立法會
Legislative Council

LC Paper No. CB(2)414/13-14(02)

Ref : CB2/PL/HS

Panel on Health Services

Background brief prepared by the Legislative Council Secretariat for the special meeting on 10 December 2013

Legislative proposals to enhance the regulation of pharmaceutical products

Purpose

This paper provides background information on the legislative proposals put forward by the Administration in the light of the recommendations made by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("the Review Committee") in 2009, and highlights the views expressed by members of the Panel on Health Services ("the Panel") when being consulted on the proposed legislative amendments.

Background

Regulatory regime for pharmaceutical products

2. The local drug regulatory regime adopts a risk management, dual target and multi-pronged approach underpinned by the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its regulations. The Pharmacy and Poisons Board ("PPB") has been established under the Ordinance to enforce the regulatory measures. PPB is assisted by a Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee, a Pharmacy and Poisons (Manufacturers Licensing) Committee, a Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee, a Pharmacy and Poisons (Listed Sellers of Poisons) Committee and a Poisons Committee in pursuing its functions relating to the regulation of pharmaceutical products (including Part I

Poisons, Part II Poisons and non-poisons[1]) and traders (including manufacturers, importers/exporters, wholesalers and retailers).

3. Under the Ordinance, any person wishing to sell, offer for sale, distribute or possess any pharmaceutical products or substance shall register the product or substance with PPB. Only those pharmaceutical products or substances that conform to the standards on safety, efficacy will be registered. Once the registration is approved, the certificate of registration will be issued for a validity of five years subject to renewal. New registration applications of pharmaceutical products are mainly classified into New Chemical Entity ("NCE") and non-NCE (or commonly known as generic). At present, there are around 19 000 registered pharmaceutical products in Hong Kong.

4. The Ordinance also stipulates that all pharmaceutical traders, except companies trading in pharmaceutical products of non-poisons within Hong Kong, are required to obtain the required licences from PPB. As of September 2013, there were 37 holders of a manufacturer's licence. Among these licensed pharmaceutical manufacturers, 24 of them were in compliance with the Hong Kong Good Manufacturing Practices[2] Guidelines for Pharmaceutical Products. As of October 2013, there were 717 licensed wholesalers of poisons, 94 registered importers and exports of pharmaceutical products, and 4 405 licensed medicine retailers (including 579 authorized sellers of poisons ("ASP") (or commonly known as "dispensaries" or "pharmacies") and 3 826 listed sellers of poisons ("LSPs") (or commonly known as "medicine companies")).

<u>The review on the regulation of pharmaceutical products in Hong Kong</u>

5. In early 2009, a series of incidents involving unsafe and unregistered pharmaceutical products had caused wide public concern. In the light of the incidents, the Government set up the Review Committee in March 2009 to conduct a comprehensive review on the existing regime for the regulation of pharmaceutical products. In its report issued in December 2009, the Review Committee has made a total of 75 recommendations covering the aspects of (a) regulation of drug manufacturers and Good Manufacturing Practice ("GMP"); (b) pre-market control of drugs; (c) regulation of importers/exporters, wholesalers and retailers; (d) procurement and supply of pharmaceutical products in the public and private medical sectors; (e) post-market control of

---

[1] The Ordinance provides for a Poisons List which is divided into two parts: Part I and Part II respectively. Part I Poisons in general are drugs with more serious side effects which warrant enhanced supervision in handling, while Part II Poisons have less serious side effects. Drugs which are not included in the Poisons List are commonly referred to as non-poisons by the traders. Some Part I Poisons are further classified into the First Schedule and the Third Schedule with additional restrictions on their sale at retailers.

[2] Good Manufacturing Practice is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to quality standards appropriate to the products' intended use. According to the Administration, most countries have adopted the set of Good Manufacturing Practice guidelines promulgated by the World Health Organization ("WHO").

drugs and pharmacovigilance; (f) risk communication, education and training; and (g) penalty review. The Administration accepted the recommendations of the Review Committee.

Proposed legislative amendments

6. Among the 75 recommendations put forward by the Review Committee, 16 recommendations require amendments to be made to the Ordinance and its subsidiary legislation. These recommendations are in **Appendix I**. To assess the impacts of the proposed legislative amendments on pharmaceutical dealers, the Administration commissioned a consultant to conduct a Regulatory Impact Assessment ("RIA") in January 2011. Having considered the RIA result concluded in January 2013 and views expressed by the relevant stakeholders, the Administration has decided to propose legislative amendments to implement most of the recommendations except for Recommendation 29, and slight modifications to Recommendations 19 and 74.

Deliberations of the Panel

7. The Panel was briefed on the recommendations of the Review Committee and the Administration's proposed legislative amendments on 11 January 2010 and 18 November 2013 respectively. The deliberations and concerns of members are summarized below.

Regulation of manufacturers

8. Members noted that the Review Committee had recommended that the current Hong Kong GMP standard should be upgraded to a higher international standard. Members were concerned that while WHO had upgraded its GMP in 2007, Hong Kong was still adopting the GMP standard promulgated by WHO in 1995, and the compliance of which was not a mandatory legal requirement.

9. The Administration advised that its plan was to require all licensees to comply with the Guide to Good Manufacturing Practice for Medicinal Products and its annexes (where applicable) published by the Pharmaceutical Inspection Cooperation Scheme ("PIC/S") by 2015, so as to be on par with international best practice. PIC/S was an international agreement between pharmaceutical regulatory authorities of different countries or territories which provided an active and constructive cooperation in the field of GMP. There were currently 43 participating authorities in PIC/S, which included that of Australia, the United Kingdom, the United States, the majority European Union countries, and the Asian countries such as Singapore and Taiwan, etc. The PIC/S standard included a stricter control over the use of active pharmaceutical ingredients for drug manufacturing, more stringent qualification requirements for the position

of the authorized person who oversaw the entire drug manufacturing process, a more enhanced inspection and licensing arrangement, and a more comprehensive training framework for all levels of personnel involved in the GMP system.

Regulation of importers/exporters and wholesalers

10. In the absence of a record and tracking system to trace if pharmaceutical products imported into Hong Kong for re-export purpose were indeed exported, some members urged the Administration to expeditiously formulate measures to prevent the illegal sale of imported unregistered pharmaceutical products in local market.

11. The Administration advised that it proposed to merge the registration of importers/exports of pharmaceutical products with the licensing of wholesalers of poisons and subject the licensees to the same set of control. In addition, wholesalers would be required to keep transaction records for both poisons and non-poisons. The records should include additional details such as registered pack size and batch number of products. DH would also set up a record and tracking system so that export licence applicants would be required to produce the relevant import licences of the imported drugs to be re-exported. In the long run, an electronic record system which was inter-operable with the Customs and Excise Department ("C&ED") and the Trade and Industry Department should be a more efficient alternative. In addition, C&ED would, after having taken into account the workload of its staff, increase the weekly quota of post-shipment consignment checks of licence.

Regulation of retailers

12. Concern was raised about the failure of the existing regulatory regime to prevent those ASPs who closed business to escape punishment after committing serious offences from restarting business at the same premises as new ASPs. There were also cases that ASPs and LSPs with drug-related convictions could successfully restart and operate new ASPs and LSPs because the directors of the convicted ASPs and LSPs might not be personally convicted of the offence. Members also expressed concern that PPB could only revoke the ASP licence for a period of time or not renew the licence upon expiry in extreme situation. They called on the Administration to improve the existing regulatory regime for drugs retailers.

13. The Administration advised that to heighten control, it proposed to tighten up the regulation of ASP by empowering PPB's Disciplinary Committee to, at the conclusion of a disciplinary inquiry of an ASP convicted of drug related offence, give direction to disqualify the ASP concerned and remove its premises from the register of premises, if it was in the public interest to do so, and for

such direction to take effect immediately. To step up the regulation of drug retailers, DH would also conduct more frequent unannounced inspections, in particular to those with a poor record of law compliance.

14. Members noted that the Ordinance, which currently required a registered pharmacist to be present in an ASP for not less than two-thirds of its opening hours, would be amended to the effect that the registered pharmacist concerned should be present whenever an ASP was opened for business. Given the current manpower supply of registered pharmacists, the Administration intended to have this amendment to take effect at a later stage. While there were views supporting the requirement for the sake of consumer protection and urging for its early implementation, there was concern that this would increase the operating cost of ASPs, in particular those in small and medium size. The requirement might also result in ASPs being monopolized by large consortia. These members considered it not an opportune time for introducing this amendment as there was inadequate supply of registered pharmacists to fill the positions and a lack of consensus support in the industry.

15. The Administration advised that at present, there were about 2 100 registered pharmacists in the territory. A Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development had been set up to conduct a strategic review on healthcare manpower planning and professional development in Hong Kong. The Steering Committee would, among others, formulate recommendations on how to cope with the anticipated manpower demand for the various healthcare professions, including pharmacists. The strategic review was aimed to conclude in 2014. The Administration would give due regard to the manpower supply of pharmacists in considering the appropriate timing for the amendment to come into operation.

Written orders of drugs by ASPs, LSPs and private doctors

16. On the Review Committee's recommendation that all ASPs, LSPs and private doctors should place orders of drugs in written form, members urged the Administration to address the concerns of the industry that the requirement would lead to an increase in administrative costs and the possibility of delay in the ordering for pharmaceutical products at retail level.

17. According to the Administration, the aim of the requirement was to build up a complete set of drug movement records, so as to facilitate the tracing of source of drugs, minimize errors in the delivery and receipt of drugs and combat illegal sale of drugs. All these serve to provide the best protection for the public. Having considered the regulation of the drug supply system and the concerns of the pharmaceutical industry, it proposed to implement the requirement by administrative means whereby PPB would incorporate the

requirement in the Codes of Practice for the relevant licenced drug traders, instead of regulating by legislation. As regards the impact of the requirement on practicing doctors, the Administration pointed out that the written order practice had already been recommended in the Good Dispensing Practice Manual issued by the Hong Kong Medical Association since 2007. All practicing doctors were recommended to comply with the provisions in the Manual.

Penalty system

18. Members were advised that the Ordinance would be amended to include provisions empowering the court to order recovery of all expenses incidental to the taking, examination and analyses of any sample of drugs in respect of which the conviction was based from the defendent. There were views that this apart, the existing maximum fines for non-compliance of the Ordinance, i.e. a fine of $100,000, should be increased to the range of $500,000 to $1 million to deter the pharmaceutical traders from malpractices. There was also a view that a demerit point system for licensed medicine retailers should be introduced.

Relevant papers

19. A list of the relevant papers on the Legislative Council website is in **Appendix II**.

Council Business Division 2
Legislative Council Secretariat
6 December 2013

Recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong which require legislative amendments

No.[1]	Details of recommendation
6	To empower the Pharmacy and Poisons Board ("PPB") to maintain an Authorized Person ("AP") register and remove any AP from the register should the AP be found incompetent to perform the role of an AP.
11	To introduce a code of practice to govern the conducts of the manufacturers and APs.
14	To replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption.
15	To delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products.
16	To extend the validity of clinical trial certificate from "not more than two years" to "not more than five years".
18	To require all wholesalers of non-poisons to be subject to inspection and licensing control.
19	To require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons, and to require wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed.
20	To require both primary and secondary packaging be carried out by a licensed manufacturer.

[1] Denotes the number of the recommendations put forward by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong as appeared in its report issued in December 2009.

No.[1]	Details of recommendation
21	To introduce a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc.
29	To require all retailers of non-poisons to be subject to licensing and inspection control.
30	In the longer term after taking into account the market operating conditions and the availability of sufficient pharmacists, to require the presence of a registered pharmacist whenever an authorized seller of poisons ("ASP") is open for business. Heightened enforcement actions should be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs.
31	To require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle.
32	To add a provision in the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") for the issuance and revision of the code of practice for ASPs in order to give a legal status to the code to enhance monitoring on the operation of ASPs; and to introduce a code of practice for listed sellers of poisons ("LSPs") which should enjoy the same legal status as the code for ASPs.
33	To give PPB the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence.
34	To tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. The Department of Health should evaluate what type of drug offences should be included based on their public health impact.
74	To amend the Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect.

Source: Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong

Appendix II

Relevant papers on the legislative proposals to enhance regulation of pharmaceutical products in Hong Kong

Committee	Date of meeting	Paper
Panel on Health Services	11.1.2010 (Item V)	Agenda Minutes
Panel on Health Services	18.11.2013 (Item III)	Agenda

Council Business Division 2
Legislative Council Secretariat
6 December 2013