion of assessment of their product labels and inserts.

Regulatory Regime for CM Drug Traders

8. Under the CMO, there is a stringent regime in place for CM drug traders. The CMO stipulated that any person who is engaged in the business of retail of Chm, wholesale of Chm, wholesale of pCm or manufacture of pCm must obtain a relevant licence from the CMB and comply with the relevant practising guidelines which include purchasing CM from reputable suppliers, ensuring the quality of CM and that it is suitable for use, and keeping related transaction documents and records (for a period of not less than 2 years from the date of the transaction) to enable tracing of the source and distribution network of CM suspected to be dubious whenever necessary.

9. According to the CMO, "wholesale" or "wholesale dealing" means the importing and selling; or the obtaining and selling of any Chm or pCm to a manufacturer; or a person who obtains such medicine for the purpose of selling again; or supplying or causing to supply such medicine to a third party in the course of business or activity carried out by that person. As such, CM drug traders who carry out the related import business shall apply to the CMB for wholesaler licences in Chm or pCm.

10. Most of the Chm currently available for sale in Hong Kong are imported as decoction pieces from the Mainland, and any business engaged in the production of decoction pieces in the Mainland must meet the requirements of the "Good Manufacturing Practice for Drugs" and obtain accreditation from the relevant provincial medical products administration under the National Medical Products Administration. In addition, responsible personnel engaged in retail and wholesale business

of Chm in Hong Kong should have basic knowledge of authentication of Chm to determine the authenticity and quality of Chm so as to ensure the safety of Chm used by public.

11. As of 31 March 2020, there were 7 183 licensed CM drug traders, including 4 874 retailers of Chm, 1 018 wholesalers of Chm, 1 004 wholesalers of pCm and 287 manufacturers of pCm. Among the licenced manufacturers of pCm, 20 were also issued with Certificate of Good Manufacturing Practice (GMP) in pCm.

12. At present, the GMP requirement in respect of pCm in Hong Kong is not mandatory. It is still in the course of consultation regarding the full-scale application of the GMP standard for the manufacture of pCm. The Government will maintain close communication with the trade on the timetable and specific arrangement in the implementation of GMP.

Market Surveillance Mechanism

13. To ensure CM products meet their safety and quality requirements, DH has continued to optimise the market surveillance mechanism. According to a risk-based principle, DH will collect CM products at import, wholesale and retail levels on a regular basis. Currently, about 540 samples of Chm listed in Schedule 1 and 2 of the CMO and about 2 100 samples of pCm are collected annually. Testing items of Chm include heavy metal contents, pesticides residues and morphological identification, while the testing items of pCm include adulteration of western medicines, heavy metal contents, pesticide residues and microbial contents.

14. In the past 3 years (2017 to 2019), DH collected about 1 600 Chm samples for testing and the overall failing rate was 0.37%. Among the failed Chm samples, 1 sample was found exceeding the limit of heavy metals and toxic element, 1 sample was found exceeding the limit of pesticides residue and 4 samples were found failing in the morphological identification. During the same period, DH also collected about 6 700 pCm samples for testing and the overall failing rate was 0.1%. Among the failed pCm samples, 5 samples were found exceeding the limit of heavy metals and toxic element while 2 samples were found to be adulterated with western medicines.

15. To safeguard public health, DH reviews the market surveillance mechanism from time to time. Since February 2017, DH has enhanced the surveillance programme by increasing the number of Chm samples

collected from 30 to 45 per month and widened the scope of sampling from retail level to wholesale level (include importer). From January 2020 onwards, DH has further increased the number of Chm samples collected to 50 per month. It plans to progressively increase the sample number to 70 per month by the end of this year.

Inspection of CM Traders

16. DH will inspect the premises of the licensed CM drug traders (retailers, wholesalers and manufacturers) from time to time to ensure their compliance with the requirements stipulated in the legislation and practising guidelines. In 2019, DH has conducted about 8 100 inspections against licensed CM drug traders. During the inspection, DH officers will check the compliance with the requirements of the legislation, licensing conditions or restrictions, and any prescribed conditions or duties in respect of the practice of the trade, such as the qualification of the responsible person, provisions in the premises and the storage facilities, labelling of CM drugs, and the related record of transactions. If any contravention is found, enforcement action will be taken and the case will be referred to the CMB for disciplinary action.

Adverse Incident Reporting System

17. To safeguard public health, DH has also established a mechanism for reporting adverse incidents related to CM drugs. Under this mechanism, DH works closely with the Hospital Authority to conduct risk assessment, management and reporting on suspected adverse incidents arising from the use of CM drugs. If any sub-standard CM products are found, DH may request the CM drug traders concerned to recall the products. If there is any violation of the CMO or practicing guidelines, DH will refer the case to the CMB for follow-up actions, and issue press statements to alert the public.

18. DH has maintained close liaison with the Mainland regulatory authorities. A communication mechanism has already been established for timely exchange of information about the safety and quality of CM drugs in both places.

Way Forward

19. The Government has been working closely with the CM drugs industry with a view to understanding its needs and formulating policy to support the development of the trade in a timely manner. Established in 2013, the Chinese Medicine Development Committee (CMDC) and its

Chinese Medicines Industry Subcommittee (CMISC) have played an important role in this respect. Since their establishment, CMDC and CMISC have provided valuable advice on various issues integral to the development of the trade, including formulation of Hong Kong Chinese Materia Medica Standards Project, establishment of the Government Chinese Medicines Testing Institute, and drawing up of the schemes under the Chinese Medicine Development Fund (CMDF). As of May 2020, CMDC and CMISC have conducted 19 meetings altogether. CMDC will continue to give recommendations to the Government in a timely manner concerning the long term strategy of the development of CM drugs in Hong Kong.

CMDF

20. The Government announced the establishment of a $500 million dedicated fund aiming to provide CM practitioners and CM drug sectors with financial support to jointly promote the development of CM under the 2018-19 Budget. The CMDF consists of various subsidy programmes including those to provide assistance to local CM drug traders and facilitate the development of CM industry (for instance, "Proprietary Chinese Medicine Registration Supporting Scheme", "Chinese Medicine Applied Studies and Research Funding Scheme" and "Proprietary Chinese Medicine Quality and Manufacturing System Enhancement Funding Scheme", with more details in paragraphs 21 to 27 below). Before launching the CMDF, the Hong Kong Productivity Council, the implementation agent of the CMDF, held three consultation and briefing sessions from January to May 2019 to introduce the CMDF to the industry and gather opinions. It also consulted the Advisory Committee on the CMDF and its subcommittee in May and June 2019. The CMDF has commenced operation in June 2019 and will continue to roll out more subsidy programmes.

Expediting Registration of pCm

21. "Proprietary Chinese Medicine Registration Supporting Scheme" under the CMDF is open for applications since September 2019. This scheme accords a higher priority to traders of pCm with transitional registration and provides technical and financial support to them with a view to expediting the registration of pCm. The financial assistance provided will help applicants of pCm registration to engage consultants to provide expert advice, collect and prepare required information and documents in respect of safety, efficacy and quality relating to the application for 'Certificate of Registration of pCm' (HKC), as well as to conduct necessary testing of the pCm.

22. Each pCm manufacturer or wholesaler can apply for subsidies for up to 10 pCm to be registered by that applicant. 50% of the cost of professional consultation and testing service will be subsidised for each project. The maximum subsidy for each manufacturer or wholesaler of pCm is $200,000.

23. As at 30 April 2020, 290 applications for Proprietary Chinese Medicine Registration Supporting Scheme have been received and are being processed. Among them, 152 applications have been approved, involving nearly $2.2 million.

CM Pharmacists Accreditation Mechanism

24. Under the CMDF, "Chinese Medicine Applied Studies and Research Funding Scheme" supports eligible local registered non-profit-making organisations, related academic associations, trade associations and universities to conduct applied studies and specific researches in order to enhance overall standard of the CM industry and foster its development, with a view to enhancing the overall development of CM industry. Examples of such studies include applied technology studies of CM and market research of the CM industry.

25. "Chinese Medicine Applied Studies and Research Funding Scheme" has approved an application for subsidy for launching research studies on CM pharmacists certification system, including determination of qualifications and academic requirements, scope of work and terms of reference, current local training and employment situation, so as to support the development of CM and the CM Hospital. The Hong Kong Productivity Council, the fund implementation agent, is working on implementation details of the scheme with the applicant. The Government will also consult the CM industry in a timely manner to ensure the recommendations would reflect the consensus of the trade such that the Government may formulate the way forward in respect of such policies on the basis of the recommendations.

Support to Chinese Medicine Traders

26. Other subsidy programmes under the CMDF aims at providing matching subsidies to CM drug traders to assist them to enhance their professional capabilities as well as production and management quality. "Proprietary Chinese Medicine Quality and Manufacturing System Enhancement Funding Scheme" will provide financial assistance to local licensed pCm manufacturers to engage consultants to conduct basic assessment and gap analysis on meeting the requirement of GMP

certification as well as to provide consultancy services on quality management system, standard operating procedures and submission of application for GMP Certificate. The scheme will also subsidise pCm manufacturers to design or procure equipment to fulfill the requirements relating to GMP certification. The scheme was launched in March 2020 and is now accepting applications from agencies providing consultancy services to become an eligible institution under the CMDF for providing technical support CM drug traders.

27. In addition, "Chinese Medicine Warehouse Management, Logistics and Services Improvement Funding Scheme" provides subsidies to eligible wholesalers and retailers of Chm to enhance the efficiency and safety of processing, storing and transporting CM. The scheme also provides subsidies to eligible retailers of Chm in order to raise the quality of CM services provided to the public. The subsidies concerned will also assist wholesalers and retailers of Chm to procure relevant equipment. The implementation agent of CMDF, the Hong Kong Productivity Council, is now drawing up relevant vetting procedures and criteria with a view to finalising the details of the programme as soon as possible and opening the scheme for application from the CM industry.

Amendments to the CMO

28. Over the last few years, some alluded pCm orally consumed products, which did not fulfill the definition of pCm, have appeared in the market. Those products may use the names of traditional pCm preparations, and even claimed to be used for treatment or prevention of diseases. The names, ingredients, claims and packaging of these orally consumed products are very similar to registered pCm hence may pose health risks to public. In view of the above-mentioned situation, the Government had commenced a legislative amendment exercise to amend the pCm definition and its relevant clauses under the CMO so as to impose more stringent regulation over those products. The major amendments are as follows:

<u>Strengthening the regulation on alluded pCm in order to protect public health</u>

29. We suggest widening the definition of pCm that a product, formulated in finished dose form, composed of or claimed to be composed of any of CM drugs which has significant medicinal properties or side-effects or which the public generally would not consume as food, would be regarded as pCm. Moreover, we suggest that any product,

formulated in finished dose form, presented as a traditional CM preparation will also be regarded as pCm regardless of its composition.

Amending the definition of "active ingredient" so as to facilitate the effective enforcement of the CMO

30. To avoid the technical difficulties in proving and ascertaining the the "active ingredient" of a pCm, we also suggest amending the definition of "active ingredient" for the effective enforcement of the CMO.

Adding exemption clauses for western medicines, food or cosmetics products

31. Since it is not our intention to regulate western medicines, food, or cosmetic products under the CMO, we shall add exemption clauses to specify that pCm does not include a product containing western medicine, customarily consumed as food or drink, or for use externally and exclusively for cosmetic purpose.

32. The Government plans to introduce the legislative amendment proposal in detail to the Legislative Council Panel on Health Services in 2020-2021 legislative session.

Advice Sought

33. Members are invited to note the content of the paper and provide their views.

Food and Health Bureau
Department of Health
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