LC Paper No. CB(2)2400/10-11(01)

For information
20 July 2011

Panel on Health Services

Subcommittee on Registration of Proprietary Chinese Medicines
Progress of the Commencement of Sections of Chinese Medicine Ordinance related to Mandatory Registration of Proprietary Chinese Medicines and the Requirements of label and package insert

PURPOSE

The provisions in the Chinese Medicine Ordinance (the Ordinance) and the Chinese Medicines Regulation (the Regulation) related to the mandatory registration of proprietary Chinese medicines (pCm) have commenced on 3 December 2010, and those related to the requirements of label and package insert will commence on 1 December 2011. This paper updates Members of the progress of the registration of pCm, and the Administration's communication with the trade as well as the launching of publicity programmes in preparation for the commencement of the provisions related to the requirements of label and package insert.

BACKGROUND OF THE REGULATION OF CHINESE MEDICINES

2. Chinese medicine is used widely and for long by the Hong Kong public. To strengthen the protection of public health and to foster the development of Chinese medicine, the Ordinance was passed in 1999 to provide a legal basis for the establishment of an effective regulatory regime for Chinese medicine.

3. After the passage of the Ordinance, the Administration established the Chinese Medicine Council of Hong Kong (CMC)[1] to implement the regulatory regime for Chinese medicine.

4. For the registration of pCm, as stipulated in the Ordinance, all products that fall within the definition of pCm should be registered. The

[1] CMC is a statutory body established under the Ordinance to implement regulatory measures for Chinese medicine practitioners (CMPs) and Chinese medicines. It comprises a Chairman, five CMPs, five persons from the trade of Chinese medicines, two persons from educational or scientific research institutions in Hong Kong, three lay persons and two public officers. The Director of Health is also an ex officio member.

following major provisions of the Ordinance are relating to pCm registration –

(i) Section 119 –No person shall sell; or import; or possess any proprietary Chinese medicine unless the pCm is registered under section 121 ;

(ii) Section 143 – No person shall sell; or have in his possession for the purpose of selling, any pCm unless the package of the pCm is labelled in the prescribed manner; and

(iii) Section 144 – No person shall sell; or have in his possession for the purpose of selling, any pCm without a package insert which complies with the prescribed requirements

5. All pCm must meet the registration requirements prescribed by CMB regarding their safety, quality and efficacy in order to register. CMB has started to accept applications for registration of pCm since 19 December 2003.

6. In view of the history of sales of pCm in Hong Kong, the Ordinance provides a transitional registration arrangement. Manufacturers, importers or local agents/representatives of manufacturers outside Hong Kong may apply for transitional registration before 30 June 2004 for pCm manufactured, sold or supplied for sale on 1 March 1999 in Hong Kong.

PROGRESS OF THE REGISTRATION OF PROPRIETARY CHINESE MEDICINES

Progress of the processing of the applications for registration of proprietary Chinese medicines

7. As of end of June 2011, the Chinese Medicines Board (CMB) under the Chinese Medicine Council (CMC) [2] has received about 16 830 applications for registration of pCm, of which about 14 100 also applied for transitional registration. So far, CMB has issued about 9 150 "Notice of confirmation of transitional registration of pCm" and 51 "Certificate of Registration of pCm". Besides, CMB has issued 1 285 "Notice of confirmation of (non-transitional) registration of pCm" (i.e. applications that

[2] CMC is a statutory body established under the Ordinance to implement regulatory measures for Chinese medicine practitioners (CMPs) and Chinese medicines. It comprises a Chairman, five CMPs, five persons from the trade of Chinese medicines, two persons from educational or scientific research institutions in Hong Kong, three lay persons and two public officers. The Director of Health is also an ex-officio member.

have submitted three acceptable basic test reports on heavy metals and toxic element, pesticide residues and microbial limit).

8. For the remaining applications, about 5 900 applications for registration of pCm were rejected due to failure to furnish sufficient information. About 1 180 of the rejected cases have applied for review under section 140 of the Ordinance. CMB considered about 1 030 applications for review in accordance with the laid down review procedures.

9. Upon the commencement of the relevant provisions on 3 December 2010, the Department of Health (DH) has continued its efforts to conduct market surveillance of pCm and proactive inspection of traders, and has set up an enquiry hotline (2319 5119) to answer public enquiries on pCm registration. Since the commencement of the provisions and up to 30 June 2011, some 440 Chinese medicine traders were inspected and 2 630 hotline enquiries have been handled. No serious violation of regulation was found so far. From the experience of the past some seven months, implementation of the provisions has been smooth and generally supported by the public.

PREPARATION FOR THE COMMENCEMENT OF PROVISIONS RELATED TO THE REQUREMENTS OF LABEL AND PACKAGE INSERT

10. In order to allow the trade to have sufficient time for preparation, the commencement of the provisions relating to label and package insert requirements is planned to come into effect on 1 December 2011, one year after the implementation of those provisions related to the mandatory registration of pCm on 3 December 2010. The applicants for pCm registration have responsibility to ascertain whether their registered products have fulfilled the requirements of label and package insert as stipulated in the Ordinance so as to avoid non-compliance upon the commencement. In fact, subsequent to the enactment of the relevant provisions relating to the requirements of label and package insert under the Regulation in early 2003, the details of the statutory requirements were promulgated. To provide assistance to the applicants, CMB and DH have all along maintained close communication with the trade, understood their situation and launched a whole range of publicity programmes as follows –

11. Representative(s) of DH has(ve) been regularly attending the meetings of the Retail Task Force under the Business Facilitation Advisory Committee to report the progress of the pCm registration and to understand the concerns of the trade and stakeholders. DH have taken follow-up actions and addressed concerns of the trade as appropriate.

12. Back in December 2003, CMB published the "Application Handbook for Registration of Proprietary Chinese Medicines" which set out detailed statutory requirements of label and package insert. In parallel, DH set up an enquiry hotline to handle applicants' enquiries on pCm registration as well as label and package insert requirements. To facilitate the trade to have a good grasp of the situation, in July 2009, CMB and DH drew up the "Guidelines on labels of proprietary Chinese medicines" and "Guidelines on package inserts of proprietary Chinese medicines" and uploaded those guidelines on the CMC website for the traders' reference and compliance. Briefing sessions were also held to familiarise the trade with the contents of the said guidelines. Between mid-2009 and end of 2010, DH and CMB have conducted or participated in a total of eleven such briefing sessions.

13. To further tie in with the commencement of the requirements of label and package insert, a whole range of publicity and educational programmes has been/will be launched as follows –

(a) five briefing seminars on the statutory requirements of label and package insert have been organised for major trade associations, traders and relevant stakeholders from mid-February to mid-March 2011;

(b) pamphlets have been distributed to travellers and to members of public through elderly homes and patient organisations to raise their awareness of the use and purchase of pCm;

(c) part-time "ambassadors" employed will continue to visit Chinese medicines traders, listed sellers of poisons and dispensaries to familiarise the trade with the statutory requirements relating to the selling, labelling and package insert of pCm;

(d) roving exhibitions will continue to be held in the 18 districts of Hong Kong;

(e) articles on labelling and package insert requirements of pCm will be published in the "Chinese Medicines Trader's Newsletter" (published in June 2011), "Newsletter of Chinese Medicine Practitioners Board", Choice Magazine, as well as the "Community Health Partnership Communication" of the District Councils respectively;

(f) letters will be issued to 18 District Councils to brief their members of the commencement of relevant legislative provisions; and

(g) radio and television Announcements in the Public Interest (APIs) will be launched and media briefings will be held nearer the time of commencement.

14. DH has all along maintained close communication with the trade and listened to their views regarding the commencement of the provisions related to the mandatory registration of pCm. In response to the trade's concerns, the following actions have been taken –

(a) label and package insert

15. Regarding the concerns of applicants for pCm registration on whether the labels and package inserts of their products have complied with the statutory requirements, DH has issued letters to individual holders of "Notice of confirmation of transitional registration of pCm", "Notice of confirmation of (non-transitional) registration of pCm" and "Certificate of Registration of pCm" informing them of the labels and package inserts information of the pCm concerned for their verification. The applicants may also request an interview with the DH officer by appointment to ascertain the contents of the labels and package inserts information of their products.

(b) situations under which pCm are exempted from registration

16. As stipulated under section 158(6) of the CMO, exemptions are given to the pCm administered or supplied by a registered or listed Chinese medicine practitioner (CMP). Having sought legal advice on the application of the said exemptions, CMB has published the relevant information in the "Newsletter of Chinese Medicine Practitioners Board" published in April 2011 for CMPs' reference.

(c) pCm manufactured for export only

17. Under section 119 of the Ordinance, no person shall sell, or import, or possess any pCm that has not been registered. Any person who violates section 119 commits an offence. As different countries or regions may have different regulatory requirements of pCm (e.g. product definition and label) and in view of traders' concern about those export-only pCm, the CMB has recently endorsed a specific set of registration requirements for export-only pCm. The requirements will be uploaded to CMC website for traders' reference.

CONCLUSION AND WAY FORWARD

18. In conclusion, the commencement of the provisions relating to pCm registration is generally supported and welcomed by the society. The progress of the commencement is rather smooth. The Administration will continue to communicate with the trade and stakeholders, provide appropriate assistance to them, and launch publicity programmes to keep the trade abreast of the latest information. If necessary, DH representatives will attend the meetings or briefings held by the trade association(s)/trade to exchange views and explain the relevant statutory requirements with a view to implementing the provisions relating to label and package insert on 1 December 2011 smoothly.

ADVICE SOUGHT

19. Members are invited to note the contents of this paper.

Department of Health
July 2011