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on 28 March 2014

Legal Service Division Report on
Pharmacy and Poisons (Amendment) Bill 2014

I. SUMMARY

1.	**The Bill**	The Bill amends the Pharmacy and Poisons Ordinance (Cap. 138), the Pharmacy and Poisons Regulations (Cap. 138A) and the Poisons List Regulations (Cap. 138B) to implement certain recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong and update the legislative provisions by - (a) revising the current rules governing the manufacturing of pharmaceutical products and licensing of manufacturers, importers, exporters and wholesalers; (b) empowering the Pharmacy and Poisons Board to issue codes of conduct and codes of practice the non-compliance of which may lead to disciplinary actions; and (c) making other amendments in relation to pharmaceutical products and trade.
2.	**Public Consultation**	The public and the relevant stakeholders generally supported the proposals to enhance the regulatory regime. However, some dealers were concerned about the likely impact of the proposed changes on their operations.
3.	**Consultation with LegCo Panel**	The Panel on Health Services was consulted on the preliminary legislative proposals and the refined legislative proposals on 18 November 2013 and 10 February 2014 respectively. The Panel also received views of deputations on the proposals on 10 December 2013. Various concerns were expressed by members.
4.	**Conclusion**	The Bill involves substantial changes to the current regulatory regime of the pharmaceutical trade. Members may wish to form a Bills Committee to study the changes in detail. The Legal Service Division is still scrutinizing the legal and drafting aspects of the Bill.

II. REPORT

The date of First Reading of the Bill is 26 March 2014. Members may refer to the LegCo Brief (File Ref.: FHB/H/23/1 Pt.9) issued by the Food and Health Bureau on 19 March 2014 for further details.

Object of the Bill

2. The Bill amends the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance), the Pharmacy and Poisons Regulations (Cap. 138A) (PPR) and the Poisons List Regulations (Cap. 138B) (PLR) to -

(a) implement certain recommendations in the Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong (the Review Committee) published by the Food and Health Bureau in December 2009 (the Review Report); and

(b) make related, consequential and miscellaneous amendments.

Background

3. The current regime for regulating the pharmaceutical trade in Hong Kong is provided for, amongst others, in the Ordinance and its subsidiary legislation. Under the Ordinance, the Pharmacy and Poisons Board (the Board) is established to administer its provisions and those contained in PPR. The Board is allowed to establish executive committees to perform its regulatory functions.

4. In early 2009, a number of incidents concerning pharmaceutical products in Hong Kong caused public concerns on drug safety. The Review Committee was therefore set up to conduct a comprehensive review on the existing regulatory framework. In December 2009, the Review Committee made a number of recommendations on measures to improve the existing regime in the Review Report, including 16 recommendations on legislative amendments required.

5. The Administration proposes, at this stage, to make only some of these legislative amendments which are conducive to enhancing the regulatory regime without causing significant impact to the relevant parties[1]. It also suggests to amend outdated provisions of the Ordinance and its subsidiary legislation in order to bring them into line with the prevailing regulatory framework.

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[1] For the rest of these recommendations, the Administration would monitor the situation and formulate appropriate implementing measures in due course.

Provisions of the Bill

Regulating the manufacture of pharmaceutical products

6. To implement the Review Committee's recommendation to enhance the quality of pharmaceutical products manufactured by licensed manufacturers and to tighten up the regulation of authorized persons (AP), clause 52 of the Bill adds new regulations 30A to 30F to PPR to provide that a licensed manufacturer is required to employ at least one AP to ensure and certify that the pharmaceutical products are manufactured and checked in accordance with the Good Manufacturing Practice Guide (the GMP Guide)[2]. The requirement to keep a register of AP is also imposed, with provisions setting out the application procedure and qualifications required for registration as AP and other registration matters.

7. To implement the Review Committee's recommendation that secondary packaging should only be carried out by licensed manufacturers, clause 4(2) of the Bill revises the definition of "manufacture" under section 2(1) of the Ordinance to cover expressly these packaging and repackaging of pharmaceutical products.

8. Clause 53 of the Bill amends regulation 31 of PPR to require licensed manufacturers to label the containers of pharmaceutical products with two additional particulars, namely, the batch number and expiry date of the products.

9. Clause 55 of the Bill amends regulation 33 of PPR to require licensed manufacturers to ensure that the registrable particulars of each batch of pharmaceutical products in a finished form correspond exactly with the registered particulars of the products. It also revises the period for which the control sample of finished pharmaceutical products is to be kept.

10. Clause 57 of the Bill amends regulation 35 of PPR to revise or state clearly the time by which licensed manufacturers must complete the records relating to the manufacture, sale or supply, testing and complaints of pharmaceutical products.

Licensing requirements of manufacturers, importers, exporters and wholesalers

Manufacturers

11. Clause 50(3) of the Bill repeals regulation 29(2) of PPR such that an authorized seller of poisons (ASP) is no longer exempted from the requirement of a licence to manufacture pharmaceutical products.

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2 Clause 49 of the Bill adds new regulation 28A to PPR to empower the Board to issue the GMP Guide to provide for the principles and guidelines of good manufacturing practice in respect of pharmaceutical products.

Importers and exporters

12. Importers and exporters of pharmaceutical products are presently required to be registered under section 28A of the Ordinance in order to carry on such business. Clause 22 of the Bill replaces that provision with a new section 28A to provide that a person may only import or export pharmaceutical products if the person is either a licensed wholesale dealer or licensed manufacturer[3].

Wholesale dealers

13. To implement the Review Committee's recommendation, clauses 45 and 46 of the Bill amend regulations 25 and 26 of PPR to expand the licensing control on the sale or supply of poisons by way of wholesale dealing to cover pharmaceutical products. As a result, a new wholesale dealer licence (covering both poisons and pharmaceutical products) is to replace the existing wholesale poisons licence.

Codes of conduct and codes of practice and other licensing, registration and disciplinary matters

14. To implement the recommendation of the Review Committee, clause 6 of the Bill adds new section 4B to the Ordinance to empower the Board to issue codes of conduct and codes of practice for providing practical guidance in respect of the Ordinance. Clauses 14, 20, 46 and 50 of the Bill amend sections 15 and 25 of the Ordinance and regulations 26 and 29 of PPR respectively to provide that non-compliance of codes of conducts by registered pharmacists or non-compliance of codes of practice by ASP, listed sellers of poisons (LSP), licensed wholesale dealers or licensed manufacturers may lead to disciplinary actions as provided in those provisions.

15. Clauses 13, 14, 15, 20, 46 and 50 of the Bill amend sections 13, 15, 16 and 25 of the Ordinance and regulations 26 and 29 of PPR respectively to update and clarify the provisions governing the registration of premises of ASP, disciplinary actions against registered pharmacists and ASP, and the issuance, suspension and revocation of licences of, and other disciplinary actions against, LSP, wholesale dealers and licensed manufacturers.

Registration of pharmaceutical products or substances

16. Clause 58 of the Bill amends regulation 36 of PPR to -

(a) add to the categories of persons who may register pharmaceutical products or substances with the Board, a new category of licensed

[3] In the case of the import of pharmaceutical products by a licensed manufacturer, the products must be imported for the purpose of manufacturing the manufacturer's own products. As for exporting pharmaceutical products, the products must be manufactured by the licensed manufacturer.

wholesale dealer who has entered into a manufacturing contract with the licensed manufacturer of the pharmaceutical products or substances concerned; and

(b) exempt from registration pharmaceutical products or substances that are possessed or to be used for treatment by certain medical professionals or to be administered for clinical trials or medicinal tests;

(c) require the production of up-to-date specified information regarding the pharmaceutical products or substances concerned on renewing the registration of the products or substances;

(d) expressly empower the imposition of conditions on registration or renewal of registration of pharmaceutical products or substances; and

(e) provide for the deregistration and suspension of the registration of pharmaceutical products or substances, and the issuance of warning letters.

Control of clinical trials and medicinal tests

17. Clause 59 amends regulation 36B of PPR to provide that it is an offence to conduct a clinical trial on human beings or medicinal test on animals without a clinical trial certificate or medicinal test certificate. To implement the Review Committee's recommendation, the maximum validity period of these certificates are extended from two years to five years. The imposition of conditions on issuing these certificates, the cancellation or suspension of these certificates, and the issuance of warning letters are also provided for.

Labelling and storage of medicines and poisons

18. Clause 37 of the Bill replaces the existing regulation 15 of PPR with a new one to dispense with the requirement that "Poison 毒藥" and other prescribed texts must be displayed on a separate label or surrounded by a line and in red lettering or set against a red background on the container of any poison.

19. To implement the Review Committee's recommendation, clause 67 of the Bill amends the Fifth Schedule to PPR to replace the text "Poison 毒藥" by "Prescription Drug 處方藥物" or "Drug under Supervised Sales 監督售賣藥物" depending on the sale restriction as to avoid confusion that the pharmaceutical products might be harmful and unsuitable for use or consumption.

20. Clause 38 of the Bill amends regulation 19 of PPR to implement the Review Committee's recommendation that all poisons listed in Part I of the Poisons List as kept at retail shops must be stored in locked receptacles and in

areas not accessible to customers with the keys retained by the registered pharmacists.

21. Clauses 39, 40 and 41 of the Bill amend regulations 22, 23 and 24 of PPR respectively to relax certain requirements on the labelling and storage of medicines and poisons applicable in relation to certain institutions such as hospitals and clinics.

Keeping of transaction records

22. To implement the Review Committee's recommendation, clause 48 of the Bill amends regulation 28 of PPR to require licensed wholesale dealers to keep transaction records of not only poisons in Part I of the Poisons List but also any pharmaceutical products. Additional particulars, such as the batch number and pack size of the pharmaceutical products are also required to be recorded.

23. The revised duty described in paragraph 22 above is also imposed on licensed manufacturers.

Other amendments

24. Clause 4 of the Bill revises the meaning of "pharmaceutical products" and "medicine" under section 2(1) of the Ordinance with reference to the definition of "medicinal product" adopted by the European Commission.

25. According to the Administration, in order to follow up on the Review Committee's recommendation to expedite the registration process of pharmaceutical products -

(a) clauses 33 and 70 of the Bill add a new regulation 2A and a new Schedule 10 to PPR respectively to relocate the Poisons List from PLR to PPR; as a result of the relocation, clause 71 of the Bill repeals PLR; and

(b) clause 23 of the Bill adds a new section 29(1B) to the Ordinance to provide that amendments to the Poisons List or any list (which is contained in a regulation made under section 29(1) of the Ordinance) of substances or articles to which any provision of the Ordinance or a regulation made under that section apply or do not apply may be made by the Board by regulation subject to negative vetting by LegCo.

26. To implement the Review Committee's recommendation, clause 30 of the Bill adds a new section 34A to the Ordinance to provide for the recovery from a person convicted of an offence under the Ordinance of the costs and expenses incurred by the Government in relation to the collection, analysis or examination

of a poison, pharmaceutical product or any other substance for the purpose of the criminal proceedings.

27. Other amendments proposed in the Bill include change of the composition of the Board (clause 5), increase the penalty levels for certain offences under the Ordinance (e.g. clause 16), replacement of prescribed forms by specified forms (e.g. clause 64), provision of payment of fees (e.g. clause 69) and other technical, drafting and consequential amendments to the Ordinance and PPR.

Commencement

28. The Bill, if passed, would come into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

Public Consultation

29. According to paragraph 24 of the LegCo Brief, the Review Committee has thoroughly considered its members' views in finalizing its recommendations. The recommendations of the Review Committee were discussed at a plenary session in the Hong Kong Pharmacy Conference on 24 January 2010. The consultant engaged by the Administration to conduct a Regulatory Impact Assessment and the University of Hong Kong have conducted stakeholder consultations and a public opinion survey respectively. According to the Administration, the public and the relevant stakeholders generally supported the proposals to enhance the regulatory regime on pharmaceutical products. However, some dealers were concerned about the likely impact of the proposed changes on their operations.

Consultation with LegCo Panel

30. As advised by the Clerk to the Panel on Health Services, at the meeting on 18 November 2013, the Administration briefed the Panel on the proposed amendments to the Ordinance and its subsidiary legislation to implement most of the Review Committee's recommendations on legislative amendments required. The Panel received views from deputations on these legislative proposals at its special meeting on 10 December 2013. At the meeting on 10 February 2014, the Panel discussed the latest decision of the Administration that in the light of the views of members and deputations, the proposal to require the registered premises of an ASP to be under the personal control of a registered pharmacist whenever the registered premises were open for business would not be pursued in this legislative exercise.

31. Members generally supported the legislative proposals in order to enhance the regulation of pharmaceutical products in Hong Kong, but raised various issues of concern including the liability of a registered pharmacist in the event of non-compliance by the owner or other staff members of an ASP of the proposed requirement that all poisons listed in Part I of the Poisons List had to be stored in locked receptacles at the registered premises of an ASP with the key kept by the registered pharmacist, the timetable to reintroduce a future bill on the proposal requiring the presence of a registered pharmacist in the registered premises of an ASP whenever that ASP was open for business, and the disqualification of an ASP for repeated drug-related offence. There was also a view that vitamin preparations should not remain as a pharmaceutical product such that wholesalers of which would become subject to the licensing and keeping of transaction records requirements.

Conclusion

32. The Bill involves substantial changes to the current regulatory regime of the pharmaceutical trade. Members may wish to form a Bills Committee to study the changes in detail. The Legal Service Division is still scrutinizing the legal and drafting aspects of the Bill.

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