Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014

The Government's Proposed Draft Committee Stage Amendments to the Pharmacy and Poisons (Amendment) Bill 2014

The Government intends to propose certain Committee Stage Amendments ("CSAs") to the Pharmacy and Poisons (Amendment) Bill 2014. Having considered the comments by the trade, Legislative Council Members and the Legal Adviser of the Bills Committee, we have consolidated the brief description of the full set of draft CSAs at Table A of **Annex I** for Members' reference. The draft CSAs are in **Annex II** and the marked-up copy incorporating the amendments[1] proposed by the draft CSAs is at **Annex III**..

Food and Health Bureau
21 November 2014

[1] The marked-up copy is for reference only. It would be necessary to check against the final version of the full set of CSAs to be moved by the Government.

Annex I

Proposed Committee Stage Amendments
to the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill")

Table A

	Provisions to be amended	Brief description of the amendments
1.	Clause 6 of the Bill – section 4B(6) of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO")	To amend section 4B(6) of the PPO so as to require the Pharmacy and Poisons Board ("the Board") to make codes of conduct and codes of practice available for inspection by the public free of charge in any manner the Board thinks fit (apart from making the codes available at the Secretary's office during normal office).
2.	Clause 7 of the Bill – section 5(2) of the PPO	To amend section 5(2) of the PPO so as to – ● specify the purposes of the register of pharmacists. This is to ensure that the operation of the register of pharmacists complies with the data protection principles enshrined in Schedule 1 to the Personal Data (Privacy) Ordinance (Cap. 486) ("PDPO"); and ● require the Secretary to make the register of pharmacists available for inspection by the public free of charge in any manner the Secretary thinks fit (apart from making the register available at the Secretary's office during normal office).
3.	Clause 10 of the Bill – section 10(1) of the PPO	A textual amendment – to renumber the clause amending section 10(1) of the PPO as clause 10(1).
4.	Clause 10 of the Bill – section 10(2) of the PPO	A textual amendment suggested by Assistant Legal Adviser ("ALA") of the Legislative Council ("LegCo") – to add "and Related Offences" after "Forgery" in order to update the reference in section 10(2) of the PPO to the heading of Part IX of the Crimes Ordinance (Cap. 200). Please also see item 1 in Table B below.

5.	Clause 12 of the Bill – section 11(1) of the PPO	A textual amendment suggested by ALA - to add "在場" before "監督" in the Chinese text of this provision to tally with the expression of "in his presence" in the English text.
6.	Clause 13 of the Bill – section 13(4)(c) of the PPO	A textual amendment suggested by ALA - to replace "by a registered pharmacist or in his presence or under his supervision" with "by a registered pharmacist, or in the presence and under the supervision of a registered pharmacist" to align with section 11(1) of the PPO.
7.	Clause 13(6) of the Bill – new subsections (7A) and (7B) under section 13 of the PPO	A textual amendment - to replace "the Secretary" in these two provisions with "the Board" to correctly reflect the current practice.
8.	Clause 15(11) of the Bill – new section 16(2)(b)(iia) of PPO	A textual amendment suggested by ALA - to add open inverted commas in the Chinese text of clause 15(11) of the Bill.
9.	Clause 20(6) of the Bill –new section 25(3B) of the PPO	A textual amendment suggested by ALA – to replace "委員會" in the Chinese text with "管理局" to align with the English text.
10.	Clause 20(7) of the Bill – section 25(5) of the PPO	An amendment in response to enquiry from ALA – to allow a person who is aggrieved by a decision of the Board under section 25(3B) to appeal against such decision.
11.	Clause 23(11) of the Bill – new section 29(1)(jb) of the PPO	A textual amendment suggested by ALA – to replace "註冊證明書及獲續期的註冊證明書" in the Chinese text with "註冊證明書或獲續期的註冊證明書" to align with the English text.
12.	Clause 23(17) of the Bill – new section 29(1)(qb) of the PPO	A textual amendment – to replace "臨床" (wherever appearing) in the Chinese text of this provision with "臨牀" to align with the current drafting practice.
13.	Clause 23(20) of the Bill – new section 29(1B)(b)(i) of the PPO	A textual amendment – to replace "a provision in this Ordinance, or in a regulation made under this section, applies" with "a provision in this Ordinance applies". Since "Ordinance" is defined in section 3 of the Interpretation and General Clauses Ordinance (Cap. 1) ("IGCO") to include any subsidiary

		legislation made under a particular piece of Ordinance, "this Ordinance" in section 29(1B)(b)(i) of PPO is wide enough to cover any regulation made under section 29 of PPO. Therefore it is not necessary to expressly mention "a regulation made under this section" in section 29(1B)(b)(i).
14.	Clause 25(1) of the Bill – section 30(1)(aa) of the PPO	An amendment in response to enquiry from ALA – to allow a person who is aggrieved by a decision of the Board under section 25(3B) to appeal against such decision.
15.	Clause 26(2) of the Bill – section 31(1)(a) of the PPO	A textual amendment suggested by ALA – to replace "registered medical practitioners" in the English text with "registered medical practitioner" as there will be only one registered medical practitioner appointed upon repealing section 3(2)(i) of the PPO as proposed by clause 5(4) of the Bill.
16.	Clause 30 of the Bill – new section 34A of the PPO	To replace "fine" with "civil debt" in the new section 34A(2) to reflect the policy intention that the amount to be recovered as ordered by the Court would be compensatory in nature in line with the concept of recovery of costs. For avoidance of doubt, to add a new subsection (3) to preserve the power of the Court to order costs under the Costs in Criminal Cases Ordinance (Cap. 492) ("CCCO") in respect of a criminal case convicted under the PPO, and for that matter the relevant provisions under CCCO and its subsidiary legislation will continue to apply.
17.	Clause 43 of the Bill – regulation 24(B) of the of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR")	A textual amendment – to renumber the clause repealing regulation 24B(a) of the PPR as clause 43(1).
18.	Clause 43 of the Bill – regulation 24B(b) of the PPR	A textual amendment suggested by ALA - to replace "in whose presence or under whose supervision" with "by whom or in whose presence and under whose supervision" to align with section 11(1) of the PPO.
19.	Clause 46(5) of the Bill – regulation 26(6) of the PPR	An amendment in response to enquiry from ALA – to allow an applicant or licensed

		wholesale dealer who is aggrieved by a decision of the Committee under subsection (5B) of this provision to appeal against such decision.
20.	Clause 49 of the Bill – new regulation 28A(6) of the PPR	To amend new regulation 28A(6) of the PPR so as to require the Board to make the GMP Guide available for inspection by the public free of charge in any manner the Board thinks fit (apart from making the GMP Guide available at the Secretary's office during normal office).
21.	Clause 52 of the Bill – new regulation 30B(5) of the PPR	To amend new regulation 30B(5) of the PPR so as to – ● specify the purposes of the register of authorized persons. This is to ensure that the operation of the register of authorized persons complies with the data protection principles enshrined in Schedule 1 to the PDPO; and ● require the Secretary to make the register of authorized persons available for inspection by the public free of charge in any manner the Secretary thinks fit (apart from making the register available at the Secretary's office during normal office).
22.	Clause 52 of the Bill – new regulation 30F(6) of the PPR	An amendment in response to enquiry from ALA – to allow a person who is aggrieved by a decision of the Committee under subsection (3) of this provision to appeal against such decision.
23.	Clause 55 of the Bill – regulation 33 of PPR	To amend regulation 33 of the PPR to provide certain flexibility for manufacturers in maintaining sample of finished products.
24.	Clause 58(3) of the Bill – regulation 36(1)(b) of PPR	A textual amendment – To add "本條例" before "第28A(1)" in the Chinese text. *(Regulation 2(5) of PPR provides that "Where in these regulations reference is made to a numbered section the reference shall be a reference to that section of the Ordinance.". It is therefore not necessary to add "of the Ordinance" after a numbered section in*

		PPR.)
25.	Clause 58(10) of the Bill – new regulation 36(1A)(c) of the PPR	A textual amendment – to replace "臨床" (wherever appearing) in the Chinese text of this provision with "臨牀" to align with the current drafting practice.
26.	New clause 59 (1A), clause 59(2) and new clause 59(2A) of the Bill –regulation 36B of the PPR (heading, new regulation 36B(1), regulation 36B(1C)	A textual amendment – to replace "臨床" (wherever appearing) in the Chinese text of the heading and the relevant provisions with "臨牀" to align with the current drafting practice.
27.	Clause 59(4) of the Bill – regulation 36B(3) of the PPR	A textual amendment – to replace clause 59(4) in the Chinese text of the Bill with "(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" 。". The amendment is proposed since the current Chinese text of clause 59(4) has the effect of repealing the phrase of "*(參閱附表8表格12)*" in regulation 36B(3) of PPR. At the same time, this phrase is also repealed by clause 59(5) of the Bill. Hence, the amendment is needed to avoid double deletion as suggested by ALA.
28.	Clause 59(6) of the Bill – new regulation 36B(3B) of the PPR	A textual amendment – to replace "臨床" in the Chinese text of this provision with "臨牀" to align with the current drafting practice.
29.	Clause 59(7) of the Bill – regulation 36B(4) of the PPR	A textual amendment – to replace "臨床" in the Chinese text of this provision with "臨牀" to align with the current drafting practice.
30.	Clause 62 of the Bill – new regulation 38B of the PPR	A textual amendment – to replace "Powers" in the heading of the provision in the English text with "Power".
31.	New clause 63A of the Bill – regulation 40 of the PPR	A consequential amendment pursuant to CSAs proposed in item 23 above. To

		provide for the penalties of breaching the conditions for exemption, to add new clause 63A of the Bill to amend regulation 40 of the PPR – "63A. Regulation 40 amended (penalties) Regulation 40 – **Repeal** "33(1), (2), (3), (4) or (5)" **Substitute** "33(1), (2), (3), (4), (4B) or (5)".".
32.	Clause 65(65) of the Bill – First Schedule to the PPR	As suggested by ALA, to repeal this clause as the amendment set out has already been made under section 2(1) of the Pharmacy and Poisons (Amendment) Regulation 2014.
33.	Clause 66(1) of the Bill – Third Schedule to the PPR	A textual amendment – to replace "附表5及附表10" with "附表5及10" in the Chinese text of clause 66(1) of the Bill.
34.	Clause 67(1) of the Bill – Fifth Schedule to the PPR	A textual amendment suggested by ALA – to replace "為施行本條例的27(c)" with "為施行本條例第27(c)" in the Chinese text of the heading of the Fifth Schedule to the PPR in clause 67(1) of the Bill.
35.	Clause 70 of the Bill – new Schedule 10 (Poisons List) to the PPR	A technical amendment suggested by ALA – to add a total of 11 new substances into the new Schedule 10 to the PPR. After the Bill was introduced into the LegCo in March 2014, a total of 11 new substances have been added to Division A of Part I of the Poisons List in the Schedule to the Poisons List Regulations (Cap. 138B) pursuant to the Poisons List (Amendment) Regulation 2014 and Poisons List (Amendment) (No. 2) Regulation 2014.
36.	Clause 70 of the Bill – new Schedule 10 (Poisons List) to the PPR	A textual amendment – to replace the numbering of bulletin "(i)" with "(d)"; and "(ii)" with "(e)" in the Chinese text under "但含有下列任何毒藥的藥劑製品除外", so as to align the numbering of the English text.

Table B

	Amendments considered not necessary after consideration	**Brief description of the amendments**
1.	Section 10(2) of the PPO – suggestion to replace "forges" with "forgery"	We consider that "forges" in section 10(2) extends to cover "forgery" by virtue of section 5 of the IGCO. Section 5 of IGCO provides that "[w]here any word or expression is defined in any Ordinance, such definition shall extend to the grammatical variations and cognate expressions of such word or expression". For reference, other ordinances contain similar definitions: section 37(2) of Dutiable Commodities Ordinance (Cap. 109), section 42 of Immigration Ordinance (Cap. 115), section 1A(1) of Registration of Persons Ordinance (Cap. 177) and section 15(4) of Business Registration Ordinance (Cap. 310).
2.	Section 19 of the PPO	We consider that the term "裁斷" is an appropriate Chinese equivalent of "finding" (or "find"). This Chinese equivalent has been used in regulations 6 and 9 of the Pharmacists (Disciplinary Procedure) Regulations (Cap. 138E). It is also commonly found in other ordinances such as section 307V of the Securities and Futures Ordinance (Cap. 571) and section 149 of the Competition Ordinance (Cap. 619).
3.	Section 25 of the PPO	We consider that "名列" conveys the meaning of "having a name on the list" accurately. "名列" is not only used in the existing section 25(3) of the PPO, but also other sections such as sections 5(4), 6, 7(1) and 10B(3). For other recent examples adopting the term "名列", please see section 15 of Residential Care Homes (Persons with Disabilities) Ordinance (Cap. 613) and section 232(1) of Companies Ordinance (Cap. 622).
4.	Clause 46(4) of the Bill – new regulation 26(5A)(b)(i) of the PPR Clause 50(5) of the Bill – new regulation 29(4A)(b)(i) of the PPR	We note the enquiry of ALA on why the phrase "an offence under the Ordinance or any of the regulations made under section 29" in these provisions could not be simplified to "an offence under the Ordinance" in view that "Ordinance" is defined in the IGCO to include any subsidiary legislation made under a particular piece of Ordinance. We would

	Clause 52 of the Bill – new regulation 30F(2)(c)(i) of the PPR	like to clarify that according to IGCO the reference to an Ordinance should be sufficient to include a reference to its subsidiary legislation unless the contrary intention appears from IGCO or the context of any other Ordinance or instrument. In the present case, arguably the reference to "Ordinance" in the PPR is used to refer to the PPO only (see e.g. regulations 2(5) and (6) and 7 of PPR) rather than the PPO and its subsidiary legislation, it is therefore preferable to refer to the PPO and its regulations (which are the regulations made under section 29 of the PPO) in regulations 26(5A)(b)(i), 29(4A)(b)(i) and regulation 30F(2)(c)(i). As regards the PPO, it is unlikely that the reference to "Ordinance" will be interpreted as the reference to the PPO only but not its subsidiary legislation

Annex II

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), after "Forgery"—

Add

"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,".

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

26 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 "fine is recoverable" and substituting "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 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 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(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**".

New By adding—

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

Regulation 40—

Repeal

"33(1), (2), (3), (4) or (5)"

Substitute

"33(1), (2), (3), (4), (4B) or (5)".".

65 By deleting subclause (65).

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

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”.

Annex III

1. Clause 6 of the Bill – section 4B(6) of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO")

Section:	4B	**Codes of conduct and codes of practice**		

(6) The Board must make a copy of every code of conduct and code of practice available for inspection by the public free of charge ~~at the office of the Secretary during normal office hours. —~~

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

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

(6) 管理局須~~在正常辦公時間內，於秘書的辦事處提供每份《行為守則》及《執業守則》的文本，免費供公眾查閱。—~~

(a) 在正常辦公時間內於秘書的辦事處；及

(b) 以管理局認為合適的其他方式，

提供每份《行為守則》及《執業守則》的文本，供公眾免費查閱。

2. Clause 7 of the Bill – section 5(2) of the PPO

Section:	5	**The register of pharmacists**		30/06/1997

~~(2) The register of pharmacists shall be kept at the headquarters of the Department of Health in the headquarters of the Department of Health in office of the Secretary and shall be open for inspection by any person during the usual hours of business without payment of fee.~~

(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.

~~(2) 藥劑師名冊須備存於在衞生署總部的秘書辦事處內，並須在通常辦公時間內免費供任何人查閱。~~

(2) 秘書須在正常辦公時間內於其辦事處，及以其認為合適的其他方式，提供藥劑師名冊，供公眾免費查閱，以使公眾人士能 —

(a) 確定某人是否註冊藥劑師；及

(b) 確定該人的註冊的詳情。

3. Clause 10 of the Bill – section 10(1) of the PPO

(1) Section 10(1)—

Repeal

everything after "an offence"

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.

Revisions made in red are amendments proposed by the Administration's CSAs.

Substitute a full stop.

(1) 第10(1) 條——

廢除

在“犯罪” 之後的所有字句

代以句號。

4. Clause 10 of the Bill – section 10(2) of the PPO

Section:	10	**Misuse of certificates of registration**	60 of 2000	01/07/1997

(2) In this section, the expression "forges" (偽造) has the same meaning as in Part IX (Forgery and Related Offences) of the Crimes Ordinance (Cap 200).

(2)在本條中，“偽造”(forges)一詞的涵義與《刑事罪行條例》(第200章)第IX部(偽造及相關的罪行)中該詞的涵義相同。

5. Clause 12 of the Bill – section 11(1) of the PPO *(for Chinesee text only)*

Section:	11	**Authorized sellers of poisons**		30/06/1997

~~(1) 由註冊藥劑師或法人團體或並非法團的團體所經營的包括毒藥零售在內的業務，如毒藥的實際銷售是由註冊藥劑師或在其在場監督的情況下在根據本條例妥為註冊的處所內進行的，則該業務即為獲授權毒藥銷售商。~~

(1) 在第16條的規限下，註冊藥劑師、法人團體或並非法團的團體(銷售商) 獲授權經營零售毒藥業務，前提是毒藥的實際銷售，是於根據本條例就該銷售商註冊的處所內，由註冊藥劑師進行，或在註冊藥劑師的在場監督下進行。

6. Clause 13 of the Bill – section 13(4)(c) of the PPO

Section:	13	**Registration of premises**		30/06/1997

(4) The Board shall not register premises under subsection (3) unless it is satisfied, in relation to the retail saleof poisons at such premises, that-

(a) the authorized seller of poisons is a fit and proper person to conduct the retail sale of poisons;

(b) the premises are suitable for conducting the retail sale of poisons thereon;

(c) the actual sale of poisons will be conducted on the premises ~~by a registered pharmacist or in his presence or under his supervision~~ by a registered pharmacist, or in the presence and under the supervision of a registered pharmacist, in accordance with section 11(1); and

(d) the premises will be under the control of a registered pharmacist in accordance with section 12.

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

(4) 除非管理局就在某處所內零售毒藥一事信納下列事項，否則不得根據第(3)款將該處所註冊
—

(a) 獲授權毒藥銷售商是從事零售毒藥業務的適當的人；
(b) 該處所適合作從事零售毒藥業務的用途；
(c) 毒藥的實際銷售將會按照第11(1)條~~由註冊藥劑師或在其在場的情況下或在其監督下在該處所內進行；及~~，於該處所內，由註冊藥劑師進行，或在註冊藥劑師的在場監督下進行；及
(d) 該處所將會按照第12條由註冊藥劑師控制。

7. Clause 13(6) of the Bill – new subsections (7A) and (7B) under section 13 of the PPO

Section:	13	**Registration of premises**		30/06/1997

(7A) An authorized seller of poisons may apply to the ~~Secretary~~ Board for approval to alter the entry, contained in the register of premises, relating to any premises registered in respect of the authorized seller of poisons.
(7B) If the ~~Secretary~~ Board approves the alteration, the authorized seller of poisons must pay the prescribed fee for the alteration.

(7A) 任何獲授權毒藥銷售商可向~~秘書~~管理局申請批准，更改載於處所註冊紀錄冊內的、關於就該銷售商註冊的任何處所的記項。
(7B) 如~~秘書~~管理局批准有關更改，有關獲授權毒藥銷售商須為該項更改，繳付訂明費用。

8. Clause 15(11) of the Bill – new section 16(2)(b)(iia) of PPO *(for Chinesee text only)*

(11) 在第16(2)(b)(ii) 條之後——
加入
"(iia) 指示對關於該銷售商的任何或全部處所的註冊的條件， 作出更改；或" 。

9. Clause 20(6) of the Bill – new section 25(3B) of the PPO *(for Chinesee text only)*

Section:	25	**Listed sellers of poisons**		30/06/1997

(3B) 管理局可在它認為適宜施加的條件的規限下，暫緩執行根據第(3) 款作出的指示，為期不超過3 年(暫緩期)， 令到只有如此施加的條件在暫緩期內遭違反，該指示才會生效；而倘有此違反情況，該指示在管理局指明的日期生效，~~委員會~~管理局在指明該日期前，須顧及該個案的整體情況。

Note:
Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

10. Clause 20(7) of the Bill – section 25(5) of the PPO

Section:	25	**Listed sellers of poisons**		30/06/1997

(5) Any person aggrieved by a ~~direction of the Board under subsection (3) may, in the prescribed manner, appeal against such decision~~ decision or direction made in respect of the person under subsection (2A), (3) ~~or (3A),~~ (3A) or (3B) may, in the prescribed manner, appeal against the decision or direction to the Tribunal. (Replaced 50 of 1980 s. 4)

(5) 任何人~~因管理局根據第(3)款作出的指示而感到受屈，可按訂明的方式，就上述決定~~"如因根據第(2A)、(3)~~或(3A)~~、(3A)或(3B)款就其作出的決定或指示而感到受屈，可按訂明方式，就該決定或指示向審裁處提出上訴。

11. Clause 23(11) of the Bill – new section 29(1)(jb) of the PPO *(for Chinese text only)*

Section:	29	**Power to make regulations**	L.N. 3 of 1999	15/01/1999

(jb) 就(ja)(i) 段所提述的任何人或任何類別的人的註冊及將該等註冊續期訂定條文，就取消或暫時吊銷註冊或更改註冊的條件訂定條文，就向任何上述的人發出警告信訂定條文，以及就遭拒絕、取消、暫時吊銷註冊、遭更改註冊的條件或獲發警告信而提出上訴訂定條文，並訂明註冊證明書~~及獲~~或獲續期的註冊證明書發出時須繳付的費用；

12. Clause 23(17) of the Bill – new section 29(1)(qb) of the PPO *(for Chinese text only)*

Section:	29	**Power to make regulations**	L.N. 3 of 1999	15/01/1999

~~(qb) 就以藥劑製品的進口商或出口商身分經營業務的人的註冊及就辦理註冊而須繳付費用的事宜訂定條文，以及就根據有關的規例遭拒准、撤銷或暫時吊銷註冊而提出上訴的事宜訂定條文；~~

(qb) 就管制對人類進行臨~~床~~牀試驗及對動物進行藥物測試訂定條文，就發出臨~~床~~牀試驗證明書及藥物測試證明書訂定條文，就取消或暫時吊銷上述證明書或更改上述證明書的條件訂定條文，就向上述證明書持有人發出警告信訂定條文，就遭拒發、取消或暫時吊銷上述證明書、遭更改上述證明書的條件或獲發警告信而提出上訴訂定條文， 以及就為申請進行上述試驗或測試及發出上述證明書而繳付費用訂定條文；

13. Clause 23(20) of the Bill – new section 29(1B)(b)(i) of the PPO

Section:	29	**Power to make regulations**	L.N. 3 of 1999	15/01/1999

(1B) Despite subsection (1), the Board may, subject to the approval of the Secretary for Food and Health and section 31, by regulation, amend—

(a) the Poisons List; or

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

(b) any list, in a regulation made under subsection (1), of any substances or articles—
(i) to which a provision in this Ordinance~~, or in a regulation made under this section,~~ applies; or

(1B) 儘管有第(1) 款的規定，管理局在獲得食物及衞生局局長的批准並符合第31 條的規定下，可藉規例修訂——

(a) 毒藥表；或

(b) 在根據第(1) 款訂立的規例中的、符合以下說明的任何物質或物品的名單——

(i) 本條例的條文適用的物質或物品~~，或根據本條訂立的規例的條文適用的物質或物品~~；或

(ii) 獲豁免而不受上述條文規限的物質或物品。

14. Clause 25(1) of the Bill – section 30(1)(aa) of the PPO

Section:	30	**Pharmacy and Poisons Appeal Tribunal**	L.N. 130 of 2007	01/07/2007

(1) There shall be a Pharmacy and Poisons Appeal Tribunal (in this Ordinance referred to as "the Tribunal") with jurisdiction to hear and determine-

(a) any appeal against a decision of the Board under section 13(3) or (7); (Replaced 58 of 1986 s. 10)

(aa) any appeal against a ~~direction of the Board under section 25(3)~~ decision or direction of the Board under section 25(2A), (3)~~ or (3A),~~ (3A) or (3B); (Added 58 of 1986 s. 10)

(b) any appeal against-

(i) a decision of a committee of the Board in respect of which provision authorizing such appeal is made in regulations under section 29; or

(ii) a decision of the Board in the performance by the Board under section 4A(8) of any function of a committee of the Board which, if made by the committee in exercise of such functions, would be a decision to which subparagraph (i) applies.

(1) 現設立藥劑業及毒藥上訴審裁處(在本條例中稱為“審裁處”)，該審裁處具有司法管轄權聆訊和裁定—

(a) 就管理局根據第13(3)或(7)條作出的決定而提出的上訴； (由1986年第58號第10條代替)

(aa) 就管理局根據第~~25(3)條作出的指示~~25(2A)、(3)~~或(3A)~~、(3A)或(3B)條作出的決定或指示而提出的上訴； (由1986年第58號第10條增補)

(b) 就下列決定而提出的上訴—

(i) 管理局屬下任何委員會作出的決定，而根據第29條訂立的規例已就該等決定訂有批准提出上訴的條文者；或

(ii) 管理局在根據第4A(8)條執行管理局屬下任何委員會的任何職能時作出的決定，而該決定為若由該委員會在行使該等職能時作出，第(i)節即會對其適用者。

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

15. <u>Clause 26(2) of the Bill –section 31(1)(a) of the PPO</u> *(for English text only)*

Section:	31	**Poisons Committee**		30/06/1997

(1) For the purposes of advising the Board on the classification and distribution of poisons in Part I and Part IIof the Poisons List and matters relating to the control of the manufacture and distribution of poisons and pharmaceutical products, there shall be a Poisons Committee consisting of-

(a) the registered medical practitioner~~s~~ appointed under section 3(2)(h) ~~and (i)~~; and

(b) 5 other members of the Board appointed by the Board, including 2 of the members appointed under section 3(2)(g).

16. <u>Clause 30 of the Bill – new section 34A of the PPO</u>

Section:	34A	**Recovery of costs and expenses of collecting or analysing poisons or pharmaceutical products etc.**		

(1) If a person is convicted of an offence under this 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.

(2) A sum ordered to be paid under subsection (1) is recoverable in the same manner as a ~~fine is recoverable~~ civil debt.

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

(1) 如某人被裁定犯本條例所訂罪行，而政府合理地就為有關刑事法律程序而收集、化驗或檢查毒藥、藥劑製品或任何其他物質而招致費用及開支，法庭可命令該人向政府繳付法庭認為就該等費用及開支屬適當的款項。

(2) 法庭根據第(1) 款命令繳付的款項，可按照追討~~罰款~~民事債項的相同方式，予以追討。

(3) 為免生疑問，本條不影響《刑事案件訟費條例》(第492章)賦予法庭的任何權力。

17. <u>Clause 43 of the Bill – regulation 24(B) of the of the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR")</u>

(1) Regulation 24B—

Repeal paragraph (a).

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.

Revisions made in red are amendments proposed by the Administration's CSAs.

18. Clause 43 of the Bill – regulation 24B(b) of the PPR

Regulation:	24B	**Applications to register premises under section 13**		30/06/1997

An application to register premises under section 13 shall be-

(a) made to the Board in the form prescribed in the Eighth Schedule; and (See Eighth Schedule, Form 15)

(b) submitted together with a copy of the certificate of registration of the registered pharmacist ~~in whose presence or under whose supervision~~ by whom or in whose presence and under whose supervision the actual sale of poisons will be conducted under section 11(1) of the Ordinance.

根據本條例第13條提出將處所註冊的申請須—

(a) 以附表8訂明的表格向管理局提出；及 (參閱附表8表格15)

(b) 連同有關註冊藥劑師(毒藥的實際銷售將會根據本條例第11(1)條~~在該註冊藥劑師在場的情況下或在其~~，由該藥劑師進行，或在該藥劑師的在場監督下進行)的註冊證明書副本一併呈交。

19. Clause 46(5) of the Bill –regulation 26(6) of the PPR

Regulation:	26	**Pharmacy and Poisons (Wholesale Licences)**		30/06/1997

(6) Any ~~person aggrieved by a decision of the Committee under this regulation~~ ~~applicant aggrieved by a decision made in respect of the applicant under paragraph (3), or any licensed wholesale dealer aggrieved by a decision made in respect of the licensed wholesale dealer under paragraph (5),~~ applicant or licensed wholesale dealer aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

(6) 任何~~人因委員會根據本條申請人如因根據第(3) 款就其作出的決定而感到受屈，或任何持牌批發商如因根據第(5)款就其~~申請人或持牌批發商人因委員會根據本條作出的決定而感到受屈，可按訂明的方式，就該決定向審裁處提出上訴。

20. Clause 49 of the Bill – new regulation 28A(6) of the PPR

Regulation:	28A	**Good Manufacturing Practice Guide**		

(6) The Board must make a copy of the GMP Guide available for inspection by the public free of charge ~~at the office of the Secretary during normal office hours.~~ —

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

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

(6) 管理局須~~在正常辦公時間內，於秘書的辦事處提供《指引》的文本，免費供公眾查閱。~~ —

(a) 在正常辦公時間內於秘書的辦事處；及

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

(b) 以管理局認為合適的其他方式，
提供《指引》的文本，供公眾免費查閱。

21. Clause 52 of the Bill – new regulation 30B(5) of the PPR

Regulation:	30B	**Register of authorized persons**		

(5) The Secretary must make the register available for inspection by the public free of charge at the office of the Secretary during normal office ~~hours.~~ 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.

(5) 秘書須在正常辦公時間內~~，於其辦事處提供名冊，免費供公眾查閱。~~於其辦事處，及以其認為合適的其他方式，提供名冊，供公眾免費查閱，以使公眾人士能 —

(a) 確定某人是否獲授權人；及

(b) 確定該人的註冊的詳情。

22. Clause 52 of the Bill – new regulation 30F(6) of the PPR

Regulation:	30F	**Cancellation or suspension etc. of registration as**		

(6) A person mentioned in paragraph (1) who is aggrieved by a decision made in respect of the person under ~~that paragraph~~ this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

(6) 第(1)款所述的人如因根據~~該款~~本條就其作出的決定而感到受屈，可按訂明方式，就該決定向審裁處提出上訴。

23. Clause 55 of the Bill – regulation 33 of PPR

Regulation:	33	**Duties of manufacturers**		30/06/1997

(4) Unless paragraph (4B) applies, a ~~A~~ licensed manufacturer must ~~shall~~ ~~maintain~~ retain a control sample of each batch of finished products under conditions of storage suitable to that product for a period of not less than ~~the normal shelf-life of the product or 2 years after the last transaction in that batch of products whichever is the shorter period.~~1 year after the expiry date of the product.

(4) 除非第(4B)款適用，否則持牌製造商須將每批製成品的一個對照樣本，保存於適合貯存該製品的情況，~~持牌製造商須將每批製成品的一個對照樣本，保持在適合貯存該製品的情況下，~~為期不短於該製品的~~正常貯存期限或就該批製品進行的最後一次交易後2年，兩者中以較短者為準。~~使用期限後的1年。

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.

(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 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 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.

(4A) 如以下所有條件獲符合，則第(4B)款就某批藥劑製品而適用於某持牌製造商—

(a) 該等製品是封裝在一個最內層容器內，而該等製品是供銷售或供應的；

(b) 該製造商就該等製品進行的製造過程，只涉及以下一項或多於一項程序 —

(i) 加入包裝附頁；

(ii) 替換包裝附頁；

(iii) (如該等製品擬作出口)在任何盛載該等製品的帶標籤容器上附貼標籤，而該標籤沒有掩蔽、更改或塗掉該容器所示的任何下列資料 —

(A) 根據第31(4)條規定須加上標籤標明的詳情；

(B) 該等製品的名稱；

(C) 該等製品的批次編號；

(D) 該等製品的使用期限；

(iv)(如該等製品並非擬作出口)在任何盛載該等製品的帶標籤容器上附貼標籤，而該標籤沒有掩蔽、更改或塗掉該容器所示的任何下列資料 —

Note:

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(A) 該等製品的註冊詳情；
(B) 該等製品的批次編號；
(C) 該等製品的使用期限；

(c) 在製造過程中，上述最內層容器一直是維持密封的。

(4B) 有關製造商只須將有關批次的製成品的以下附頁或說明的一個樣本，保留為期不短於該等製品的使用期限後的1年 —

(a) (如第(4A)(b)(i)款適用)加入的包裝附頁；
(b) (如第(4A)(b)(ii)款適用)經替換的包裝附頁；
(c) (如第(4A)(b)(iii)或(iv)款適用)附貼的標籤。

~~(6) In this regulation —~~
~~expiry date (使用期限) has the meaning given by regulation 31(2)(d);~~
~~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.~~

(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.”.”.

~~(6) 在本條中 ——~~
~~使用期限 (expiry date) 具有第31(2)(d) 條給予該詞的涵義；~~
~~註冊詳情 (registered particulars) 具有第35A 條給予該詞的涵義；~~
~~須註冊詳情 (registrable particulars) 具有第35A 條給予該詞的涵義。~~

(6) 儘管有第(4)及(4B)(c)款的規定，如某持牌製造商並不就第29(1)條而言視為製造某批藥劑製品，則該製造商無須就該等製品而遵從第(4)或(4B)(c)款(視何者適用而定)。

(7) 在本條中 —
包裝附頁 (package insert)具有第36(3A)條給予該詞的涵義；
批次編號 (batch number)具有第31(2)(c)條給予該詞的涵義；

Note:
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帶標籤容器 (labelled container)就藥劑製品而言，指以下詳情於其上顯示的容器 —

(a) 該製品的名稱；

(b) 該製品的批次編號；

(c) 該製品的使用期限；

使用期限 (expiry date)具有第31(2)(d)條給予該詞的涵義；

最內層容器 (primary container)就藥劑製品而言，指直接接觸該製品的容器；

註冊詳情 (registered particulars)具有第35A條給予該詞的涵義；

須註冊詳情 (registrable particulars)具有第35A條給予該詞的涵義。

24. Clause 58(3) of the Bill – regulation 36(1)(b) of PPR *(for Chinese text only)*

Regulation:	36	**Registration of pharmaceutical products and**	L.N. 227 of 2003	19/12/2003

(1) 除第(1A)、(1B)及(1C)款另有規定外，任何人不得銷售、要約出售或分銷，或為銷售、分銷或其他用途而管有任何藥劑製品或物質，除非該製品或物質已由下列的人向管理局註冊— (1987年第85號法律公告；1995年第366號法律公告)

(a) (如該藥劑製品或物質是在香港製造的)製造商；

(b) (如該藥劑製品或物質是在香港以外地方製造的)~~進口商~~本條例第28A(1) 或(3) 條所提述的、將該藥劑製品或物質輸入香港的人；或

(c) 在香港以外地方的製造商的本地分支機構、附屬公司、代表、代理人或分銷商。

(1978年第137號法律公告；1998年第23號第2條)

25. Clause 58(10) of the Bill – new regulation 36(1A)(c) of the PPR *(for Chinese text only)*

Regulation:	36	**Registration of pharmaceutical products and**	L.N. 227 of 2003	19/12/2003

(c) 將會為進行臨~~床牀~~試驗(將會按照根據第36B(3) 條發出的臨~~床牀~~試驗證明書進行者)而施用；或

26. Clause 59 of the Bill – heading of regulation 36B of the PPR*(for Chinese text only)*

27. Clause 59(4) of the Bill – regulation 36B(3) of the PPR *(for Chinese text only)*

28. Clause 59(6) of the Bill – new regulation 36B(3B) of the PPR *(for Chinese text only)*

29. Clause 59(7) of the Bill –regulation 36B(4) of the PPR *(for Chinese text only)*

Regulation:	36B	**Clinical trials and medicinal tests** **臨~~床牀~~試驗及藥物測試**		30/06/1997

(1) 任何人不得對人類進行臨~~床牀~~試驗，或安排進行或准許進行上述試驗，但如該人根據第(3) 款獲發臨~~床牀~~試驗證明書，而上述試驗按照該證明書進行，則屬例外。

(1A) 任何人不得對動物進行藥物測試，或安排進行或准許進行上述測試，但如該人根據第(3) 款獲發藥物測試證明書，而上述測試按照該證明書進行，則屬例外。

Note:

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(1B) 任何人違反第(1) 或(1A) 款，即屬犯罪，可處第2 級罰款。
(1C) 為對人類進行臨~~床牀~~試驗或對動物進行藥物測試，須以書面向委員會提出申請，並附上附表9訂明的費用。
(2) 有關的申請須附上~~製品或物質的樣本以及~~試驗或測試的計劃書。
(3) 委員會可在附表9訂明的費用繳付後~~，以附表8訂明的表格發出臨床試驗證明書或藥物測試證明書，該證明書的有效期不超逾2年。 (參閱附表8表格12)~~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~~床牀~~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 年。
(3A) 委員會如認為，更改根據第(3) 款施加的條件屬合適， 可更改該條件。
(3B) 委員會可取消臨~~床牀~~試驗證明書或藥物測試證明書，或在它指明的期間內，暫時吊銷上述證明書，或向上述證明書的持有人發出警告信，而委員會行使上述權力的前提，是——
(a) 它認為有關證明書的持有人，已違反該證明書的某項條件；或
(b) 它認為行使該權力是符合公眾利益的。
(3C) 委員會如根據第(1C) 款拒絕某申請，須給予有關申請人拒絕註冊的通知，並須在該通知內，述明拒絕理由。
(3D) 委員會如根據第(3B) 款，決定取消或暫時吊銷某證明書，須給予有關證明書的持有人取消或暫時吊銷(視屬何情況而定) 的通知，並須在該通知內，述明其決定的理由
(4) 任何~~人~~申請人或臨~~床牀~~試驗證明書或藥物測試證明書的持有人，因委員會根據本條作出的決定而感到受屈，可按訂明的方式，就該決定向審裁處提出上訴。

30. Clause 62 of the Bill – new regulation 38B of the PPR *(for English heading only)*

Regulation:	38B	**Power~~s~~ to specify forms**		

31. New clause 63A of the Bill – regulation 40 of the PPR

Regulation:	40	**Penalties**		30/06/1997

Any person who contravenes any of the provisions of regulation 9(1) or (4), 10, 10A, 11, 12, 15, 16(1) or (2), 18, 19, 20, 21(1) or (2), 22(2), (3), (4) or (5), 23(1), (2) or (3), 24, 25, 27, 28, 29(1), 30(1), 31(1), 32, ~~33(1), (2), (3), (4) or (5)~~ 33(1), (2), (3), (4), (4B) or (5), 34, 35, 36(1), 36A(6)(b), 38(1), 38A or 39 commits an offence and is liable on conviction to the penalties specified in section 34 of the Ordinance.

任何人違反第9(1)或(4)、10、10A、11、12、15、16(1)或(2)、18、19、20、21(1)或(2)、22(2)、(3)、(4)或(5)、23(1)、(2)或(3)、24、25、27、28、29(1)、30(1)、31(1)、32、~~33(1)、(2)、(3)、(4)或(5)~~ 33(1)、(2)、(3)、(4)、(4B)或(5)、34、35、36(1)、36A(6)(b)、38(1)、38A或39條的任何條文，即屬犯罪，一經定罪，可處本條例第34條指明的刑罰。

Note:
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32. Clause 65(65) of the Bill – First Schedule to the PPR

~~(65) First Schedule, Chinese text, Division A, item "洋地黃的甙類；洋地黃的其他有效成份"~~

~~**Repeal**~~

~~"份"~~

~~**Substitute**~~
~~"分".~~

~~(65) 附表1，中文文本，A 分部，"洋地黃的甙類；洋地黃的其他有效成份" 項目~~
~~**廢除**~~
~~"份"~~
~~**代以**~~
~~"分"。~~

33. Clause 66(1) of the Bill – Third Schedule to the PPR *(for Chinese text only)*

附表：	3		L.N. 134 of 2014	31/10/2014

[~~第9(1)條~~第3及9條及附表5及~~附表~~10]

34. Clause 67(1) of the Bill – Fifth Schedule to the PPR *(for Chinese text only)*

附表：	5	~~為本條例第**27(c)**條的施行而根據本規例第**15**條訂明的說明~~為施行本條例~~的~~27(c) 或(ca) 條而根據本規例第15 條訂明的字句	L.N. 132 of 2002	19/07/2002

35. Clause 70 of the Bill – new Schedule 10 (Poisons List) to the PPR
(not in marked-up version)

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";

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(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".

在建議的附表10中，在第2條中，在表中，在第I部中，在A分部中 —
(a) 在"氨基比林；其鹽類"項目之後加入"5-氨基酮戊酸；其鹽類；其衍生物；它們的鹽類"；
(b) 在"米諾地爾"項目之後加入"考比司他；其鹽類"；
(c) 在"達促紅素α"項目之後加入"達格列淨；其鹽類"；
(d) 在"艾塞那肽"項目之後加入"艾維雷韋；其鹽類"；
(e) 在"利札曲坦；其鹽類"項目之後加入"利司那肽"；
(f) 在"米拉貝隆；其鹽類；其酯類；它們的鹽類"項目之後加入"米非司酮；其鹽類；其酯類；它們的鹽類"；
(g) 在"吡卡酯"項目之後加入"吡侖帕奈"；
(h) 在"培加尼布；其鹽類"項目之後加入"培妥珠單抗"；
(i) 在"瑞西那明"項目之前加入"瑞戈非尼；其鹽類"；
(j) 在"托拉塞米"項目之後加入"托法替布；其鹽類"；
(k) 在"維A酸"項目之後加入"維蘭特羅；其鹽類"。

36. <u>Clause 70 of the Bill – new Schedule 10 (Poisons List) to the PPR</u> (for Chinese text only)

採用製造商供應的原裝零售的藥劑製品，而該藥劑製品含有本列表第I 部的A 分部所列某種毒藥——
(a) 如該種毒藥屬三氧化二砷、斑蝥素、可卡因、毒芹鹼、芽子鹼、氫氰酸(氰化酸)、士的寧、烏頭生物鹼、古柯生物鹼或鈎吻生物鹼，則其比例以重量計算不超逾0.01%；
(b) 如該種毒藥屬在只供外用的溶液內所含的紅汞，則其比例以重量／容積比計算不超逾2%；及
(c) 如該種毒藥屬其他毒藥，則其比例以重量計算不超逾0.1%，但含有下列任何毒藥的藥劑製品除外——
~~(i)~~(d) 列於附表3 的毒藥；或
~~(ii)~~(e) 乙基嗎啡；其鹽類
丙卡特羅；其鹽類
去甲可待因；其鹽類
可待因；其鹽類
右甲嗎喃；其鹽類

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布托；其鹽類
甲辛胺；其鹽類
曲托喹酚；其鹽類
沙美特羅；其鹽類

Note:

Revisions made in purple are amendments proposed by the Pharmacy and Poisons (Amendment) Bill 2014.
Revisions made in red are amendments proposed by the Administration's CSAs.