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For information

Legislative Council Panel on Health Services
Subcommittee on Issues Relating to the Development of Chinese Medicine

Introduction of Good Manufacturing Practice ("GMP") Requirements to Proprietary Chinese Medicine

PURPOSE

This paper briefs Members on the introduction of Good Manufacturing Practice ("GMP") requirements to proprietary Chinese medicines ("pCms") in Hong Kong and the corresponding support measures put in place by the Government.

BACKGROUND

2. At present, the GMP requirement in respect of pCms in Hong Kong is not mandatory. However, in accordance with the Chinese Medicine Ordinance (Cap 549), pCm manufacturers are still required to apply for licences issued by the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong, irrespective of whether they are GMP-compliant. There are at present 279 pCm manufacturers in Hong Kong licensed in accordance with the Chinese Medicine Ordinance. Most of them are small and medium enterprises ("SMEs") (i.e. with less than 100 employees).

3. Currently, a licensed pCm manufacturer who wishes to be certified as complying with the GMP requirements in the production and quality control of pCms may apply to the CMB for a GMP Certificate for Manufacturer. The 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 Poisons Board of Hong Kong. Up to the present, 12 local licensed pCm manufacturers have been awarded with GMP Certificates.

CURRENT POSITION

4. To ensure the safety of pCm and enhance its quality, and to align with international trend of GMP development in the production of medicines, it was announced in the 2010-11 Policy Address that the Government would actively engage the trade to work out a timetable for mandatory compliance with the GMP for the manufacture of pCm.

Consultation with stakeholders

5. Having taken reference of the GMP development in other countries and regions, the CMB recommended in May 2011 to adopt in due course the GMP standard of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme ("PIC/S") as a licensing requirement for local pCm manufacturers. Since May 2011, the CMB has been widely consulting traders of Chinese medicines to gather their views through various channels [e.g. conducting a series of briefings (about once every three months) through the Department of Health ("DH"), attending 11 meetings with Chinese medicine associations and meeting with pCm manufacturers] on the timetable for the implementation of GMP and specific arrangements.

6. Regarding the implementation of GMP in pCm manufacture, we note the key concerns of the trade are as follows:

(i) Selection of manufacturing sites;

(ii) Capital requirement;

(iii) Manufacturing and testing technologies; and

(iv) Professional training.

MEASURES TO SUPPORT THE TRADE TO IMPLEMENT THE GMP

7. The trade generally agrees that GMP will bring benefits to pCm manufacture. In response to the concerns of the trade and to assist manufacturers in introducing GMP to the pCm manufacture, relevant experts [including the representatives from the Hong Kong Institute of Biotechnology ("HKIB"), Hong Kong Productivity Council, SGS Hong Kong Limited and International Society for Pharmaceutical Engineering] and relevant government agencies (including the Trade and Industry Department, Hong Kong Science & Technology Parks Corporation, Innovation and Technology Commission, Employees Retraining Board and the DH) have been invited to brief the Chinese medicines traders on the requirements of hardware and software for GMP, training and consultancy service in relation to GMP and support measures provided by the Government. Licensed pCm manufacturers who have been awarded with GMP Certificate will also been invited to share their experiences in the implementation of GMP. Meanwhile, the DH has provided information on the proposed GMP implementation plan to all licensed Chinese medicines traders through the Chinese Medicines Traders Newsletter. All relevant information is available online (www.cmd.gov.hk) for reference by the trade. Besides, the DH will meet (on average once every three weeks) with pCm manufacturers who are interested in the implementation of GMP and already have preliminary designs of their factory premises, and explain to them the current GMP guidelines as well as discussing with them on various issues including the plant setup, facilities and manpower, in order to assist the pCm manufacturers to implement GMP.

8. The General Support Programme under the Innovation and Technology Fund ("ITF") approved funding in June 2013 to support a one-year training project conducted by the HKIB to provide basic GMP training to all local manufacturers free of charge. A series of activities were organised by this project, including 9 batches of a 2-day basic GMP training class (with 194 attendees from local licensed pCm manufacturers and other organisations) and 15 GMP facility visits. The pCm manufacturers participating in the training activities would not only be enriched with the basic knowledge in GMP, but also receive expert advice and know more about the financial considerations involved in the implementation of GMP. The project also conducted surveys

by questionnaires and on-site company interviews in order to better understand their situations and views on the implementation of GMP.

9. To better support the trade in implementing GMP, the ITF and the Hong Kong Jockey Club Charities Trust will jointly support HKIB to conduct a three-year project to set up a GMP product development and technical support platform for traditional oral solid pCm products. At present, the project concerned is still at its planning stage. Upon completion of the project, HKIB's existing pCm GMP production area will be expanded from 2,880ft^2 to 8,500ft^2; and production lines for 2 new types of pCm solid formulations (i.e. pills and granules; the existing two are capsules and powder) will be established, which will enable HKIB to provide GMP contract manufacturing services for the 4 most common types of pCm solid formulations in Hong Kong.

10. In addition, the jointly-funded project mentioned above will also set up a GMP training platform on pCm manufacturing to provide internship opportunities for Chinese medicines workers and students (such as students studying relevant professional programmes at the Vocational Training Council) so as to equip them with the necessary skills and practical experience which will be conducive to supporting the upgrading and development of local Chinese medicine industry.

WAY FORWARD

11. We envisage that the above support measures would provide local pCm manufacturers (particularly SMEs) with the necessary technology supports and professional training, facilitate them to produce high quality and safe pCm products, as well as strengthen their capability to meet GMP requirements in the future so that the local pCm production standard could be raised, thereby bringing direct benefits to the Chinese medicines trade. The CMB and the DH will maintain close communication with the trade on the timetable and specific arrangements in the implementation of GMP.

ADVICE SOUGHT

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

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