Legislative Council Motion Debate on
"Concern about the quality and regulation of proprietary Chinese medicines" on 19 May 2010

Progress Report

Background

At the meeting of Legislative Council on 19 May 2010, the following motion moved by Dr Hon Joseph LEE Kok-long, as amended by Dr Hon PAN Pey-chyou, was carried:

"That, given that recently some proprietary Chinese medicines are found to contain ingredients of forbidden drugs and toxic substances and hence have to be recalled from the market, arousing the concern of various sectors and, at the same time, exposing the loopholes in the Government's policy on Chinese medicine as well as the deficiencies of its regulatory system, which have led to problems in the registration system for proprietary Chinese medicines at the present stage and the fact that the quality of proprietary Chinese medicines available on the market cannot be assured, thus posing a threat to the life and health of the public, this Council urges that the Government must expeditiously improve the policy on Chinese medicine, strengthen regulation and ensure the quality and safety of proprietary Chinese medicines available on the market, so as to safeguard pubic health; and the Government, while exercising regulation, also has the responsibility to provide support for the trade, including considering the establishment of a 'committee on the development of Chinese medicine' to promote long-term development of the Chinese medicine trade in Hong Kong, thereby enabling the trade to upgrade its quality and enhance its self-regulation on the safety of proprietary Chinese medicines."

Progress

Commencement of Sections of Chinese Medicine Ordinance related to Mandatory Registration of Proprietary Chinese Medicines

2. The Administration plans to commence in phases from December 2010 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), and the requirements of label and package inserts on pCm. This will enhance the regulation of Chinese medicines and will provide a legal basis for combating more effectively the selling of unregistered pCm. This can also help create a favourable and fair business environment, boost public confidence in Chinese medicines and in turn foster the development of Chinese medicine in Hong Kong.

3. At present, the following major provisions of the Ordinance are yet to be commenced –

(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

In view of the completion of assessment of all applications for transitional registration by the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong (CMC), we propose to put into full implementation the relevant provisions under the Ordinance in phases as follows –

(a) December 2010 – commencement of s119 the sale, import or possession of unregistered pCm in Hong Kong will be an offence by then; and

(b) December 2011 – commencement of s143 and s144 to allow the trade to have adequate time to comply with the labelling and package insert requirements.

4. Upon the commencement of the provisions, any person who sell; or import; or possess any unregistered pCm in Hong Kong will be an offence and shall be liable to a fine at level 6 (i.e. $100,000) and imprisonment for two years. Unregistered pCm cannot be sold in the market until they have obtained registration status.

5. To prepare the Chinese medicines trade for the full implementation of the mandatory registration of pCm, CMB and the Department of Health (DH) have already carried out the following consultation activities –

(a) held a number of briefing sessions in 2009 to facilitate the trade to have a better understanding of the requirements of product quality documents and guidelines on labels and package inserts of pCm;

(b) uploaded the guidelines on the label and package insert requirements and other relevant information on registration of pCm on the CMC website for the traders' reference;

(c) publicised the statutory requirements of pCm registration in the "Chinese Medicine Traders Newsletter", which was distributed to all licensed Chinese medicine traders and trade associations;

(d) attended meetings of Chinese medicines traders associations to facilitate the trade in understanding the pCm registration requirements;

(e) held seven briefing sessions for the major trade associations, the trade/stakeholders from late May to early July 2010 to collect their feedback on the commencement of the legislative provisions;

(f) attended the meetings of the Retail Task Force under the Business Facilitation Advisory Committee to report the progress of the pCm registration regularly and to understand the concerns of the trade and stakeholders regarding the commencement of the relevant legislative provisions; and

(g) consulted the trade and stakeholders on the commencement of the legislative provisions through the Business Consultation e-Platform under the GovHK Portal (www.bce.gov.hk).

6. The trade and stakeholders have indicated their support to the implementation plan and the related timeframe. The views on the implementation details collected from the trade in the consultation/briefing sessions have been reported to CMB and will be publicized through the "Chinese Medicines Traders Newsletter" and the CMC website.

7. It is also planned that the following publicity and educational activities will be carried out in the coming months –

(a) to publicise the commencement plan through various channels such as CMC and DH websites, the Consumer Council, and issuing

letter to individual traders, Chinese medicine practitioners and other relevant associations; and

(b) to employ Chinese medicines students in tertiary education institutions as "ambassadors" to visit Chinese medicines traders and listed sellers of poisons and dispensaries with a view to assisting traders to familiarize with the statutory requirements relating to the selling, labelling and package inserts of pCm.

8. We have also briefed the Legislative Council Panel on Health Services on the commencement plan and related works at its meeting on 12 July 2010. Related law drafting work is in progress.

Other Regulatory Measures on Proprietary Chinese Medicine

9. Apart from the registration system of pCm, other related measures have been put in place, including regulation of pCm manufacturers, setting up of product recall system, enforcing import control of pCm, conducting market surveillance on pCm, as well as other related laws to strengthen the regulation of pCm. These measures are set out as follows.

Regulation of pCm manufacturers

10. Manufacturers of pCm are already subject to licensing requirements including sanitary premises, suitable environment of humidity, lighting, temperature and ventilation for manufacturing and storage areas, and adequate and suitable fittings and equipment for the manufacturing of pCm. Furthermore, the person who supervises the manufacturing process should possess an appropriate level of knowledge and experience, as prescribed in the Regulation. Before issuing a manufacturer licence in pCm, DH will conduct inspection to ensure that the relevant premises and facilities meet the requirements set by CMB in all aspects. After the issuance of the licence, DH will also conduct routine and unannounced inspections. When a violation of the Ordinance or the practising guidelines is detected, DH will take enforcement actions and may consider prosecution. The case will also be referred to CMB for disciplinary actions.

11. Moreover, pursuant to Section 133 of the Ordinance, a pCm manufacturer licence holder may apply to CMB for a Certificate for Manufacturer (Good Manufacturing Practice in respect of Proprietary Chinese

Medicines) (GMP Certificate), certifying that they follow the requirements of good practices in manufacture and quality control of pCm. To facilitate the implementation of quality management, CMB has issued the "Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines" to provide guidance to pCm manufacturers. However, at present the GMP system is not a statutory requirement and therefore licensed pCm manufacturers can decide whether they would apply to CMB for a GMP Certificate. To enhance the standard of the trade, the Government will actively discuss with CMB and the trade to work out a timeframe for the introduction mandatory GMP requirements for manufacturing of pCm so as to regulate more effectively the manufacturing of pCm .

Setting up of product recall system

12. Licensed pCm traders have to observe the law and the requirements of practising guidelines, which include the need to make sure that the pCm manufactured and distributed meet the specified requirements. Besides, there should also be an effective recall system to ensure prompt recall of any defective pCm from the market.

Enforcing import control

13. Import control of pCm will be enforced in accordance with the Import and Export Ordinance (Cap. 60). An import licence issued by the Director of Health must be obtained for each consignment of pCm imported into Hong Kong. DH will consider whether the pCm to be imported meet the basic safety requirements before a licence is issued.

Conducting market surveillance

14. DH will collect samples of pCm from the market on a regular basis for testing. If any problem is detected, i.e. adulteration with western medicines, exceeding the limits for heavy metals, etc., DH will conduct investigation and take appropriate actions in accordance with the relevant regulations. If necessary, DH may order the importers or manufacturers to recall the products in question. Where registered pCm are involved, the cases may be referred to CMB for consideration as to whether the registration of the products should be de-registered to safeguard public health.

15. DH has adopted a risk based approach to collect samples of registered pCm under transitional arrangement from licensed pCm manufacturers and

pCm wholesalers for testing and will also monitor cases of adverse drug reactions.

Other related legislation

16. Apart from the Ordinance governing the mandatory registration for sale, import and possession of pCm, other relevant laws include –

(a) the Pharmacy and Poisons Ordinance (Cap. 138) imposes regulation on drugs containing any western medicine as ingredients. pCm should not contain any western medicine as ingredients;

(b) the Public Health and Municipal Services Ordinance (Cap.132) imposes regulation on medicines including pCm on whether they are suitable for human consumption, and the affixing of false label;

(c) the Protection of Endangered Species of Animals and Plants Ordinance (Cap. 586) imposes regulation on pCm containing ingredients of endangered species;

(d) the Trade Descriptions Ordinance (Cap. 362) imposes regulation on counterfeit medicines and false representations;

(e) the Undesirable Medical Advertisements Ordinance (Cap.231) imposes regulation on advertising of medicines (including pCm); and

(f) the Waste Disposal Ordinance (Cap. 354) imposes regulation on the disposal of waste.

Establishment of a 'Committee on the Development of Chinese Medicine'

17. The Government has all along attached great importance to the development of Chinese medicine industry in Hong Kong. We have in place a comprehensive regulatory framework for Chinese medicine and Chinese medicine practitioners through CMC and DH. We are also working closely with the Innovation and Technology Commission on the long-term development of Chinese medicine through scientific research. The existing arrangements have been effective and we do not see the need to establish a 'committee on the development of Chinese medicine'.

Food and Health Bureau
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