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For discussion

On 19 March 2013

Legislative Council Panel on Commerce and Industry

Good Manufacturing Practice (GMP) for the Chinese Medicines Sector – Possible Areas of Support to the Industry

PURPOSE

This paper aims to report to Members possible areas of support which the Innovation and Technology Commission (ITC) is studying to be provided to the Chinese medicines (CM) sector on the future implementation of proprietary CM (pCm) GMP.

BACKGROUND

2. To ensure the quality and safety of pCm and to keep up with international trends of developing GMP for medicines, the Chief Executive announced in his 2010-11 Policy Address that a timetable for mandatory compliance with GMP for manufacture of pCm would be worked out. The Government will actively engage the industry and conduct consultations to gather views from the CM industry on the timetable and detailed proposal for implementation of mandatory GMP.

3. The purpose of introducing GMP to pCm manufacturing is to promote the standardisation of the pCm manufacturing industry and enhance the standard of the CM trade to assure the quality and safety of pCm, thus to safeguard public health and boost the public confidence in using pCm. Implementation of GMP for pCm manufacturing is also in line with international trends and requirements for manufacturing of medicinal products. There is currently no timetable for the introduction of mandatory GMP requirements for manufacturing of pCm.

4. To facilitate the implementation of quality management of pCm manufacturing, the Chinese Medicines Board (CMB) under the Chinese Medicine Council of Hong Kong has issued the "Guidelines on Good Manufacturing Practice in respect of Proprietary Chinese Medicines" to provide guidance to the industry to comply with the GMP requirements. There are the following areas which should be attended to in the implementation of GMP:

(a) quality management;

(b) personnel;

(c) factory premises;

(d) equipment;

(e) documentation;

(f) manufacturing management;

(g) validation;

(h) quality control;

(i) contract manufacture and test;

(j) complaints;

(k) product recalls; and

(l) Self-inspection and quality audits.

5. There are at present 295 proprietary Chinese medicines (pCm) manufacturers in Hong Kong who, in accordance with the Chinese Medicine Ordinance (Cap 549), hold manufacturer licenses issued by CMB. To date, 11 of these pCm manufacturers have obtained GMP Certificates from CMB.

POSSIBLE AREAS OF SUPPORT TO THE INDUSTRY BY ITC

6. While the Food and Health Bureau and Department of Health are responsible for the regulatory side and implementation of pCm GMP in Hong Kong, ITC and the Committee on Research and Development of Chinese Medicines hope to play a supportive role in facilitating the industry to upgrade and meet the various challenges ahead. [Note - The Committee on Research and Development of Chinese Medicines is chaired by the Commissioner for Innovation and Technology and its membership comprises representatives from the Government, industry, academic and research sectors. It was set up in

December 2011 with a view to facilitate collection of views from stakeholders and better coordinate effort in promoting R&D and testing of CM to meet the future needs of Hong Kong. There is close liaison between the Committee on Research and Development of Chinese Medicines and the newly established Chinese Medicine Development Committee chaired by the Secretary for Food and Health. The latter has a much wider scope of work in the areas related to Chinese medicine development, including personnel training and professional development, Chinese medical services, scientific research and the development of the Chinese medicine industry.]

7. Noting that GMP is a complicated issue, and various factors would affect its implementation, the Committee on Research and Development of Chinese Medicines has formed a Working Group of Chinese Medicines Manufacturing (WG) to study the subject in greater detail, as well as other important R&D and technical aspects of CM manufacturing which would facilitate industry upgrading in the long run.

Support on the training front

8. The WG has held two meetings with particular focus on understanding the technology needs of the CM industry in GMP implementation. The WG generally agrees that competence of the personnel engaging in CM manufacturing is a prerequisite for upgrading of the industry and that a lack of understanding on GMP among the CM manufacturing sector is one of the factors deterring local pCm manufacturers from setting up GMP production. The WG recommends that relevant training in a systematic manner should be organised to help local pCm manufacturers to get prepared for the future implementation of mandatory GMP requirements. The WG also suggests that there should be different types of GMP training activities in terms of content, duration and format for different target groups, such as top management, middle management and front-line staff, according to their skill levels and roles in the companies.

9. To follow up these suggestions, ITC is currently in discussion with GMP consultants to organise appropriate training activities which would suit the needs of different levels of persons in the

industry. ITC also welcomes potential local implementation agents to submit proposals to seek funding support from the General Support Programme (GSP) of the Innovation and Technology Fund (ITF) for running GMP-related training programmes for enhancing local CM manufacturing capability. [Note - The GSP is one of the funding programmes under the ITF catering for non-R&D projects that contribute to the upgrading and development of our industries as well as fostering an innovation and technology culture in Hong Kong.]

Support on the facility front

10. The Committee on Research and Development of Chinese Medicines and ITC are also aware of the concerns of the industry for hardware support for GMP, especially for small and medium enterprises that lack the financial strength and expertise to support the building of GMP facilities and their subsequent operation. In this connection, the possibility/options of expanding the GMP consultancy services and contract manufacturing arrangements of existing GMP service providers are being explored by ITC. In particular, ITC is in discussion with the

the Hong Kong Institute of Biotechnology to understand its present CM contract manufacturing services and whether its GMP facilities can be expanded if necessary to help address the eventually increasing demand of the industry for pCm GMP support. Since local CM manufacturers vary widely in their technical knowledge and scale of operation, the Committee on Research and Development of Chinese Medicines and ITC also need to examine the overall potential demand, the size and needs of each subsector, etc., in conjunction with relevant stakeholders for better planning on this front.

ADVICE SOUGHT

11. Members are invited to note and advise on the above.

Innovation and Technology Commission

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