Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Update on the progress of registration of proprietary Chinese medicines – September 2014

Purpose

This paper provides members with an update on the progress of registration of proprietary Chinese medicines (pCm) and the enforcement arrangement upon the commencement of the provisions related to the requirements for labeling and package insert of pCm.

Background

2. The system of registration of pCm is established in accordance with the Chinese Medicine Ordinance (CMO). The Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong has started to accept applications for registration of pCm since 19 December 2003.

3. According to the system of transitional registration of pCm under the CMO, where a pCm was manufactured or sold in Hong Kong on 1 March 1999, the relevant manufacturer, importer or local agent/representative of a manufacturer outside Hong Kong may apply for transitional registration of the pCm before 30 June 2004. CMB has started to issue "Notice of confirmation of transitional registration of pCm" (i.e. HKP) since 31 March 2008 and "Certificate of registration of pCm" (i.e. HKC) since end of November 2010.

Progress of pCm registration

4. As at 3 September 2014, CMB has received about 17 940 applications for registration of pCm, of which about 14 110 also applied for transitional registration. The updated statistics are set out in the **Annex.**

Trade facilitation measures for processing transitional registration of pCm to formal registration

5. To facilitate the processing of transitional registration of pCm to formal registration, the holders of HKP have to submit the necessary documents in respect of safety, quality and efficacy to CMB. HKC will be issued if the pCm has been assessed by CMB as meeting the registration requirements.

6. Having regard to the situation of the Chinese medicines trade, CMB in June 2013 decided to extend the deadline for submission of the certificate of analysis of product specification and general stability test report by HKP holders from 30th Jun 2013 to 30th Jun 2015. In addition, having considered the progress of submission of registration documents by the holders and feedback from the trade, CMB formulated a set of updated arrangements in May 2014 regarding the processing of transitional registration of pCm to formal registration so as to expedite such processing. The updated arrangements mainly focus on the following three aspects:

(a) Product efficacy documents — Adjust the qualification of the author of the "interpretation and principle of formulating a prescription"

- Aforementioned documents written by researchers or owners of the prescription, other than professionals, will also be accepted by CMB.

(b) Product quality documents - Adjust the technical requirements of certificate of analysis and stability test report

- In the above reports, if there is inappropriate selection of markers for identification test and assay test (e.g. same marker for both tests or not using the principal, precious constituent in the prescription) or if there is omission of individual inspection tests, CMB will accept the certificate of analysis or reports, consider conditional approval and issue HKC to the HKP holder provided that all other documents meet the requirements as determined by CMB. The HKC holders need to submit the second and third batch of stability reports, together with the corrected certificate of analysis, upon the renewal of such registration.

- If the method validation report of identification and assay tests submitted by the HKP holder does not include negative control test, the holder can either supplement the negative control test, or apply other techniques to validate the specificity of the method. If all other registration requirements are fulfilled and upon submission of documentary proof issued by laboratories showing the commencement of the related negative control test or application of other techniques, CMB may consider conditional approval of HKC of the product.

(c) Variation of information of the manufacturer — Adjust the requirement for re-submission of documents

- With the approval by CMB in variation of information of the manufacturer, HKP holders need to submit the certificate of analysis of pCm manufactured by the new manufacturer during the conversion of transitional registration of pCm to formal registration. However, if a holder has already submitted the certificate of analysis of the product manufactured by the previous manufacturer and that report meets the registration requirements; and the holder and the new manufacturer can issue a statement that the product specification remains unchanged, the certificate of analysis of the previous manufacturer will, in such circumstance, be provisionally accepted as a valid certificate of analysis of the new manufacturer. CMB will request the holder to supplement the certificate of analysis of the product manufactured by the new manufacturer at the time of renewal of such registration.

7. From May to July in 2014, 5 seminars have been held by CMB and the Department of Health (DH) to introduce the above updated arrangements and other new arrangements of pCm registration to the traders and applicants.

Enforcement arrangement after the commencement of relevant provisions related to the requirements of label and package insert

8. The provisions relating to the requirements of labeling and package inserts of pCm commenced on 1 December 2011. Having considered the current operation of the Chinese medicines trade, CMB decided that if a pCm is found in violation of the legislative requirements, DH will require the

trader concerned to cease selling that pCm, and issue warning letter to the trader, provided that no hazard to public health will be caused. However, DH may take prosecution action against serious offence. The pCm, after rectification, complies with the requirements for labeling and package insert would be approved for resumption of sale.

9. As of 3 September 2014, over 40 700 registered pCms were checked and 391 pCms were found to have failed to comply with the requirements on label and package insert as prescribed under the law. The traders were asked to remove these pCms from sale, and warning letters were issued. Those products' information is published at http://www.cmd.gov.hk/html/eng/index.html for the public's and trade's reference.

10. The above enforcement arrangements have been reviewed after one year of implementation of the legislative provisions. In general, the implementation was well received by the community and the trade. Majority of pCm complied with the legal requirements (failure rate less than 1%). CMB agreed to continue with the existing enforcement arrangements and subsume the active surveillance to Chinese medicines traders under the prevailing market surveillance mechanism, and to continue with the related publicity activities.

Chinese medicines traders operating in domestic premises

11. According to the CMO, the premises to which the trader licence relates shall in all respects be suitable for carrying on a business of Chinese medicines. Having regard to the practicing requirements and the operation of Chinese medicines trade and after consultation with the Buildings Department, CMB has decided that Chinese medicines traders are not suitable to conduct Chinese medicines business at domestic premises. CMB, therefore, starting from June 2011, no longer accepts any new application for licences operating at domestic premises (premises which are constructed or intended to be used for habitation). Having considered that a number of licensed Chinese medicines traders were still carrying out their business at domestic premises, CMB had allowed sufficient time for the traders concerned to find and/or relocate to suitable premises to continue their business. The grace period started from 1 January 2012 and lasted until 31 December 2013 or the date of enforcement action taken in accordance with the Buildings Ordinance, whichever was earlier.

12. On 31 December 2013 (i.e. the last day of the grace period), the licensing matters related to the relocation of affected Chinese medicine traders at domestic premises were completed. Since then, no Chinese medicine traders shall conduct Chinese medicines business at domestic premises. With the cooperation and support from the trade, the process was successfully concluded.

Advice sought

13. Members are invited to note the paper and offer comments, if any.

Department of Health
September 2014

Annex

Progress of proprietary Chinese medicine (pCm) registration as at 3 September 2014

Progress of pCm registration including those applied for transitional registration	**Nos. of Cases**
Issued with "Notice of confirmation of transitional registration of pCm" (the Notice)	8,610
To be issued with Notice	0
Assessed cases	0
Rejected for registration of pCm due to: (a) without three acceptable test reports [1]; (b) without the required documents, information, samples and other materials; (c) not fulfilling the eligibility to be the applicant; and (d) not fulfilling the definition of pCm. (e) withdrawn by applicants	5,500
Not eligible for transitional registration	0
Sub-total	**14,110**
Progress of non-transitional pCm registration [2]	
Submitted with the three test reports and issued with "Notice of confirmation of (non-transitional) registration application of pCm" (HKNT) [3]	610
Others (Including rejected cases or processing new application cases)	2,810
Sub-total	**3,420**
Issued with "Certificate of registration of pCm"	**410**
Total	**17,940**

[1] The test reports are: (1) heavy metals and toxic element test report; (2) pesticide residue test report; and (3) microbial limit test report.

[2] Including cases which are not eligible for transitional registration and subsequently opted to apply for non-transitional registration.

[3] HKNT cases are cases not eligible for transitional registration and submitted with the three tests reports as stated in footnote 1.

Progress of applications for review made to the Chinese Medicines Board	**Nos. of Cases**
Processed cases	1,542 (660)[4]
Pending processing	112
Total	**1,654**

[4] ( ) cases resubmitted with required information and being further processed by the Chinese Medicines Committee.