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Panel on Commerce and Industry

Meeting on 19 March 2013

Background brief on Good Manufacturing Practice requirement in respect of proprietary Chinese medicine in Hong Kong

Purpose

This paper provides background information on the Good Manufacturing Practice (GMP) requirement in respect of proprietary Chinese medicine (pCm) in Hong Kong. It also provides a summary of views and concerns expressed by Members on the subject in previous discussions.

Background

2. GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to appropriate quality standards. Most countries have adopted the GMP guidelines promulgated by the World Health Organization (WHO), although countries such as the United States, European Union and Australia have drawn up their national GMP guidelines which are recognized to be of a standard higher than the WHO guidelines. The spirit of the GMP emphasizes that the assessment of "good quality" should be based on scrutiny of the manufacturing process and not by testing of the end products alone.

3. A GMP manufacturer should have adequate premises, spaces, laboratories, appropriately qualified and trained personnel, storage facilities and transport. All the manufacturing processes must be validated and clearly defined, systematically reviewed and shown to be capable of consistently manufacturing pharmaceutical products of the required quality and complying with their specifications. Instructions and procedures are required to be written in clear and unambiguous language, and specifically applicable to the

facilities provided. Records must be made during manufacturing to show that all the steps required by the defined procedures and instructions have in fact been taken and that the quantity and quality of the product are as expected. Any significant deviations must be fully recorded and investigated. In addition, appropriate materials, containers and labels must be used.

4. GMP has been adopted in Hong Kong since 2002 to facilitate regularization of the western drug manufacturing industry and ensure the quality and safety of pharmaceutical products.

5. To ensure the quality and safety of pCm, the Chief Executive announced in his 2010-2011 Policy Address that a timetable for mandatory compliance with GMP for manufacture of pCm would be worked out to keep up with international trends of developing GMP for medicines. Having taken reference of the development of GMP in other countries and regions in the world, Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong recommended in May 2011 the adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme GMP standard as a licensing requirement for local pCm manufacturers.

6. At present, GMP requirement in respect of pCm in Hong Kong is not mandatory. Manufacturers holding a pCm manufacturer licence may apply to the CMB for a Certificate for Manufacturer, certifying that they follow the requirements of good practices in manufacture and quality control of pCm. There are currently 293 pCm manufacturers in Hong Kong of which 11 manufacturers have been awarded GMP Certificates.

Previous discussions

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7. At the meeting of the Panel on Commerce and Industry on 18 December 2012, the Administration briefed members on the progress of efforts made in promoting research and development of Chinese medicines in Hong Kong. On development of the pCm manufacturing industry, Panel members expressed concern about the difficulties faced by pCm manufacturers in becoming GMP-compliant, such as financial constraints, lack of technical know-how and expertise, and shortage of suitable land space for establishing GMP facilities. Panel members were particularly concerned about the lack of Government support and assistance to pCm manufactures, worrying that most of the local pCm manufacturers, which were small and medium enterprises (SMEs), would be forced to cease operation upon the implementation of the mandatory GMP requirements.

8. In view of the shortage of suitable plants and facilities for the manufacture of pCm, some Panel members enquired whether the Administration would consider setting aside sites at existing industrial estates for the development of the pCm manufacturing industry. The Administration was requested to take the lead in setting up a traditional Chinese medicine science and technology industrial park with GMP facilities for use by the pCm manufacturing industry, especially SME manufacturers.

9. Regarding the provision of contract manufacturing services by manufacturers with GMP Certificates to SME pCm manufacturers, some Panel members cautioned that such contract manufacturing arrangements might result in market domination by large companies at the expense of SME manufacturers. These members were of the view that care should be exercised to protect local pCm SMEs from being acquired and merged by large companies.

10. Panel members agreed that issues on the support and assistance to the pCm manufacturing industry to facilitate compliance with the implementation of GMP requirements should be discussed at a future Panel meeting. The Panel would also receive views from relevant stakeholders on the subject.

Council questions

11. At the Council meetings on 22 February, 13 June and 24 October 2012, Members raised questions, among other things, relating to the Administration's plan and overall strategy on development of the pCm manufacturing industry as well as assistance to SME pCm manufacturers in terms of manpower resources, research and technology, funding, land and infrastructural support. Question on whether the Administration would consider offering special tax concessions to SME pCm manufacturers to allay their financial burden in various aspects such as testing, research and development was also raised.

Latest position

12. The Panel will receive views from deputations on 19 March 2013 on difficulties facing the pCm industry in moving towards GMP.

Relevant papers

13. A list of relevant papers is in **Appendix**.

Council Business Division 1
Legislative Council Secretariat
15 March 2013

Appendix

Good Manufacturing Practice requirement in respect of proprietary Chinese medicine in Hong Kong

List of relevant papers

Date of meeting	Meeting	Minutes/Paper	LC Paper No.
22/2/2012	Council meeting	Question No. 14 raised by Dr Hon LAM Tai-fai	Hansard (Page 6083-6092) http://www.legco.gov.hk/yr11-12/english/counmtg/hansard/cm0222-translate-e.pdf
13/6/2012	Council meeting	Question No. 7 raised by Hon Vincent FANG Kang	Hansard (Page 14958-14964) http://www.legco.gov.hk/yr11-12/english/counmtg/hansard/cm0613-translate-e.pdf
24/10/2012	Council meeting	Question No. 6 raised by Dr Hon CHIANG Lai-wan	Hansard (Page 587-597) http://legco.gov.hk/yr12-13/english/counmtg/hansard/cm1024-translate-e.pdf
18/12/2012	Panel on Commerce and Industry	Administration's paper Background brief Minutes of meeting	CB(1)299/12-13(03) http://legco.gov.hk/yr12-13/english/panels/ci/papers/ci1218cb1-299-3-e.pdf CB(1)299/12-13(04) http://legco.gov.hk/yr12-13/english/panels/ci/papers/ci1218cb1-299-4-e.pdf CB(1)532/12-13 http://legco.gov.hk/yr12-13/english/panels/ci/minutes/ci20121218.pdf