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Paper for the House Committee meeting on 9 January 2015

Report of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Purpose

This paper reports on the deliberations of the Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014.

Background

2. The current regime for regulating pharmaceutical products in Hong Kong is provided for, among others, in the Pharmacy and Poisons Ordinance (Cap. 138) ("the Ordinance") and its subsidiary legislation. Under the Ordinance, the Pharmacy and Poisons Board ("the Board") is established to enforce the regulatory measures over pharmaceutical products, drug traders and pharmacists. The Board is allowed to establish executive committees to perform its regulatory functions.

3. In early 2009, a series of incidents involving the safety of pharmaceutical products had aroused wide public concern. The Government set up the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong ("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 made a total of 75 recommendations to enhance the coverage and depth of the regulatory regime, including 16 recommendations which require amendments to the Ordinance and its subsidiary legislation for implementation.

4. The Administration accepted the recommendations of the Review Committee. For the 59 recommendations which do not require legislative amendments, the Administration has been taking steps to implement them by

phases and most of them have already been implemented. To assess the impacts of the Review Committee's 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, the Administration briefed the Panel on Health Services ("the Panel") on the preliminary proposals to be included in the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill") in November 2013. The Panel held further discussions on these proposals in December 2013 and February 2014, and made certain suggestions for the Administration to consider in finalizing its proposals to amend the Ordinance and its subsidiary legislation.

The Bill

5. The Bill was introduced into the Legislative Council ("LegCo") on 26 March 2014. The Bill aims to amend the Ordinance, the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR") and the Poisons List Regulations (Cap. 138B) ("PLR") to implement certain recommendations of the Review Committee which, in the view of the Administration, are conducive to enhancing the regulatory regime without causing significant impact to the relevant parties[1], and amend those outdated provisions to bring them into line with the prevailing regulatory framework.

6. 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.

The Bills Committee

7. At the House Committee meeting on 28 March 2014, Members agreed to form a Bills Committee to study the Bill. The membership list of the Bills Committee is in **Appendix I**.

8. Under the chairmanship of Prof Hon Joseph LEE Kok-long, the Bills Committee has held nine meetings with the Administration. The Bills Committee has also received views from the public and members of the industry at one of these meetings. A list of organizations and individual that have/who has given oral representation of their views to the Bills Committee is in **Appendix II**. A total of 797 written submissions on the Bill have been received.

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[1] For the rest of the recommendations of the Review Committee which require legislative amendments, the Administration has advised that it would monitor the situation and formulate appropriate implementation measures in due course.

Deliberations of the Bills Committee

9. Members of the Bills Committee are generally in support of the objectives of the Bill which seek to enhance the safety of pharmaceutical products and protect public health. The major issues discussed and concerns raised by members are summarized below.

Definition of authorized seller of poisons

10. Under the proposed amended section 2 of the Ordinance, "*authorized seller of poisons*" ("ASP") is defined to mean a registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11 of the Ordinance. Some deputations have submitted views to the Bills Committee that the proposed amendment is ambiguous about the legal liability of a registered pharmacist who is an employee of an ASP to oversee its operations, but not the holder of certificate of registration of premises of the ASP concerned.

11. According to the Administration, the proposed amendment is purely a technical amendment to accurately reflect the usage of the term in the legislation as an entity that carries on a business of retail sales of poisons. It should be noted that according to the Ordinance, if a natural person wants to carry on a business as an ASP, such person must be a registered pharmacist. For a registered pharmacist who is an employee of an ASP, his/her legal liability remains unchanged under the proposed amendment. The Administration has pointed out that in case of non-compliance with the relevant provisions in the Ordinance, the person who will be liable to prosecution will depend on the evidence available and the circumstances of each case. It is the common law principle that the burden of proof rests with the prosecution.

Definition of pharmaceutical product and medicine

12. Members note the concern expressed by some deputations about the scope of products that will be covered under the proposed revised definition of "*pharmaceutical product*" and "*medicine*" as provided under the proposed revised section 2 of the Ordinance. According to the proposed revised definition, "*pharmaceutical product*" and "*medicine*" is any substance or combination of substances (a) presented as having properties for treating or preventing disease in human beings or animals; or (b) that may be used in, or administered to, human beings or animals, either with a view to (i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or (ii) making a medical diagnosis.

13. The Administration has advised that the aim to revise the definition of "*pharmaceutical product*" and "*medicine*" to include the limb of "combination of substances presented as having properties for treating or preventing disease in human beings or animals" is to codify the current registration requirement set out in the Guidance Notes on Registration of Pharmaceutical Products/Substances published by the Department of Health which specifies that a product may fall within the definition of pharmaceutical product under the Ordinance if it contains a drug substance in its composition, or if it carries medicinal claims in its label, leaflet, brochure, wrapper, advertisements and other promotional materials. In addition, the revision will make the definition of "*pharmaceutical product*" and "*medicine*" more closely aligned with the definition of medicinal product adopted by the European Commission and similar definitions adopted by Australia and the United Kingdom.

Code of conduct and codes of practice promulgated by the Board

Empowerment of the Board

14. Pursuant to the proposed new section 4B of the Ordinance, the Board may promulgate corresponding code of conduct ("CoC") and codes of practice ("CoPs") for providing practical guidance in respect of the Ordinance and its subsidiary legislation to registered pharmacists, as well as different licensed traders and traders subject to registration requirement (including ASP, listed seller of poisons, holder of the new wholesale dealer licence introduced by the Bill, holder of the licence to manufacture pharmaceutical products and authorized person ("AP")). Under the proposed revised sections 15 and 25 of the Ordinance and regulations 26 and 29 of PPR, non-compliance of CoC by registered pharmacists or non-compliance of CoPs by the drug traders may lead to disciplinary actions. Some members share the concern expressed by some deputations that the proposal provides the Board with too much power. They have enquired whether the Administration can rely on the existing practice to govern the conduct of activities of registered pharmacists and drug traders. They have also expressed concern about whether the Administration is trying to circumvent the scrutiny of LegCo on the formulation or revision of these codes. Noting the view of some deputations that the industry has not been fully consulted on the drafting of the codes, these members have requested the Administration to provide the draft of the codes to the Bills Committee for perusal.

15. The Administration has explained that at present, three individual sets of Codes of Ethics are promulgated by the pharmacist associations to govern the professional conduct of their members. While the Board has introduced a CoP for ASP in 1997, the CoP serves as a guideline for ASP and carries no legal status. There are currently no CoPs for other drug traders. It is thus considered necessary and appropriate for the Bill to empower the Board to formulate and revise the

relevant CoC and CoPs. In the Administration's view, the empowerment provides the Board with the flexibility to draw up or revise the codes with regard to local circumstances and changes. Some existing Ordinances also empower the relevant authorities to issue CoPs, such as the Broadcasting Ordinance (Cap. 562) and the Insurance Companies Ordinance (Cap. 41). The Administration has stressed that the contents of CoC and CoPs are not part of the primary and subsidiary legislation. No one will be deemed to have violated the relevant legislation simply because that person has contravened the relevant CoC or CoPs, unless the matter concerned constitutes an offence under the Ordinance or its subsidiary legislation. The proposed new section 4B(3) and (5) of the Ordinance also provides that if a CoC or CoP is issued or revised, the Board must, by notice published in the Gazette, identify the code or part revised and specify the date on which the code or revision is to take effect. The Board will, at the same time, write to inform the registered pharmacists and relevant drug traders of the issuance or revision of the CoC or CoPs concerned.

16. The Administration has further advised that the Board has set up different working groups, comprising trade representatives and stakeholders as members, since January 2012 to provide comments on the formulation or revision of the relevant CoC and CoPs. In addition, during the process of formulating or revising the codes, the Board has gathered views from, among others, members of the industry, through a number of consultation meetings, public consultation and briefing sessions. In the view of the Administration, the Board has carried out sufficient consultation with the industry when formulating or revising the relevant CoC and CoPs.

Proposed requirement of placing drug orders in written form

17. Members note that a requirement to place drug orders in written form, as recommended by the Review Committee, is proposed to be added to the relevant CoPs for licensed drug traders. Under the proposed requirement, drug traders have to obtain orders in writing issued by their purchasers (e.g. private doctors) before the completion of a sale of the drugs covered by the requirement, and arrange the delivery of the drugs accordingly. While members in general agree that the proposed requirement will prevent errors from spoken communication and help establish a complete set of movement records of drugs to better protect patient safety in the use of medicine, they are concerned about the impact to be brought about by the requirement on the trade.

18. The Administration has advised that the acceptable means of placing drug orders in written form, in addition to mail and fax, also include various kinds of retainable electronic records such as e-mails and textual messages. To facilitate the trade to adapt to the requirement, the Board is considering implementing the requirement by phases such that it will initially apply to antibiotics, dangerous

drugs, and drugs in Part I of the Poisons List to be migrated from PLR to PPR under the Bill. The Board will closely monitor the implementation of the requirement for written orders and consider extending the requirement to drugs with lower risk, such as drugs in Part II of the Poisons List and drugs not included in the Poisons List, at a later stage. The Administration has further advised that it does not anticipate that the proposed requirement will bring about a significant cost impact on drug suppliers and private doctors, as many drug suppliers have designed standard procurement forms for use by their clients to save their efforts. It is also given to understand from the drug distributors that a written order as compared to a verbal order will not cause a delay in the delivery of drugs.

19. Members have sought clarification as to whether drug orders placed by the purchasers through voice mail, and drug orders sent by a sales representative on behalf of their clients in electronic mode would be regarded as written orders. The Administration has advised that voice mail will not be considered as an acceptable form of written order having taken into account that the pronunciations of the names of certain drugs are quite similar and, hence, the verbal order may be wrongly taken by the drug suppliers. As regards a drug order sent by a sales representative on behalf of the client in electronic mode, it will be regarded as a written order only if the purchaser concerned has sent a written message to the sales representative beforehand to confirm the order.

20. The Bills Committee notes that while the proposed requirement is well supported by patient groups and licensed drug traders, the Hong Kong Doctors Union has raised strong opposing view to the requirement since it has become a member of the Review Committee. Dr Hon LEUNG Ka-lau has enquired whether the keeping of the drug suppliers' delivery notes by the medical clinics can serve the same purpose of facilitating the tracing of the source of drugs. The Administration, however, maintains its position that the proposed requirement of placing orders of drugs in written form is necessary in order to minimize errors in the delivery and receipt of drugs. It has explained to the Bills Committee that the Hong Kong Medical Association ("HKMA") has already recommended in its Good Dispensing Practice Manual in July 2005 that the ordering of drugs from suppliers should be made in writing via post or fax by the doctor concerned. HKMA revised the Manual in May 2007 to further recommend that the written orders should be kept for verification upon delivery of the drugs and for future reference. As recommended by the Medical Council of Hong Kong, all practising doctors should comply with the Manual.

The new CoP for ASP

21. Members note that the new CoP for ASP endorsed by the Board will take effect on 2 January 2015 for replacing the existing one which was introduced in 1997 as a condition for registration of ASP's premises under section 13 of the

Ordinance. Taking into account that the Bill will not have been passed by LegCo at the time the new CoP takes effect, some members consider the arrangement undesirable and enquire if the new CoP could become effective after the passage of the Bill.

22. The Administration has explained that the revision of the existing CoP for ASP is not part of the legislative proposals under the Bill. The drafting of the new CoP is conducted by the Working Group on the Code of Practice for Authorized Seller of Poisons comprising representatives from the trade and ASPs set up under the Board. The Board will introduce the new CoP for ASP on 2 January 2015 as a licensing condition under existing section 13 of the Ordinance.

Appointment of Disciplinary Committee

23. Members note that the proposed new section 15(1)(e) of the Ordinance preserves the existing power of the Board to appoint a Disciplinary Committee as provided for in the current section 15(1) of the Ordinance such that the Board may appoint a Disciplinary Committee to inquire into the conduct of a registered pharmacist, an employee of a registered pharmacist, an ASP or an employee, officer or partner of an ASP if it appears necessary or desirable to the Board to inquire into the conduct of any of these persons. The word "conduct" is not defined under the Ordinance and the Bill. Some members consider that the scope of the conduct referred to in the provision should be restricted to conduct that is relevant to the practice of pharmacy.

24. The Administration takes the view that the proposed retention of the power of the Board to appoint a Disciplinary Committee to inquire into the conduct of registered pharmacist is necessary in order to maintain public confidence in the pharmacist profession. It has pointed out that past cases revealed that the Board will only exercise its power to appoint a Disciplinary Committee under the current section 15(1) of the Ordinance when the conduct involved might affect the pharmacists' fitness to practice. Of the three registered pharmacists disciplined by the Disciplinary Committee from 2008 to June 2014, one was disciplined for conviction of behaving in a disorderly manner in a public place under the Public Order Ordinance (Cap. 245) and the other two were disciplined because of conviction of obtaining property by deception and conviction of fraud respectively under the Theft Ordinance (Cap. 210). While the conduct concerned in these three cases is not directly related to the practice of pharmacy, the conduct could however reasonably be regarded as disgraceful or dishonest by members of the pharmacist profession of good repute and competency.

25. Members also note that it is expressly stipulated in the Medical Practitioners (Registration and Disciplinary Procedure) Regulation (Cap. 161E), the Dentists (Registration and Disciplinary Procedure) Regulations (Cap. 156A)

and the Nurses (Registration and Disciplinary Procedure) Regulations (Cap. 164A) that complaint or information relating to misconduct in any professional respect or unprofessional conduct is one of the grounds for disciplinary inquiry. The Administration, however, has pointed out that past cases reveal that the conduct inquired into may be conduct that does not directly relate to the professional practice.

Recovery of conviction-related expenses

26. Some deputations have submitted views to the Bills Committee that they have reservations about the proposed new section 34A of the Ordinance which provides that if a person is convicted of an offence under the Ordinance, the court may order the person to pay to the Government the sum the court considers appropriate for the costs and expenses reasonably 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. The Administration has pointed out that section 11 of the Costs in Criminal Cases Ordinance (Cap. 492) already empowers a magistrate to recover costs, which could include the expenses referred to in the proposed new section 34A of the Ordinance, from a convicted defendant. The proposed addition of a specific provision for the recovery of costs and expenses in the Ordinance is aimed at providing a clearer message to the trade and increase the deterrent effect. It has stressed that the proposal will only be applicable to convicted traders. In line with the concept of recovery of costs, the amount to be recovered as ordered by the court will be compensatory in nature. To reflect this intention, the Administration will move Committee stage amendments ("CSAs") to amend the new section 34A(2) of the Ordinance under clause 30 of the Bill by replacing "fine is recoverable" with "civil debt".

Good Manufacturing Practice Guide

28. Under the proposed new regulation 28A of PPR, the Board is empowered to issue the Good Manufacturing Practice Guide ("the GMP Guide") to provide for the principles and guidelines of good manufacturing practice ("GMP") in respect of pharmaceutical products. Some members have suggested that the Administration should consult the Panel before the finalization of any revision to the GMP Guide which will not be a subsidiary legislation, and therefore not subject to the scrutiny of LegCo.

29. The Administration has explained that GMP is a quality assurance approach used by the drug manufacturing industry worldwide. The Board will revise the GMP Guide, which serves as a licensing condition for licensed manufacturers, from time to time taking into account the latest GMP standards

adopted by the World Health Organization and other overseas countries, as well as the views and capacity of local drug manufacturers. If the GMP Guide has been revised, the Board has to, by notice published in the Gazette, identify the Guide or part revised. In the light of members' views, the Administration has undertaken to, upon the gazettal of the notice, provide a copy of the GMP Guide to the Panel for information.

Regulation of APs

Qualification requirement of AP

30. 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 AP, the proposed new regulations 30A to 30F of PPR provide, among other things, 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 GMP Guide. Some members have expressed concern about the qualifications required for registration as an AP, in particular, how the competence of APs can be ensured if any person, who is not a registered pharmacist, can act as an AP if he/she holds a qualification awarded on completion of a course recognized by the Pharmacy and Poisons (Manufacturers Licensing) Committee and has three or more years of experience in the pharmaceutical product manufacturing or quality control in compliance with the GMP Guide.

31. The Administration has explained that given the diversified and complicated nature of the manufacturing of pharmaceutical products, various scientific considerations are involved in the course of manufacturing. Hence, the qualification requirements for APs also need to be diversified, with being a registered pharmacist remains to be one of the qualifications required for registration as an AP. The proposal is in line with international practice, such as the European Union ("EU") where the holders of manufacturing authorization are required to, among others, comply with the principles and guidelines of GMP for medicinal products. According to the Administration, the Department of Health is drawing up the relevant requirements for APs, including, inter alia, holding recognized university qualifications and qualifications awarded on completion of recognized courses related to drug manufacturing, such as microbiology and toxicology. Details of the recognition system will be submitted to the Board for consideration and announced to the public when available.

32. Members have enquired whether the standard of local drug manufacturing is on par with the standard of EU. The Administration has advised that at present, all 24 licensed manufacturers engaged in the manufacturing of pharmaceutical products are in compliance with the Hong Kong GMP Guidelines for

Pharmaceutical Products and they are required to comply with the Guide to GMP for Medicinal Products and its annexes (where applicable) published by the Pharmaceutical Inspection Cooperation Scheme ("PIC/S") by 2015. Under the proposed revised definition of "*manufacture*", secondary packaging activities (with an exemption for certain activities which do not affect the safety, efficacy and quality of the products) will also be required to be carried out by a licensed manufacturer in compliance with the relevant PIC/S GMP requirements.

Register of AP

33. According to the proposed new regulation 30B(5) of PPR under clause 52 of the Bill, the register of APs is required to be made available for public inspection at the office of the secretary to the Board ("the Secretary") free of charge during normal office hours. The Administration has accepted members' suggestion that the register of APs should also be made available for public inspection via the Internet. The Administration will move CSAs to amend the above provision to the effect that the Secretary has to make the register available for inspection by the public free of charge at the office of the Secretary during normal office hours and in any other manner the Secretary thinks fit. This will cover, among others, online inspection.

34. The Bills Committee notes that the Administration will move similar CSAs to the proposed new section 4B(6) of the Ordinance under clause 6 of the Bill, the proposed revised section 5(2) of the Ordinance under clause 7 of the Bill, and the proposed new section 28A(6) of PPR under clause 49 of the Bill concerning public inspection of CoC for registered pharmacists and CoPs for relevant drug traders, the register of pharmacists and the GMP Guide.

<u>Proposed requirement of keeping samples of finished pharmaceutical products</u>

35. The proposed revised regulation 33 of PPR requires 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. Hon WONG Ting-kwong has requested the Administration to address the concern of drug manufacturers that keeping samples of expensive drugs is costly. The Administration has agreed to move CSAs to amend the proposed revised regulation 33 of PPR to provide certain flexibility for licensed manufacturers in maintaining sample of finished products if certain conditions are satisfied.

Regulatory framework for registered pharmacists

36. Members share the grave concern of some deputations that the Board does not have sufficient representation of the pharmacist profession in its composition. For instance, while the existing members of the Board include two members holding qualifications in pharmacology (each of whom is teaching at and nominated by The University of Hong Kong and The Chinese University of Hong Kong respectively) and three registered pharmacists nominated by the industry, community pharmacists working in ASPs are not represented in the Board. Some members are of the view that the regulatory power of the Board, which covers pharmaceutical products, drug traders and pharmacists, is too extensive. Holding the view that the standard of practice and professional conduct of registered pharmacists should best be left to self-regulation by the profession, they have requested the Administration to establish a separate statutory body to take over the existing function of the Board for regulating registered pharmacists. Hon Paul TSE has, however, pointed out that the international trend is to move from the premises of self-regulation of the profession for the protection of its own interests to one of co-regulation in partnership with the government.

37. The Administration has explained that the Bill does not touch on the regulatory framework for registered pharmacists, as its main purpose is to implement certain recommendations put forth by the Review Committee. Given that issues pertaining to the regulatory framework for registered pharmacists and in that connection the role and composition of the Board involve wide policy implications, it is necessary for the Administration to study the issues separately. In the meantime, the Government has set up a Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development ("the Steering Committee") to formulate recommendations on, among others, the long-term professional development of the 13 healthcare professions subject to statutory regulation, including pharmacists. The Administration has informed the Bills Committee that the Pharmacists Sub-group under the Steering Committee met on 16 December 2014 and will study the suggestion for establishing a separate regulatory body for registered pharmacists in due course.

Commencement of the Bill

38. The Administration plans to appoint, by notice in the Gazette, 30 January 2015 as the commencement date of all the provisions of the Bill (except the proposed amendments to section 27 of the Ordinance and regulation 15 of PPR) following the passage of the Bill. Members raise no objection to the Administration's plan.

Committee stage amendments

39. Apart from CSAs to be moved by the Administration as elaborated in paragraphs 27, 33, 34 and 35 above, the Administration will move some technical, textual and consequential amendments to the Bill. A full set of the draft CSAs to be moved by the Administration is in **Appendix III**. The Bills Committee supports these CSAs.

40. The Bills Committee will not propose any CSAs to the Bill.

Resumption of Second Reading debate on the Bill

41. The Bills Committee raises no objection to the resumption of the Second Reading debate on the Bill at the Council meeting of 21 January 2015, subject to the moving of the CSAs by the Administration.

Advice sought

42. Members are invited to note the deliberations of the Bills Committee.

Council Business Division 2
Legislative Council Secretariat
8 January 2015

Appendix I

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Membership list

Chairman	Prof Hon Joseph LEE Kok-long, SBS, JP, PhD, RN
Members	Hon LEUNG Yiu-chung Hon Emily LAU Wai-hing, JP Hon Vincent FANG Kang, SBS, JP Hon WONG Ting-kwong, SBS, JP Dr Hon LEUNG Ka-lau Hon CHEUNG Kwok-che Hon Mrs Regina IP LAU Suk-yee, GBS, JP Hon Paul TSE Wai-chun, JP Hon Alan LEONG Kah-kit, SC Hon LEUNG Kwok-hung Hon Albert CHAN Wai-yip Hon WONG Yuk-man Hon Claudia MO Hon CHAN Han-pan, JP Hon Alice MAK Mei-kuen, JP Dr Hon KWOK Ka-ki Dr Hon Fernando CHEUNG Chiu-hung Dr Hon Elizabeth QUAT, JP (Total : 19 members)
Clerk	Ms Maisie LAM
Legal Adviser	Ms Wendy KAN
Date	2 July 2014

Appendix II

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

Organizations and individual that have/who has given oral representation to the Bills Committee

1. Alliance of Safe and Quality Use of Medicines
2. Asia Regulatory Professional Association
3. College of Consultant Pharmacist
4. College of Geriatric Pharmacy
5. College of Primary Healthcare Pharmacists
6. Department of Pharmacology and Pharmacy, The University of Hong Kong
7. Drug Safety Consortium
8. Hong Kong Academy of Pharmacy
9. Hong Kong Alliance of Patients' Organizations
10. Hong Kong Doctors Union
11. Hong Kong General Chamber of Pharmacy Limited
12. Hong Kong Pharmaceutical Manufacturers Association
13. Hong Kong Pharmacists Union
14. Pharmaceutical Trade Alliance
15. Primary Healthcare Quality Alliance
16. School of Pharmacy, The Chinese University of Hong Kong
17. The Hong Kong Association of the Pharmaceutical Industry
18. The Practising Pharmacists Association of Hong Kong
19. The Pharmaceutical Society of Hong Kong
20. The Society of Hospital Pharmacists of Hong Kong
21. Ms Celine CHENG

Pharmacy and Poisons (Amendment) Bill 2014

Committee Stage

Amendments to be moved by the Secretary for Food and Health

Clause	Amendment Proposed
6	In the proposed section 4B(6), by deleting everything after "of charge" and substituting— "— (a) at the office of the Secretary during normal office hours; and (b) in any other manner the Board thinks fit.".
7	By deleting the clause and substituting— "**7. Section 5 amended (the register of pharmacists)** Section 5— **Repeal subsection (2)** **Substitute** "(2) The Secretary must make the register of pharmacists available for inspection by the public free of charge at the office of the Secretary during normal office hours, and in any other manner the Secretary thinks fit, so as to enable a member of the public— (a) to ascertain whether a person is a registered pharmacist; and (b) to ascertain the particulars of the registration of the person.".".
10	By renumbering the clause as clause 10(1).

10 By adding—

"(2) Section 10(2)—

Repeal

"Forgery"

Substitute

"forgery and related offences".".

12 In the Chinese text, by adding "在場" before "監督".

13 By adding—

"(1A) Section 13(4)(c)—

Repeal

"by a registered pharmacist or in his presence or under his supervision"

Substitute

"by a registered pharmacist, or in the presence and under the supervision of a registered pharmacist".".

13(6) In the proposed section 13(7A) and (7B), by deleting "Secretary" and substituting "Board".

15(11) In the Chinese text, by adding "“" before "(iia)".

20(6) In the proposed section 25(3B), in the Chinese text, by deleting "委員會" and substituting "管理局".

20(7) By deleting "or (3A)" and substituting ", (3A) or (3B)".

23(11) In the proposed section 29(1)(jb), in the Chinese text, by deleting "及獲" and substituting "或獲".

23(17) In the proposed section 29(1)(qb), in the Chinese text, by deleting "床" (wherever appearing) and substituting "牀".

23(20) In the proposed section 29(1B)(b)(i), by deleting ", or in a regulation made under this section,".

24 In the proposed section 29A(2)(a) and (b), in the Chinese text, by deleting "免費供公眾" and substituting "供公眾免費".

25(1) By deleting "or (3A)" and substituting ", (3A) or (3B)".

26 In the English text, by deleting subclause (2) and substituting—

"(2) Section 31(1)(a)—

Repeal

"practitioners appointed under section 3(2)(h) and (i)"

Substitute

"practitioner appointed under section 3(2)(h)".".

30 In the proposed section 34A(2), by deleting "in the same manner as a fine is recoverable" and substituting "as a civil debt".

30 In the proposed section 34A, by adding—

"(3) To avoid doubt, this section does not affect any power conferred on the court under the Costs in Criminal Cases Ordinance (Cap. 492).".

43 By renumbering the clause as clause 43(1).

43 By adding—

"(2) Regulation 24B(b)—

Repeal

"in whose presence or under whose supervision"

Substitute

"by whom or in whose presence and under whose supervision".".

46 By deleting subclause (5) and substituting—

"(5) Regulation 26(6)—

Repeal

"person"

Substitute

"applicant or licensed wholesale dealer".".

49 In the proposed regulation 28A(6), by deleting everything after "of charge" and substituting—

"—

(a) at the office of the Secretary during normal office hours; and

(b) in any other manner the Board thinks fit.".

52 In the proposed regulation 30B(5), by deleting "hours." and substituting—

"hours, and in any other manner the Secretary thinks fit, so as to enable a member of the public—

(a) to ascertain whether a person is an authorized person; and

(b) to ascertain the particulars of the registration of the

person.".

52 In the proposed regulation 30F(6), by deleting "that paragraph" and substituting "this regulation".

55 By deleting subclause (5) and substituting—

"(5) Regulation 33(4)—

Repeal

"A manufacturer shall maintain"

Substitute

"Unless paragraph (4B) applies, a licensed manufacturer must retain".".

55 By adding—

"(6A) After regulation 33(4)—

Add

"(4A) Paragraph (4B) applies to a licensed manufacturer in respect of a batch of pharmaceutical products if all of the following conditions are satisfied—

(a) the products are enclosed in a primary container in which the products are to be sold or supplied;

(b) the process of manufacture that the manufacturer carries out, in respect of the products, only involves one or more of the following—

(i) adding a package insert;

(ii) replacing a package insert;

(iii) (if the products are intended for export) affixing a label to any labelled container of the products, and the label does not obscure, change or obliterate any of the following particulars

appearing on that labelled container—

(A) particulars required to be labelled under regulation 31(4);

(B) the name of the products;

(C) the batch number of the products;

(D) the expiry date of the products;

(iv) (if the products are not intended for export) affixing a label to any labelled container of the products, and the label does not obscure, change or obliterate any of the following particulars appearing on that labelled container—

(A) the registered particulars of the products;

(B) the batch number of the products;

(C) the expiry date of the products;

(c) throughout the process of manufacture, the primary container remains closed.

(4B) The manufacturer is only required to retain a sample of the following of the batch of finished products for a period of not less than 1 year after the expiry date of the products—

(a) if paragraph (4A)(b)(i) applies, the package insert added;

(b) if paragraph (4A)(b)(ii) applies, the replacing package insert;

(c) if paragraph (4A)(b)(iii) or (iv) applies, the label affixed.".".

55 By deleting subclause (8) and substituting—

"(8) After regulation 33(5)—

Add

"(6) Despite paragraphs (4) and (4B)(c), a licensed manufacturer is not required to comply with

paragraph (4) or (4B)(c) (as applicable) in respect of a batch of pharmaceutical products if the manufacturer is not regarded as manufacturing the products for the purposes of regulation 29(1).

(7) In this regulation—

batch number (批次編號) has the meaning given by regulation 31(2)(c);

expiry date (使用期限) has the meaning given by regulation 31(2)(d);

labelled container (帶標籤容器), for a pharmaceutical product, means a container of the product on which the following particulars appear—

(a) the name of the product;

(b) the batch number of the product;

(c) the expiry date of the product;

package insert (包裝附頁) has the meaning given by regulation 36(3A);

primary container (最內層容器), for a pharmaceutical product, means the container that is in direct contact with the product;

registered particulars (註冊詳情) has the meaning given by regulation 35A;

registrable particulars (須註冊詳情) has the meaning given by regulation 35A.".".

58(3) In the Chinese text, by adding "本條例" before "第 28A(1)".

58(6) In the Chinese text, by deleting "而".

58(10) In the proposed regulation 36(1A)(c), in the Chinese text, by deleting "床" (wherever appearing) and substituting "牀".

59 By adding before subclause (1)—

"(1A) Regulation 36B, Chinese text, heading—

Repeal

"**床**"

Substitute

"**牀**".".

59(2) In the proposed regulation 36B(1), in the Chinese text, by deleting "床" (wherever appearing) and substituting "牀".

59 By adding—

"(2A) Regulation 36B(1C), Chinese text—

Repeal

"床"

Substitute

"牀".".

59 In the Chinese text, by deleting subclause (4) and substituting—

"(4) 第 36B(3)條 —

廢除

在"後，"之後而在"年"之前的所有字句

代以

"在它認為適宜施加的條件的規限下，發出符合指明格式的臨牀試驗證明書或藥物測試證明書，而該證明書的有效期不超逾 5"。".

59(6) In the proposed regulation 36B(3B), in the Chinese text, by deleting "床" and substituting "牀".

59(7) In the Chinese text, by deleting "床" and substituting "牀".

62 In the proposed regulation 38B, in the English text, in the heading, by deleting "**Powers**" and substituting "**Power**".

62 In the proposed regulation 38B(2)(a) and (b), in the Chinese text, by deleting "免費供公眾" and substituting "供公眾免費".

New By adding—

"**63A. Regulation 40 amended (penalties)**

Regulation 40, after "33(1), (2), (3), (4)"—

Add

", (4B)".".

65 By deleting subclause (65).

65(106)(b) By deleting "After item "托芬那酸；其鹽類"" and substituting "Before item "托屈嗪；其鹽類"".

66(1) In the Chinese text, by deleting "附表 10" and substituting "10".

66(100)(b) By deleting "After item "托芬那酸；其鹽類"" and substituting "Before item "托哌酮；其鹽類"".

67(1) In the Chinese text, by deleting "**本條例的**" and substituting "**本條例第**".

70 In the proposed Schedule 10, in section 2, in the Table, in Part I, in Division A—

(a) by adding "5-Aminolevulinic acid; its salts; its derivatives; their salts" after the item "Aminoglutethimide";

(b) by adding "Cobicistat; its salts" after the item "Clozapine; its salts";

(c) by adding "Dapagliflozin; its salts" after the item "Dalteparin; its salts";

(d) by adding "Elvitegravir; its salts" after the item "Eltrombopag; its salts; its esters; their salts";

(e) by adding "Lixisenatide" after the item "Lithium sulphate";

(f) by adding "Mifepristone; its salts; its esters; their salts" after the item "Midodrine; its salts";

(g) by adding "Perampanel" after the item "Pentolinium; its salts";

(h) by adding "Pertuzumab" after the item "Perindoprilat; its salts; its esters; their salts";

(i) by adding "Regorafenib; its salts" after the item "Recombinant human erythropoietin";

(j) by adding "Tofacitinib; its salts" after the item "Todralazine; its salts";

(k) by adding "Vilanterol; its salts" after the item "Vigabatrin".

70 In the proposed Schedule 10, in the Chinese text, in section 2, in the Table, in Part II, in Division A, by deleting—

"(i) 列於附表3的毒藥；或

(ii) 乙基嗎啡；其鹽類"

and substituting—

"(d) 列於附表3的毒藥；或

(e) 乙基嗎啡；其鹽類".