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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 21 January 2015

Pharmacy and Poisons (Amendment) Bill 2014

Committee stage amendments

The Second Reading debate on the above Bill will be resumed at the Council meeting of 21 January 2015. Subject to the Bill receiving Second Reading, the President has given permission for the Secretary for Food and Health to move proposed amendments to the Bill at its Committee stage.

2. As directed by the President, the proposed amendments are attached for Members' consideration.

(Ms Doris LO)
for Clerk to the Legislative Council

Encl.

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".