Business Facilitation Advisory Committee
Wholesale and Retail Task Force

Hong Kong's Accession to the
Pharmaceutical Inspection Co-operation Scheme

Purpose

This paper aims to brief members on the background, process and implications of Hong Kong's accession to the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Background

2. In late 2009, the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong made a total of 75 recommendations after reviewing the regulatory regime of pharmaceutical products.

3. One of these recommendations was to upgrade Hong Kong's Good Manufacturing Practice (GMP) licensing standards to PIC/S standards to reflect changes in industry technology and to be on par with international best practice. In this connection, the Department of Health (DH) commissioned a consultant to assist in the upgrade of the licensing standards and to prepare the Pharmacy and Poisons Board of Hong Kong (PPBHK), the statutory licensing authority of drug manufacturers, for the accession to PIC/S.

PIC/S

4. PIC/S is an international instrument between pharmaceutical inspection authorities that provides together an active and constructive co-operation in the field of GMP. The mission of PIC/S is to lead the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal

products. Currently, there are 48 participating authorities in PIC/S while PPBHK became the 47th member with effect from 1 January 2016.

5. PIC/S membership is open to GMP inspectorates having an inspection system comparable to that of other PIC/S Members. The main conditions are to have legislation on medicinal products, a GMP Guide equivalent to that of PIC/S as licensing standards, a GMP inspectorate fulfilling PIC/S quality system requirements and with statutory authority, and experienced GMP inspectors.

Our Road to PIC/S Accession

6. In order to upgrade the GMP licensing standards and to accede to PIC/S, not only the local manufacturers had to upgrade their practicing standards, the GMP inspection team under DH also had to enhance its quality system. As such, DH, PPBHK as well as the local pharmaceutical trade had made enormous efforts in the past few years.

7. In 2011, DH formed a Task Force with local manufacturing trade and derived a roadmap for the trade to upgrade their GMP standards in about three years' time. The Task Force also facilitated dialogues between the Government and the trade on various challenges during the upgrade.

8. In 2012, DH commissioned a consultancy to assist the Drug Office in conducting gap assessments for the trade and the DH's GMP inspection team, upgrading the quality system, training of GMP inspectors, deriving standards for authorized persons of manufacturers, and preparing guidelines for the trade. With the assistance of the consultant, the GMP inspection team thoroughly revised the inspection procedures and prepared seven guidance notes for industry.

9. In order to enhance the regulatory regime of pharmaceutical products and to be in line with international practice, the Government introduced the Pharmacy and Poisons (Amendment) Bill in 2014. In the Bill, secondary packaging of pharmaceutical products was also considered as manufacturing and required a licence. The Bill also introduced the registration of authorized persons of manufacturers and codes of practice for both

manufacturers and authorized persons. The trade in general supported the Bill. Subsequently, the Pharmacy and Poisons (Amendment) Ordinance came into force in February 2015.

10. To further enhance the communication with the trade, the Drug Office had established a dedicated webpage with comprehensive information under its website. A total of 16 seminars were also organized between 2014 and 2015 for the trade to discuss the requirements of secondary packaging and to provide guidance on common GMP deficiencies. The Drug Office also prepared a GMP Guide for secondary packaging manufacturers to facilitate their compliance. In October 2015, the PIC/S GMP standards became a mandatory licensing standard for drug manufacturers in Hong Kong.

11. In August 2013, PPBHK applied for PIC/S accession. Having evaluated the application dossier of PPBHK, the PIC/S Committee decided to send an assessment team to conduct on-site audit in Hong Kong in January 2015. In the meeting held in May 2015, the PIC/S Committee accepted PPBHK as the 47th member of PIC/S with effect from 1 January 2016.

Enhanced Regulatory Environment for the Pharmaceutical Industry

12. The main purpose of PIC/S is to ensure the quality of medicines by concerted efforts of participating authorities under a set of harmonized GMP standards. This is of paramount importance in protecting the public health. PPBHK's accession to PIC/S signifies that both the GMP standards of Hong Kong drug manufacturers and the quality system of the GMP inspectorate have gained international recognition. As a result, other drug regulatory authorities would be more receptive towards registration applications from Hong Kong manufacturers.

13. To better protect the health of Hong Kong people, imported medicines for use in Hong Kong should also be subject to the same GMP requirements. PPBHK is now requiring evidence of GMP (PIC/S or equivalent) compliance from applicants of new product registration as well as registration holders of pharmaceutical products upon their registration renewal. With heightened quality standards for pharmaceutical products marketed in Hong

Kong, issues relating to substandard medicines (e.g. recall or refund) are expected to decrease.

Way Forward

14. Members are requested to note the content of this paper and offer comments, if any.

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