Miss Rita Yung
Panel on Commerce and Industry
Legislative Council
HKSAR Government

11th March 2013

Re: Invitation for submissions on difficulties facing the proprietary Chinese medicine industry in moving towards Good Manufacturing Practice

Dear Miss Yung,

The Hong Kong Institute of Biotechnology (HKIB) has the mission to support the development of biotechnology and Traditional Chinese Medicine (TCM) through infrastructure establishment. Previously between 1996 and 2002, HKIB was funded by Innovation Technology Commission, and had successfully helped all local generic pharmaceutical manufacturers to achieve GMP standard. In the past few years, we are preparing these local pharmaceutical manufacturers to achieve higher international GMP standard by offering professional training to the managerial level, and also giving various supports to pCm manufacturers to establish GMP, from facility design to validation services.

We understand that GMP implementation is expected to strengthen Hong Kong's pCm industry. We have the following recommendations for the council;

1. Expansion of GMP Talents

The expansion of GMP talents is vital to support compulsory GMP implementation in pCm industry. Currently, majority of GMP personnel are in the generic pharmaceuticals and already there is a shortage of trained professional to support this industry and prepare the migration to international PIC/s GMP by June 2015. Needless to say, the other GMP personnel in the current 11 GMP pCM manufacturers will not be sufficient to support fraction of remaining non-GMP manufacturers, or otherwise affecting the overall GMP standard in Hong Kong manufacturing.

Hong Kong Institute of Biotechnology Limited 香港生物科技研究院有限公司
2 Biotechnology Avenue, 12 Miles, Tai Po Road, Shatin, N.T., Hong Kong. 香港新界沙田大埔公路十二哩生物科技路二號
Tel電話: (852) 2603 5111 Fax傳真: (852) 2603 5012 Website網址: http://www.hkib.org.hk

2. Knowledge-Science-Risk based approach to Product Quality Regulation

Majority of local GMP experiences are based on generic pharmaceutical production which entails well established manufacturing processes and quality control (QC) methodology. It is extremely challenging to adopt an identical GMP expectation in TCM production because there are unique TCM manufacturing processes and QC issues not demonstrated yet. Therefore, it is recommended that the product quality regulation should take into the account of; 1) historical knowledge of the product, 2) scientific information based on current technology, and 3) combined with the assessment of product risk to the patients.

3. Platform for Innovation

As there is unique product quality regulation for pCm, innovation on regulation and manufacturing technologies are inevitable. Both soft and hard platforms can be created to stimulate these innovations, thus enabling Hong Kong to develop a comprehensive and cost-effective GMP for pCm. This may be facilitated by interdisciplinary studies incorporating diverse views from regulators, corporate executive, and researchers.

4. Define GMP implementation schedule

Schedule for GMP implementation by phases will be valuable to bring industry to participate.

In the meantime, we are looking forward to share our recommendations in the Legislative Council meeting on 19th March 2013.

Yours sincerely,

Dr. Ken Yeung
General Manager,
Biologics and GMP Consultation Department

Hong Kong Institute of Biotechnology Limited 香港生物科技研究院有限公司
2 Biotechnology Avenue, 12 Miles, Tai Po Road, Shatin, N.T., Hong Kong. 香港新界沙田大埔公路十二哩生物科技路二號
Tel電話: (852) 2603 5111 Fax傳真: (852) 2603 5012 Website網址: http://www.hkib.org.hk