For information
on 21 July 2015

Legislative Council Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Arrangements for the Formal Registration of Proprietary Chinese Medicines

Background

According to the Chinese Medicine Ordinance (Cap. 549) ("the Ordinance"), all products falling within the definition of proprietary Chinese medicines ("pCms") must be registered by the Chinese Medicine 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 the CMB.

2. Taking into account the history and practical circumstances of the sale of pCms in Hong Kong, the Government has implemented transitional measures for the registration system for pCms so as to provide the trade with sufficient time to prepare for registration. In this regard, although the registration system for pCms was implemented on 19 December 2003, the Ordinance provides a transitional registration system. That is, for pCms already manufactured, sold or supplied for sale in Hong Kong on 1 March 1999, 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). If a pCm is assessed by the CMB as meeting the aforesaid transitional registration requirements, and the relevant basic safety test reports (including heavy metal and toxic element, pesticide residue and microbial limit test reports) are submitted, a "Notice of confirmation of transitional registration of pCm" ("HKP") will be issued.

3. To facilitate the processing of transitional registration of pCms to formal registration by the CMB, holders of HKP are required to submit, according to the registration groups chosen, the necessary documents in respect of safety, quality and efficacy to the CMB. A "Certificate of registration of pCm" ("HKC") will be issued if the pCm has been assessed by the CMB as meeting the registration requirements.

Deadline for submission of the relevant reports for registration of pCms

4. To provide the trade with a clearer picture of the registration arrangements of pCms, the CMB first published the "Application Handbook for Registration of Proprietary Chinese Medicines" as early as in December 2003. It sets out the documents required and the deadline for HKP registration. Under the original arrangement, HKP holders were required to submit the product quality and stability test reports by 30 June 2009. However, having regard to the request of the trade for a longer testing period due to the difficulties encountered during the process, the CMB extended the deadline twice. In June 2006, the CMB announced for the first time the extension of submission deadline from 30 June 2009 to 30 June 2013. Having assessed the overall situation of the trade, the CMB resolved in June 2013 to further extend the deadline to 30 June this year. In other words, the trade has been given more than ten years to prepare the reports. Moreover, the CMB has adjusted the technical requirements of the reports in 2014 with a view to expediting the processing of HKP cases where the reports have been submitted before 30 June 2015.

5. Recently, after considering the latest situation about submission of reports by HKP holders, the CMB has decided to maintain the deadline for submission of product specification documents and general stability test reports by HKP holders as 30 June 2015. The CMB has, in accordance with the procedures, issued reminder letters to those HKP holders who have not submitted the two types of documents/reports, requiring them to submit the documents/reports within three months from the date of the reminder letters issued. If they cannot do so, they should provide sufficient reasons (e.g. evidence issued by a testing centre that testing being conducted) for consideration by the CMB. Otherwise, the CMB may consider rejecting the HKC applications concerned.

6. As at 3 July 2015, the CMB has issued 503 HKC and 8 537 HKP. Besides, over 89% of HKP holders have submitted the product quality or stability test reports. The CMB will continue to process the applications for migrating to HKC.

7. To facilitate the applications 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 Department of Health (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 on the "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 its compliance with the registration requirements. It will continue maintaining close communication with the trade.

8. The Government has been providing technical support to the trade in respect of registration of pCm. 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.

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