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For information

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

Further Discussion on the Arrangements for the Formal Registration of Proprietary Chinese Medicines

Purpose

This paper briefs Members on the background, latest progress and future work regarding the registration of proprietary Chinese medicines ("pCms") so as to facilitate Members to further discuss on the arrangements for the formal registration of pCms.

Background

2. The Chinese Medicine Council of Hong Kong ("CMCHK") is an independent statutory body established under the Chinese Medicine Ordinance (Cap. 549) ("CMO") to implement regulatory provisions for Chinese medicine. The Department of Health ("DH") provides professional and administrative support for the CMCHK in devising and implementing regulatory measures for Chinese medicine.

3. All products falling within the definition of pCms must be registered by the Chinese Medicines Board ("CMB") under the CMCHK before they can be imported, manufactured or sold in Hong Kong. To be registered in Hong Kong, a pCm must meet the registration requirements regarding safety, quality and efficacy prescribed by the CMB.

4. Taking into account the history and practical circumstances of the sale of pCms in Hong Kong, the CMO provides an arrangement of transitional registration. For any pCm which was manufactured, sold, or supplied for sale in Hong Kong on 1 March 1999, an application may be made according to the CMO for transitional registration with the issue of a "Notice of confirmation of transitional registration of pCm" ("HKP"). Such registration will remain valid until the pCm is formally registered,

or until the refusal of its application for formal registration, or until a date to be promulgated in the Gazette by the Secretary for Food and Health, whichever date is the earliest. The relevant manufacturer, importer or local agent/representative of a manufacturer outside Hong Kong has to submit the application for transitional registration within the designated period (i.e. from 19 December 2003 to 30 June 2004):

(a) If the pCm has been assessed by the CMB as meeting the transitional registration requirements, a HKP will be issued. For migration from the transitional registration to formal registration, the HKP holder has to submit the necessary documents in respect of safety, quality and efficacy to the CMB. If the pCm has been assessed by the CMB as meeting the formal registration requirements, a "Certificate of registration of pCm" ("HKC") will be issued;

(b) If the pCm has been assessed by the CMB as not meeting the transitional registration requirements (for instance, because the pCm was manufactured after 1 March 1999) but basic safety test reports required by the CMB were submitted on or before 31 March 2010, a "Notice of confirmation of (non-transitional) registration application of pCm" ("HKNT") will be issued.

Progress in pCm Registration

5. The CMB started accepting applications for pCm registration on 19 December 2003. As at 17 November 2015, a total of about 18 000 applications for pCm registration were received, of which about 14 110 also applied for transitional registration. After assessment by the CMB, 8 052 pCm products were issued with HKP, 559 with HKC and 399 with HKNT.

Deadline for submission of reports by HKP holders

6. To provide the trade with a clearer picture of the arrangements for formal registration of pCms, the CMB published the "Application Handbook for Registration of Proprietary Chinese Medicines" for the first time as early as in December 2003. The handbook sets out the documents required and the submission deadline for formal registration

of pCms. HKP holders were originally required to submit the product specification and stability test reports (collectively called as "product quality reports") by 30 June 2009, but the CMB extended the deadline twice subsequently in response to the request of the trade for more time for the tests to address difficulties encountered in the process. The first postponement was announced in June 2006, extending the deadline from 30 June 2009 to 30 June 2013. In June 2013, after assessing the overall situation of the trade, the CMB resolved to further extend the deadline to 30 June 2015. In other words, the trade has been given more than ten years to prepare the product quality reports. For the long-term development of pCm, the Administration has to make final arrangements to bring transitional registration to an end.

7. Having considered the progress in the submission of the relevant reports by HKP holders, the CMB decided in May 2015 that the deadline for HKP holders to submit product quality reports should remain unchanged at 30 June 2015. Following the established procedure, the Chinese Medicines Committee ("CMSC") under the CMB has issued reminder letters to those HKP holders who have yet to submit the product quality reports, requiring them to submit the required reports within three months from the date of the letter or provide sufficient reasons for failing to do so (supported by objective information, such as evidence issued by laboratories of tests being conducted) for consideration by the CMSC on a case-by-case basis. In case of non-compliance, another letter will be issued according to the procedure to request for submission of the reports or reasons before a specified deadline (i.e. within 14 days). If the HKP holder still fails to submit the required reports or reasons before the deadline specified in the letter, the pCm registration application concerned will be refused in pursuance of section 121(4) of the CMO.

8. In connection with the procedures outlined in paragraph 7 above, as at 12 November 2015, the CMSC has issued letters to refuse applications of formal pCm registration by the HKP holders who have failed to comply with the afore-mentioned requirements, and informed them that their HKPs will become invalid effective from 17 November 2015. The total number of applications for formal registration of pCm which have been rejected was 361, among which 249 products have not been circulating on the market prior to this date. The rest of 112 products have already been removed from the market. The list of the concerned pCms has been uploaded to the website of the CMCHK for reference by traders and public since 17 November 2015.

9. Excluding the 361 pCms in paragraph 8 above, as at 17 November 2015, a total of 8 052 pCms still have their HKPs remaining valid. The CMB will continue to process the applications for migration from HKP to HKC.

Initiatives to assist the trade

Providing support

10. To facilitate the application for formal registration of pCms, the CMB has issued guidelines on the registration requirements to help the trade understand the specific requirements for the submission of various reports. The CMB and the DH have been actively communicating with the trade through different channels including seminars, briefings, interviews with individual applicants, and the Chinese Medicines Traders Newsletter published by the CMB. The aim is to explain to the trade and applicants the requirements for pCm registration and testing as well as the latest arrangements for pCm registration. In respect of the difficulties encountered by the trade in pCm testing, the DH regularly holds exchange sessions entitled "Technical Issues in Registration of pCms" on subjects of concern to help the trade understand the requirements for pCm registration and technical issues for the establishment of quality specifications. The Government has also been providing technical support for the trade (such as release of information on laboratory testing) to facilitate compliance with registration requirements.

Adjusting the technical requirements

11. In the light of the progress of submission of registration documents by HKP holders and feedback from the trade, the CMB formulated the "Updated Arrangement for Processing Transitional Registration of pCm to Formal Registration" last year so as to expedite the processing. The arrangements have been updated with a focus on the following three aspects:

(a) Product efficacy documents – Adjusting the qualification of the author of "interpretation and principle of formulating a prescription";
(b) Product quality documents – Adjusting the technical

requirements for product specification and stability test reports (applicable to reports submitted before 30 June 2015); and

(c) Variation of information of the manufacturer – Adjusting the requirement for re-submission of documents.

Adjusting the requirements for changing the coating material of pCm tablets

12. Regarding the situation encountered by HKP holders who applied for variation of product information related to the change of sugar coated tablet to film coated tablet, having considered traders' opinion and the fact that the nature of change was an improvement of dose form, CMB has resolved, under the premise of safeguarding public health, to approve application for change if the respective HKP holder has submitted sufficient scientific evidence to prove the stability of the improved dose form, and the HKP holder would be allowed to submit the remaining stability reports during the migration from HKP to HKC and the renewal of HKC.

Extending the transitional period for replacing labels and package inserts for migration from HKP to HKC

13. According to the original requirement, when a pCm issued with HKP was approved for HKC by the CMB, the HKP holder had to print and replace new labels and package inserts for the pCm within six months' time. In response to the trade's request for more time for labeling replacement, the CMB has extended the transitional period for replacing labels and package inserts for migration from HKP to HKC from six months to twelve months. Where necessary, further extension up to another twelve months may be considered by application to the CMB.

Future Work of pCm Registration

14. The CMB will actively deal with the migration of pCms from transitional registration to formal registration and process the submitted applications for formal registration (including HKNTs and the registration applications submitted after 1 April 2010). Meanwhile, the registration of the first batch of pCms issued with HKC will expire in December 2015. The CMB has started processing the registration

renewal applications according to the relevant arrangements formulated in 2014.

15. The Government has been providing technical support for the trade in respect of pCm registration. The CMB and DH will maintain close liaison with the trade and laboratories to ensure smooth migration from transitional registration to formal registration as well as medication safety for the public.

Advice Sought

16. Members are invited to note the latest progress and future work of pCm registration.

Food and Health Bureau
Department of Health
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