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Panel on Health Services

Subcommittee on Issues Relating to the Development of Chinese Medicine

Background brief prepared by the Legislative Council Secretariat for the meeting on 25 November 2014

Introduction of the Good Manufacturing Practice requirement in respect of proprietary Chinese medicines

Purpose

This paper gives an account of the past discussions of the Panel on Health Services ("the HS Panel") and the Panel on Commerce and Industry ("the CI Panel") on the introduction of the Good Manufacturing Practice ("GMP") requirement for the manufacture of proprietary Chinese medicines ("pCm") in Hong Kong.

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. The spirit of 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. A GMP manufacturer should have adequate premises, space, 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.

3. Under the Chinese Medicine Ordinance (Cap. 549), pCm manufacturers must apply for licenses issued by the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong. At present, GMP requirement in

respect of pCm in Hong Kong is not mandatory. Manufacturers holding a pCm manufacturer licence may apply to CMB for a Certificate for Manufacturer, certifying that they follow the requirements of good practices in manufacture and quality control of pCm.

4. CMB issued the "Hong Kong GMP Guidelines for Proprietary Chinese Medicines" in 2003 with reference to the relevant GMP guidelines published by the World Health Organization and the Pharmacy and Poison Board of Hong Kong. As at mid-November 2014, there were 279 pCm manufacturers in Hong Kong of which 12 manufacturers had been awarded GMP Certificates.

5. To ensure the safety of pCm and to keep up with the international trends of developing GMP for medicines, it was announced in the 2010-2011 Policy Address that a timetable for mandatory compliance with GMP for manufacture of pCm would be worked out. In May 2011, CMB recommended the adoption of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") GMP standard as a licensing requirement for local pCm manufacturers.

Deliberations of the HS Panel and the CI Panel

6. The HS Panel and the CI Panel have discussed issues relating to the GMP requirement for the manufacture of pCm. The HS Panel discussed the issue in the context of the development of Chinese medicine on 18 March 2013, whereas the CI Panel discussed the relevant GMP requirement on 18 December 2012, 19 March 2013 and 17 June 2014. The deliberations and concerns expressed by members of the two Panels are summarized below.

<u>GMP requirement for pCm manufacturing</u>

7. Members of both Panels expressed grave concern about the difficulties faced by local pCm manufacturers in order to be GMP-compliant, such as financial constraints, lack of technical know-how and expertise as well as shortage of suitable land space for establishing GMP facilities. Members of the CI Panel generally considered the pCm manufacturing industry not yet GMP-ready. Some members opined that as most local pCm manufacturers were small and medium enterprises ("SMEs"), the adoption of GMP standards should be voluntary rather than a mandatory requirement so as to allow room for the survival of SME pCm manufacturers. Otherwise, they might be squeezed out from the pCm manufacturing industry despite the proven efficacy of their traditional formula. The market would then be dominated by large companies that were GMP-capable at the expense of the SME pCm manufacturers.

8. The Administration advised that the purpose of introducing GMP to pCm manufacturing was to promote the standardization and quality control of pCm manufacturing, and to keep up with international trends of developing GMP for medicinal products. It was also aimed to boost public confidence in using pCm. There was currently no timetable for imposing mandatory compliance with GMP. The Administration would continue to listen to the views of the industry before deciding on the way forward.

9. Some members of the CI Panel questioned whether the adoption of PIC/S GMP standard would suit Hong Kong as most pCm SMEs were only targeting the Greater China and Asian markets rather than the international market. These members considered that different pCm manufacturers should be free to choose whether or not they would apply for the GMP Certificates, taking into account their financial capacity, business model and target markets. Some members shared the view of some deputations that the Administration should facilitate the local pCm industry in developing Hong Kong's own production-management model with unique traditional Chinese characteristics, leveraging on the opportunities presented by the Greater China and Asian markets.

Government support for pCm manufacturers to comply with GMP requirement

10. Noting that only a small number of local pCm manufacturers had been awarded GMP Certificates, some members of the CI Panel queried whether it was due to the lack of government support to help the local industry to become GMP-ready. They called on the Administration to formulate comprehensive policies and provide the necessary hardware and software support, including direct financial assistance or tax incentives, manpower training and provision of facilities to help local pCm manufacturers overcome the GMP-compliance challenges. Consideration should also be given to revitalizing vacant industrial buildings or setting up a Chinese medicine science and technology park to provide GMP-standard factory premises. Some members of the HS Panel urged the Administration to take the lead in setting up GMP factory premises for the use by the pCm manufacturing industry, so that pCm manufacturers in need could apply for tenancy on these premises.

11. According to the Administration, as the lack of proper understanding on GMP was one of the factors deterring many local pCm manufacturers from setting up GMP production, the General Support Programme under the Innovation and Technology Fund had approved funding of about $2.1 million in June 2013 to support a one-year project by the Hong Kong Institute of Biotechnology ("HKIB") to provide free GMP training to all the local pCm manufacturers.

12. Some members of the CI Panel expressed reservations about the Administration's proposal to expand the current GMP consultancy services and the contract manufacturing arrangements provided by HKIB to SME pCm manufacturers. They considered that such a move might result in acquisition and merger of SMEs by pharmaceutical giants. There was a view that the Administration should encourage more public organizations to set up GMP hardware facilities to bring in competition among service providers and to give SME pCm manufacturers more choices in procuring contract manufacturing services.

Relevant papers

13. A list of the relevant papers on LegCo website is in **Appendix**.

Council Business Division 2
Legislative Council Secretariat
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Appendix

Relevant papers on the introduction of the Good Manufacturing Practice requirement in respect of proprietary Chinese medicines

Committee	Date of meeting	Paper
Panel on Commerce and Industry	18.12.2012 (Item IV)	Agenda Minutes
Panel on Health Services	18.3.2013 (Item IV)	Agenda Minutes
Panel on Commerce and Industry	19.3.2013 (Item V)	Agenda Minutes
Panel on Commerce and Industry	17.6.2014 (Item IV)	Agenda Minutes CB(1)2005/13-14(01)

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