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Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Background brief prepared by the Legislative Council Secretariat for the meeting on 13 March 2015

Arrangements for migration of proprietary Chinese medicines from transitional registration to formal registration

Purpose

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

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 the 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 the 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 the end of November 2014, CMB has received about 17 970 applications for registration of pCms, of which about 14 110 also applied for transitional registration. Of these, about 8 600, 420 and 600 have been issued with HKP, HKC and HKNT respectively after approval by CMB.

Deliberations of the Subcommittee

6. Issues relating to the arrangements for the migration of pCms from transitional registration to formal registration were discussed in the context of the registration and testing of pCms at the Subcommittee meetings on 25 November 2014, 16 December 2014 and 26 January 2015. The concerns expressed by Subcommittee members are summarized in the following paragraphs.

7. Members expressed serious concern about the difficulties encountered by the trade in the testing of safety and quality of pCms (e.g. expensive testing costs, difficulties to identify laboratories for the testing, and technical difficulties in establishing product specification). They enquired about the availability of measures to facilitate the trade to migrate their transitional registration to formal registrations. The Administration advised that having assessed the overall situation, CMB had resolved in June 2013 to extend the deadline for submitting the product specification and general stability reports by HKP holders from 30 June 2013 to 30 June 2015. Also, CMB had adjusted the processing arrangements in May 2014 to expedite the processing of transitional registration

of pCms to formal registration[1]. In addition, to address the difficulty encountered by the applicants in producing safety and quality testing reports as evidence for fulfilling the registration requirements, CMB had provided the following relief measures for the trade –

(a) if an applicant failed to submit the testing reports within the prescribed deadline, he might apply for extending the deadline with CMB if he could provide reasonable justifications;

(b) if necessary, CMB might request the regulatory authorities in the Mainland to expand the list of recommended laboratories so as to increase the number of laboratories qualified for conducting the testing; and

(c) The Department of Health ("DH") had been regularly holding briefing sessions on "Technical Issues in Registration of pCm" to brief the trade on the registration requirements of pCm and exchange views with the trade on technical issues for establishment of quality specifications.

8. 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. These members pointed out that less than 3% of the pCms issued with HKP had been issued with HKC. They urged the Administration to strengthen assistance for the trade in resolving the difficulties, such as by setting up a dedicated fund to support their development. The Administration advised that it would liaise with CMB on the trade's concerns and strengthen the provision of information to the trade, particularly on the arrangements for review against decisions of CMB in relation to applications for registration. As regards the request for setting up a dedicated fund, the Administration advised that it would be considered whenever appropriate.

9. Regarding the extended deadline of 30 June 2015 for submitting the product specification and general stability reports by HKP holders for application for HKC, some members expressed concern about the arrangements

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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.

for these HKP holders if they were still unable to meet the deadline. The Administration advised that DH had been actively communicating with the trade and applicants through various channels on the requirements for pCm registration and testing of pCm. These included the conduct of a series of seminars, briefings or interview with applicants, and the promulgation of the "Chinese Medicines Traders' Newsletter" by CMB. The Administration noted the concerns on pCm registration which would also be reflected to the Chinese Medicine Development Committee and CMB.

10. 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.

11. 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. According to CMB, the relevant registration holders could apply for an extension of the six-month grace period if more time was needed for the labelling replacement work.

Relevant papers

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

Council Business Division 2
Legislative Council Secretariat
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Appendix

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Committee	Date of meeting	Paper
Subcommittee on Issues Relating to the Development of Chinese Medicine	25.11.2014 (Item I)	Agenda Minutes
	16.12.2014 (Item I)	Agenda Minutes
	26.1.2015 (Item I)	Agenda

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