

Executive Summary Direct Investigation Report

Government's Regulation of Proprietary Chinese Medicine

Foreword

Since the provisions in the Chinese Medicine Ordinance (“CMO”) (Cap. 549) covering registration of proprietary Chinese medicine (“pCm”) took effect in 2003, only a small portion of applications for registration of pCm have been issued the Certificate of Registration (“HKC”). Meanwhile, many purported “health food products” have appeared in the market, their main ingredients being Chinese herbal medicines. However, as long as other non-Chinese medicine ingredients such as wheat and minerals are added to these products, they can be on sale in the market without registration under the CMO. People are thus concerned about the quality and safety of such “Chinese medicine health food products” (“CM health products”).

Our Findings

2. Our investigation has revealed inadequacies on the part of the Food and Health Bureau (“FHB”) and Department of Health (“DH”) in the following four areas.

(1) Definition under CMO Leaves Loopholes in Regulation

3. At the vetting stage of the CMO, the words “composed solely of” were added to the definition of pCm, which has caused loopholes in regulation. We have compared a number of registered pCm in the market with “CM health products” bearing similar names and containing Chinese medicines but are not required to be registered. We found that with identical names, similar ingredients and purported effects, and even the same manufacturer as pCm, those “CM health products” can circumvent the regulation under the CMO as long as ingredients other than Chinese medicines (e.g. grape seed) are added in the products, regardless of their composition and drug effect. Moreover, some of those products contain Chinese herbal medicines with strong toxicity listed in Schedule 1 of the CMO, which may be hazardous to people's health.

4. FHB and DH have indicated that they will regulate those “CM health products” in accordance with other relevant legislation and regulation, such as the Public Health and Municipal Services Ordinance, and the Food and Drugs (Composition and Labelling) Regulations. Nevertheless, the above laws do not focus on the safety, quality and efficacy of the products, and they have their limitations. For example, when the Centre for Food Safety under the Food and Environmental Hygiene Department conducts random checks on pCm, it aims to assess the risk of their consumption. Therefore, it will not test whether those “CM health products” actually contain the claimed Chinese herbal medicines, let alone to test their efficacy. Moreover, prosecutions against unregistered pCm for violation of those legislation are few and far between.

5. The Government agrees that there should be more stringent regulation of those purported “CM health products”. In this light, the Medicines Board under the Chinese Medicine Council of Hong Kong (“CMCHK”) has set up a taskforce to conduct a comprehensive review and give comments regarding amendment to the definition of pCm (including its scope).

(2) *Slow Progress of Registration*

6. There are three types of certificate/notice in the registration of pCm, namely: (1) HKC; (2) the Notice of confirmation of transitional registration of proprietary Chinese medicine” (“HKP”); and (3) the Notice of confirmation of (non-transitional) registration application of proprietary Chinese medicine (“HKNT”). HKP and HKNT are intended to be transitional arrangements for the registration system. Since the provisions requiring mandatory registration of pCm under the CMO were implemented in 2010, these transitional arrangements have been in place for eight years already, and the “final deadline” for submission of relevant documents (30 June 2015) set by the Medicines Board expired three years ago. As at 30 June 2018, there were over 18,000 applications for registration of pCm, but only less than 10% (1,539 cases) succeeded in obtaining HKC. The number was even less than applications rejected/withdrawn. Of all the applications, more than one-third are still holding transitional registration (including 6,781 HKP cases and 58 HKNT cases). For HKP, only those pCm manufactured, sold or supplied for sale in Hong Kong on or before 1 March 1999 can apply. In other words, most of the transitional products (HKP) have been on sale for nearly 20 years and yet they still could not get HKC.

7. Members of the public may not be able to tell the difference between HKP, HKNT and HKC. Besides, since it is very difficult to obtain HKC, and those HKP/HKNT holders are still allowed to be sold in the market, there is less incentive for the manufacturers to invest and seek full registration after obtaining HKP.

8. In our view, that so many applicants are still holding HKP and HKNT after a long period indicates that the Government has not set any clear objective and time schedule for transforming the HKP and HKNT cases into HKC. Moreover, if the Government does not see any problem with those HKP and HKNT products being sold in the market for such a long time, people may doubt whether the requirement for HKC is necessary and justifiable.

(3) Inadequate Support and Lack of Communication with the Trade

9. People in the Chinese medicine trade have expressed a lot of opinions regarding the current regulatory system and registration requirements, notably the shortage of qualified laboratories, the harsh registration requirements, and the high costs involved. Although DH has adopted a number of measures to support the trade, the traders generally consider the technical support from the Government still inadequate. The Government's failure to address this issue may hinder the long-term development of pCm.

10. The Government has on one hand imposed stringent regulatory requirements on the registered pCm, but on the other hand failed to plug the existing legal loopholes regarding "CM health products" which are not subject to control of the CMO. This is tantamount to encouraging the manufacturers to continue selling their pCm under the cover of health food products. It will inevitably undermine the public's confidence in the current regulatory system.

(4) Consider Setting up a Certification System for Chinese Medicine Pharmacists

11. Several universities in Hong Kong offer degree programmes in Chinese medicine. However, Chinese medicine pharmacist has not been recognised as a professional qualification. Unlike pharmacists in western medicine, there is currently no registration or certification system for Chinese medicine pharmacists in Hong Kong. On the other hand, our neighbour Macao will soon set up a new registration system for Chinese medicine pharmacists to establish their legal status and professional

recognition. Its development is ahead of Hong Kong.

12. To expedite the processing of applications for pCm registration, DH has beefed up its manpower. However, the newly recruited Assistant Chinese Medicine Officers are employed on limited term contracts. This means that the extra staff are merely for meeting transient operational needs. Given that more than 6,000 applications for HKP are still under processing, it is essential for the Government to review the manpower arrangements.

Conclusion

13. **The CMO was enacted with the intent of preventing unregistered pCm from spreading in the market and thus endangering people's health. Regrettably, since the enactment of the CMO in July 1999, nearly two decades have passed and yet over 80% of the registered pCm have not been issued HKC. FHB and DH should be held accountable for the slow progress. What is more worrying is that some manufacturers have taken advantage of the legal loopholes by adulterating certain pCm, which are required to be registered, with non-Chinese medicine ingredients. As a result, the pCm was "transformed" into health food products, thereby circumventing regulation under the CMO. Such shortcut of "less investment, less regulation" must be blocked as soon as possible. Otherwise, the proliferation of "CM health products" in the market may become a threat to public's health.**

Recommendations

14. In the light of the above, The Ombudsman makes 12 improvement recommendations to the Government.

Review of Current Legislation

15. **FHB** should quickly review whether any amendments to the relevant provisions of the CMO are necessary, covering the following areas:

- (1) to plug the legal loopholes in the definition of pCm as soon as possible;
- (2) to impose more stringent regulation on those health food products containing Chinese medicines with stronger toxicity listed in Schedule 1 of the CMO, making it mandatory for these products to obtain

registration;

- (3) to restrict “CM health products” from using the same names as pCm;
- (4) to require all products containing Chinese medicine to adopt the Chinese and English names given in the Schedules of the CMO when listing out their ingredients; and
- (5) to regulate the efficacy claims of “CM health products”.

Addressing the Registration System

- (6) **DH** should help the CMCHK in reviewing the current registration system, explore why a large number of applicants are still holding transitional registration after such a long period, and implement effective measures focusing on assisting those applicants to obtain full registration as soon as possible.
- (7) **DH** should help the CMCHK to set a target timeframe for transforming the more than 6,000 transitional registrations into full registration, and review any need for more staff to handle the vetting and approval work.
- (8) **DH** should consider engaging more specialists in Chinese medicines to assist the CMCHK in devising the registration system and vetting applications.

Strengthening Communication with the Trade and Offering More Support

- (9) **DH** should strengthen its communication with the trade and various stakeholders (including academics and laboratories).
- (10) **DH** should provide more assistance to the trade in resolving the problems in pCm registration, such as expanding the number of accredited Mainland drug testing institutes.
- (11) **FHB** should take reference from the experience of other cities and consider establishing a registration/certification system for Chinese medicine pharmacists, so as to enhance their professional status and recognition.

Publicity and Public Education

- (12) **DH** should step up its publicity efforts to educate the public to differentiate between pCm and “CM health products”.

**Office of The Ombudsman
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