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Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Updated background brief prepared by the Legislative Council Secretariat for the meeting on 15 December 2015

Arrangements for the formal registration of proprietary Chinese medicines

Purpose

This paper summarizes the concerns of the members of the Subcommittee on Issues Relating to the Development of Chinese Medicine ("the Subcommittee") on issues relating to the arrangements for the formal registration of proprietary Chinese medicines ("pCms").

Background

2. The Chinese Medicine Ordinance (Cap. 549) ("the Ordinance") stipulates, among others, that all products falling within the definition of pCms must be registered by the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong before they can be imported, manufactured or sold in Hong Kong. To be registered in Hong Kong, all pCms must meet the registration requirements regarding safety, quality and efficacy prescribed by CMB.

3. Having taken into account the history and practical circumstances of the sale of pCms in Hong Kong, the Ordinance provides a transitional registration system for pCms manufactured, sold or supplied for sale in Hong Kong on 1 March 1999. For such pCms, the relevant manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may, in accordance with the Ordinance, apply for transitional registration of the pCms within the specified period (i.e. from 19 December 2003 to 30 June 2004).

4. A "Notice of confirmation of transitional registration of pCm" (i.e. "HKP") will be issued if pCm has been assessed by CMB as meeting the registration requirements. To facilitate the processing of transitional registration of pCm to formal registration, holder of HKP concerned has to submit the necessary documents in respect of safety, quality and efficacy to CMB. "Certificate of registration of pCm" (i.e. "HKC") will be issued if pCm has been assessed by CMB as meeting the registration requirements. Those applications which are not eligible for transitional registration but have submitted three acceptable basic test reports (i.e. (a) heavy metals and toxic element test report, (b) pesticide residue test report and (c) microbial limit test report) will be issued with "Notice of confirmation of (non-transitional) registration application of pCm" (i.e. "HKNT").

5. Relevant legislation related to the mandatory registration of pCms has become effective since 3 December 2010. The legislation related to the requirements of label and package inserts has become effective since 1 December 2011. According to the Administration, as at 31 January 2015, CMB has received about 17 980 applications for registration of pCms, of which some 14 110 applied for transitional registration at the same time. About 7 470 of the pCm registration applications were rejected by CMB. The reasons for rejection includes (a) failure to furnish the required documents, information and/or samples for registration; (b) withdrawal by applicants; (c) not fulfilling the definition of pCm; and (d) not fulfilling the application eligibility.

Deliberations of the Subcommittee

6. The Subcommittee held a number of meetings between November 2014 and July 2015 to discuss issues relating to the formal registration of pCms and received views from deputations at two meetings. The major views and concerns expressed by members are summarized in the following paragraphs.

<u>Stringent requirements for registration of pCms</u>

7. Members shared with deputations' grave concern that the requirements for pCm registration were too stringent and the processing time was too long. Members noted that only 503 pCm products were issued with HKC as at 3 July 2015. Given that only a small number of pCms were issued with HKC, there was a view that the Administration should consider reviewing the pCm registration system, including the registration classifications, requirements and procedures. In the meantime, the Administration should streamline the application procedures and provide clear guidelines for the applicants to follow.

8. According to the Administration, in formulating the registration requirements for pCm, CMB had made reference to the regulatory requirements on pCm in other places, taken into account the practical circumstances of the trade, and collated views of the trade through extensive consultations. Individual applicants who had difficulties in complying with the registration requirements could approach CMB for assistance.

9. On the processing time of registration applications, members were advised that CMB would allow a reasonable period of time for applicants to submit outstanding documents or test reports. If applicants failed to submit precise information for their applications for pCm registration or applicants amended or correct product information, CMB would need to take time for follow-up in each case. On the other hand, in view of the new scientific research findings, information regarding the safety of Chinese medicines and amendments to other local legislation (e.g. Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586)), CMB would, where necessary, introduce additional registration requirements or update these requirements correspondingly so as to comply with the new statutory requirements and protect public safety. These might, in turn, affect the progress of processing applications for pCm registration.

10. There was concern that pCm products which failed to meet the registration requirements concerning the safety and quality might be available for sale in the market as health food products. The Administration advised that all products falling within the definition of pCms were subject to regulation of the Ordinance. Health food items were also required to comply with other ordinances, such as the Undesirable Medical Advertisements Ordinance (Cap. 231) and Food and Drugs (Composition and Labelling) Regulations (Cap. 132W). A market surveillance on health food was put in place and samples were collected from the market for testing on a regular basis.

Difficulties encountered by the trade in pCm testing

11. Members expressed serious concern about the difficulties encountered by the trade in the testing of safety and quality of pCms. Apart from expensive testing costs, pCm manufactures and traders had difficulty in identifying laboratories for testing, as well as technical difficulties in establishing product specification. Concern was also raised about the capacity of the existing accredited laboratories to provide testing services for the trade.

12. The Administration advised that CMB had issued guidelines on the requirements of registration applications, so as to help the trade understand clearly the specific requirements in respect of the reports required to be

submitted. The Department of Health ("DH") also communicated with the trade through various channels such as sharing sessions, regular briefing sessions on "Technical issues in registration of pCm" or meetings with individual applicants. As regards the accredited laboratories, there were currently nine local laboratories and 17 Mainland laboratories recognized by the China Food and Drug Administration and CMB providing pCm testing services for the trade. Where necessary, CMB might request the relevant Mainland regulatory authorities to expand the list of recommended laboratories so as to increase the number of laboratories qualified for conducting pCm testing.

13. To assist the trade in meeting the testing requirements, some members called on the Administration to consider setting up a non-government organization to provide consultation services and assistance to pCm manufacturers in respect of testing and registration matters.

Migration of pCms from transitional registration to formal registration

14. Members expressed serious concern about the difficulties encountered by the trade in submitting the documents and test reports required for the formal registration of pCms. They noted that measures were introduced to facilitate migration of pCms from transitional registration to formal registration. Apart from extending the deadline for submitting the product specification and general stability reports by HKP holders from 30 June 2013 to 30 June 2015, CMB adjusted the processing arrangements in May 2014 to expedite the processing of transitional registration of pCms to formal registration[1]. In addition, CMB had provided relief measures for the trade in order to address the difficulty encountered by the applicants in producing testing reports as evidence for fulfilling the registration requirements.

15. Notwithstanding the relief measures, some members expressed grave concern that pCm manufacturers and traders still had great difficulties in meeting the registration requirements, particularly the high threshold for the standard of testing reports and the expensive testing costs. They urged the Administration to strengthen the assistance for the trade in resolving the difficulties, such as setting up a dedicated fund to support their development.

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[1] The adjusted arrangements mainly focus on the following three aspects:
(i) Product efficacy documents: adjust the qualification of the author of the formula and principle of formulating the formula;
(ii) Product quality documents: adjust the technical requirements of product quality and stability test reports; and
(iii) Change of particulars of the manufacturer: adjust the requirement for re-submission of documents.

16. The Administration advised that it would liaise with CMB on the trade's concerns and strengthen the provision of information to the trade regarding the requirements for and implementation of pCm registration in Hong Kong. As regards the request for setting up a dedicated fund, the Administration advised that it would be considered when appropriate.

17. The Subcommittee noted that after the deadline of 30 June 2015 for submitting the product specification and general stability reports by HKP holders, there were still 8 537 pCm products issued with HKP, 11% of which had not submitted the required reports yet. The Administration advised that for these HKP holders, CMB had issued reminder letters to them requiring them to submit the reports within three months from the date of the reminder letters issued (i.e. by early October 2015). If they were unable to do so, they would be given another 14 days to provide sufficient reasons for consideration by CMB. Otherwise, CMB might consider rejecting the HKC applications concerned. If the HKC application was rejected, the relevant HKP holder still had the right to appeal against the decision in 14 days. The Administration advised that some of these pCm products carrying HKP status with outstanding quality specification and stability test reports had not been actively traded in the local market.

18. Some members indicated that some of the HKP holders concerned were just unwilling to disclose the master formula of their pCm products. In their view, a new registration category which did not require the provision of the master formula should be created for those traditional pCm products with proven safety and efficacy.

19. The Administration advised that in accordance with the Ordinance, pCm manufacturers or traders had to disclose the master formulae of their pCm concerned in the registration. A mechanism was in place to protect the confidentiality of the master formularies of pCms. The Administration undertook to explain the relevant mechanism to the trade to address their concern.

20. Some members proposed to "freeze" the HKP status of certain pCms and allow the HKP holders concerned to resume the application for formal registration at any time during the frozen period. This would obviate the need for the manufacturer concerned to apply afresh for formal registration when he/she was financially or technically in a better position to fulfill the registration requirements. The Administration explained that under the Ordinance, there was also no provision which allowed "freezing" the HKP status of pCms which failed to comply with the requirements on safety, quality and efficacy. CMB was not empowered to allow pCms to "freeze" their HKP status. When a HKC application was being processed by CMB, the HKP concerned would continue

in effect and the pCm concerned would continue to be permitted for sale, until (i) the issue of a HKC; (ii) the refusal of HKC application; or (iii) such date as specified and promulgated by the Secretary for Food and Health by notice published in the Gazette, which was the earliest. If the HKC application of a pCm issued with HKP was rejected by CMB, the HKP concerned would be invalidated and the pCm concerned would no longer be allowed for sale in the market. The existing arrangement was in line with the principle of ensuring the efficacy of pCms and their safe use by the public.

Conversion from HKP to HKC

21. Members noted that for those pCms issued with HKP for which HKC had been approved by CMB, the manufacturers and traders concerned had to print and replace new labels and package inserts for their pCms within six months' time. Some members shared with the trade's view that more time, say two years, should be allowed for the labelling replacement work. They requested the Administration to allow these manufacturers and traders to sell out their pCms issued with HKP, instead of requiring them to conduct product recall, when migrating to HKC in order to avoid unnecessary wastage.

22. The Administration explained that to comply with the Ordinance and to avoid causing confusion to customers, pCm manufacturers and traders were required to replace new labels and package inserts for pCms issued with HKP when application for HKC had been approved for these pCms. To address the trade's concern, CMB had subsequently decided to extend the deadline for replacing labels and package inserts. pCm manufacturers and traders were given 12 months to receive HKC and replace their HKP concomitantly. If more time was needed, HKP holders might apply to CMB for further extension which would not be longer than 12 months. The Administration considered that under the extension arrangements, sufficient time was allowed for product holders to deal with the transitional/interfacing matters.

Relevant papers

23. A list of the relevant papers on the Legislative Council website is in **Appendix**.

Council Business Division 2
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Appendix

Relevant papers on the arrangements for migration of proprietary Chinese medicines from transitional registration to formal registration

Committee	Date of meeting	Paper
Subcommittee on Issues Relating to the Development of Chinese Medicine	25.11.2014 (Item I)	Agenda Minutes
Subcommittee on Issues Relating to the Development of Chinese Medicine	16.12.2014 (Item I)	Agenda Minutes CB(2)983/14-15(01)
Subcommittee on Issues Relating to the Development of Chinese Medicine	26.1.2015 (Item I)	Agenda Minutes CB(2)983/14-15(01)
Subcommittee on Issues Relating to the Development of Chinese Medicine	13.3.2015 (Items II & III)	Agenda Minutes
Subcommittee on Issues Relating to the Development of Chinese Medicine	14.4.2015 (Item II)	Agenda Minutes CB(2)1559/14-15(01)
Subcommittee on Issues Relating to the Development of Chinese Medicine	9.6.2015 (Item II)	Agenda Minutes CB(2)76/15-16(01)
Subcommittee on Issues Relating to the Development of Chinese Medicine	21.7.2015 (Item II)	Agenda Minutes CB(2)76/15-16(01)

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