Ord. No. 2 of 2015
A133

Pharmacy and Poisons (Amendment) Ordinance 2015

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HONG KONG SPECIAL ADMINISTRATIVE REGION

ORDINANCE NO. 2 OF 2015

L.S.

C. Y. LEUNG
Chief Executive
29 January 2015

An Ordinance to amend the Pharmacy and Poisons Ordinance and related Regulations to implement certain recommendations in the Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong published in December 2009; and to make related, consequential and miscellaneous amendments.

[ ]

Enacted by the Legislative Council.

Part 1

Preliminary

1. Short title and commencement

(1) This Ordinance may be cited as the Pharmacy and Poisons (Amendment) Ordinance 2015.

(2) This Ordinance comes into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

Part 2

Amendments to Pharmacy and Poisons Ordinance

2. Pharmacy and Poisons Ordinance amended

The Pharmacy and Poisons Ordinance (Cap. 138) is amended as set out in sections 3 to 30.

3. Long title amended

The long title, after "pharmacy"—

Add

", pharmaceutical products".

4. Section 2 amended (interpretation)

(1) Section 2(1), definition of ***authorized seller of poisons***—

Repeal

"business authorized to sell"

Substitute

"registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of".

(2) Section 2(1), definition of ***manufacture***—

Repeal

everything after "means" and before "the individual"

Substitute

"—

(a) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for sale or distribution; or

(b) the repackaging of pharmaceutical products as finished products for sale or distribution,

but does not include".

(3) Section 2(1), definition of ***pharmaceutical product*** and ***medicine***—

Repeal

everything after "any substance or"

Substitute

"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;".

(4) Section 2(1), definition of ***Poisons List***, after "regulations"—

Add

"made under section 29".

(5) Section 2(1), English text, definition of ***Tribunal***—

Repeal the full stop

Substitute a semicolon.

(6) Section 2(1)—

Add in alphabetical order

"***code of conduct*** (《行為守則》) means a code of conduct issued under section 4B as revised from time to time under that section;

code of practice (《執業守則》) means a code of practice issued under section 4B as revised from time to time under that section;

court (法庭) includes a magistrate;

licensed manufacturer (持牌製造商) means a holder of a licence to manufacture pharmaceutical products issued under any regulations made under section 29;

licensed wholesale dealer (持牌批發商) means a holder of a wholesale dealer licence;

specified form (指明格式), in relation to a purpose under this Ordinance, means the form specified for that purpose by the Board under section 29A;

wholesale dealer licence (批發商牌照) means a wholesale dealer licence issued under any regulations made under section 29.".

(7) After section 2(1)—

Add

"(1A) In the definition of ***manufacture*** in subsection (1)—

packaging (包裝) means any operation, including filling and labelling, that a bulk product (being a product that has completed all processing stages up to, but not including, final packaging) has to undergo to become a finished product.".

5. Section 3 amended (the Pharmacy and Poisons Board)

(1) Section 3(2)—

Repeal paragraph (d)

Substitute

"(d) the Assistant Director of Health in the Drug Office of the Department of Health;".

(2) Section 3(2)(g)—

Repeal

"Executive;"

Substitute

"Executive; and".

(3) Section 3(2)(h)—

Repeal

"; and"

Substitute a full stop.

(4) Section 3(2)—

Repeal paragraph (i).

6. Section 4B added

After section 4A—

Add

"**4B. Codes of conduct and codes of practice**

(1) The Board may issue codes of conduct and codes of practice that it considers suitable for providing practical guidance in respect of this Ordinance.

(2) A code of conduct or code of practice—

(a) may consist of a code, standard, rule, specification or any other documentary form of practical guidance prepared by the Board or any other body or authority; and

(b) may apply, incorporate or refer to a document that has been formulated or published by a body or authority either as in force at the time when the document is so applied, incorporated or referred to or as amended, formulated or published from time to time.

(3) If a code of conduct or code of practice is issued, the Board must by notice published in the Gazette—

(a) identify the code; and

(b) specify the date on which the code is to take effect.

(4) The Board may from time to time revise the whole or any part of a code of conduct or code of practice.

(5) If a code of conduct or code of practice is revised, the Board must by notice published in the Gazette—

(a) identify the code or part revised; and

(b) specify the date on which the revision is to take effect.

(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—

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

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

(7) A code of conduct, code of practice and notice published under subsection (3) or (5) are not subsidiary legislation.

(8) To avoid doubt, different codes of conduct or codes of practice may be issued under this section for different purposes of this Ordinance.".

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.".

8. Section 8 amended (qualifications for registration as pharmacists)

Section 8(3)—

Repeal paragraph (c)

Substitute

"(c) the Assistant Director of Health in the Drug Office of the Department of Health;".

9. Section 9 amended (certificate of registration as a pharmacist)

Section 9(1)—

Repeal

"prescribed form"

Substitute

"specified form".

10. Section 10 amended (misuse of certificates of registration)

(1) Section 10(1)—

Repeal

everything after "an offence"

Substitute a full stop.

(2) Section 10(2)—

Repeal

"Forgery"

Substitute

"forgery and related offences".

11. Section 10A amended (registered pharmacist not to practise without practising certificate)

After section 10A(2)—

Add

"(2A) A practising certificate must be in the specified form.".

12. Section 11 amended (authorized sellers of poisons)

Section 11(1)—

Repeal

everything before "under this"

Substitute

"(1) Subject to section 16, a registered pharmacist, body corporate or unincorporated body of persons (***seller***) is authorized to carry on a business of retail sale of poisons if the actual sale of poisons is conducted on premises registered in respect of the seller".

13. Section 13 amended (registration of premises)

(1) Section 13(2)—

Repeal

"prescribed form"

Substitute

"specified form".

(2) 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".

(3) After section 13(4)—

Add

"(4A) Without limiting any other ground on which the Board may be satisfied that a person is not a fit and proper person to conduct the retail sale of poisons at any premises for the purposes of subsection (4)(a), a person is not such a fit and proper person if—

(a) the person is disqualified from being an authorized seller of poisons under a direction made under section 16(2)(b)(i); and

(b) the period of disqualification has yet to expire.".

(4) Section 13(5)(a)—

Repeal

"prescribed form"

Substitute

"specified form".

(5) Section 13(7)(b)—

Repeal

"subsection (3)."

Substitute

"subsection (3); and".

(6) After section 13(7)(b)—

Add

"(c) the authorized seller of poisons must pay the prescribed fee for the renewal of the certificate of registration.".

(7) After section 13(7)—

Add

"(7A) An authorized seller of poisons may apply to the 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 Board approves the alteration, the authorized seller of poisons must pay the prescribed fee for the alteration.".

14. Section 15 amended (appointment of Disciplinary Committee)

(1) Section 15—

Renumber subsection (1) as subsection (1A).

(2) Before section 15(1A)—

Add

"(1) If—

(a) a complaint is received by the Board regarding the conduct of a registered pharmacist or an employee of a registered pharmacist, or it appears to the Board that a registered pharmacist has contravened a code of conduct applicable to the registered pharmacist;

(b) a complaint is received by the Board regarding the conduct of an authorized seller of poisons or an employee, officer or partner of an authorized seller of poisons, or it appears to the Board that an authorized seller of poisons has contravened a code of practice applicable to the authorized seller of poisons;

(c) any of the persons mentioned in paragraph (a) or (b) is convicted of—

(i) an offence under this Ordinance, the Dangerous Drugs Ordinance (Cap. 134), the Antibiotics Ordinance (Cap. 137) or the Undesirable Medical Advertisements Ordinance (Cap. 231); or

(ii) an offence under section 52, 54 or 61 of the Public Health and Municipal Services Ordinance (Cap. 132) or section 7, 7A or 9 of the Trade Descriptions Ordinance (Cap. 362);

(d) it appears to the Board that a condition imposed under section 13 in respect of the registration of any premises of an authorized seller of poisons has been contravened; or

(e) it otherwise appears necessary or desirable to the Board to inquire into the conduct of any of the persons mentioned in paragraph (a) or (b),

the Board may appoint a Disciplinary Committee to inquire into the conduct of the person concerned.".

(3) Section 15(1A)—

Repeal

everything before "of—"

Substitute

"(1A) A Disciplinary Committee is to consist".

15. Section 16 amended (powers of a Disciplinary Committee)

(1) Section 16(1)—

Repeal

"or body" (wherever appearing).

(2) Section 16(1), English text—

Repeal

"or which".

(3) Section 16(2)(a)—

Repeal

"either".

(4) Section 16(2)(a)(i)—

Repeal

"or".

(5) After section 16(2)(a)(i)—

Add

"(ia) to issue a warning letter to the registered pharmacist; or".

(6) Section 16(2)(a)(ii)—

Repeal

"subject to subsection (5),".

(7) Section 16(2)(b)—

Repeal

"a body which is an authorized seller of poisons or in respect of an officer or employee of or partner in such body"

Substitute

"an authorized seller of poisons or an employee, officer or partner of an authorized seller of poisons".

(8) Section 16(2)(b)(i)—

Repeal

"body"

Substitute

"authorized seller of poisons".

(9) Section 16(2)(b)(ii)—

Repeal

everything after "direct that" and before "as may"

Substitute

"any or all of the premises of that authorized seller of poisons be removed by the Secretary from the register of premises, either until the expiry of the certificate of registration issued to that authorized seller of poisons in respect of the premises under section 13(5) or for a shorter period".

(10) Section 16(2)(b)(ii)—

Repeal

", from being registered therein; or"

Substitute a semicolon.

(11) After section 16(2)(b)(ii)—

Add

"(iia) direct that variations be made to the conditions relating to the registration of any or all of the premises of that authorized seller of poisons; or".

(12) Section 16(2)(b)(iii)—

Repeal

"body"

Substitute

"authorized seller of poisons".

(13) After section 16(2)—

Add

"(2A) Subject to subsections (2B) and (2C), a direction under subsection (2) takes effect—

(a) immediately if the Disciplinary Committee considers it in the public interest to bring the direction into immediate effect; or

(b) in any other case—

(i) if no appeal has been lodged under subsection (3), on the date specified by the Disciplinary Committee having regard to all the circumstances of the case, being a date—

(A) after the expiry of the period for lodging an appeal under subsection (3)(a); and

(B) on or before the expiry of 3 months from the date on which the direction is made; or

(ii) if an appeal has been lodged under subsection (3), on the date on which the appeal is finally determined.

(2B) The Disciplinary Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a direction made under subsection (2)(a)(ii) or (b)(i) or (ii) so that the direction takes effect only if a condition so imposed is contravened during the suspension period.

(2C) The Disciplinary Committee, on finding that a contravention mentioned in subsection (2B) has been committed, must specify a date on which the direction is to take effect having regard to all the circumstances of the case, being a date—

(a) after the expiry of the period for lodging an appeal against the finding under subsection (3)(a); and

(b) on or before the expiry of 3 months from the date on which the finding is made.".

(14) Section 16(3)(a)—

Repeal

"or body in respect of whom or which a direction has been made under subsection (2)"

Substitute

"in respect of whom a direction or finding has been made under subsection (2) or (2C)".

(15) Section 16(3)(b)—

Repeal

"direction"

Substitute

"direction or finding".

(16) Section 16(4)—

Repeal

"subject to subsection (5), cause its decision in any inquiry held under this section"

Substitute

"on or after the date on which a direction under subsection (2) (as varied on appeal, if applicable) takes effect, cause the direction".

(17) Section 16—

Repeal subsection (5).

(18) Section 16(6)—

Repeal

"or body concerned,"

Substitute

"concerned".

(19) Section 16(6)(b), Chinese text—

Repeal

"某團體"

Substitute

"該人".

(20) Section 16(7)—

Repeal

"subsection (5)"

Substitute

"subsection (2A)".

16. Section 16A amended (powers of Disciplinary Committee at inquiries)

(1) Section 16A(3)—

Repeal

"of $500"

Substitute

"at level 3".

(2) Section 16A(5)—

Repeal

"of $500"

Substitute

"at level 3".

17. Section 17 amended (liability of authorized sellers of poisons for acts of employees)

Section 17(2)(d)—

Repeal

"under this Ordinance, the Dangerous Drugs Ordinance (Cap. 134) or the Antibiotics Ordinance (Cap. 137)"

Substitute

"mentioned in section 15(1)(c)".

18. Section 19 amended (provisions as to directions given by Disciplinary Committee)

(1) Section 19, heading, after "**directions**"—

Add

"**or findings**".

(2) Section 19(1)—

Repeal

"any direction"

Substitute

"any direction or finding".

(3) Section 19(1)—

Repeal

"the direction"

Substitute

"the direction or finding".

(4) Section 19—

Repeal subsection (2).

19. Section 22 amended (limitations on sale of Part I poisons)

(1) Section 22(1)(a)—

Repeal

"in writing"

Substitute

"in the specified form and".

(2) Section 22(2), after "poisons book"—

Add

"in the specified form".

(3) Section 22(4)—

Repeal

"of $5,000"

Substitute

"at level 2".

20. Section 25 amended (listed sellers of poisons)

(1) After section 25(2)—

Add

"(2A) The Board may impose any conditions subject to which a person's name is entered on the list.

(2B) A person whose name is on the list and who wishes to retain the name on the list must pay to the Board the prescribed annual fee for retaining the name on the list.

(2C) A person whose name is on the list—

(a) may apply to the Board for approval to alter the entry relating to the person on the list; and

(b) if the Board approves the alteration, must pay the prescribed fee for the alteration.".

(2) Section 25(3), after "or to remove"—

Add

"or suspend for a period specified by the Board".

(3) Section 25(3), after "fees prescribed"—

Add

", who has contravened a code of practice applicable to the person or a condition imposed in respect of the person under subsection (2A),".

(4) Section 25(3), after "direction to remove"—

Add

"or suspend".

(5) Section 25(3), after "such removal"—

Add

"or suspension".

(6) After section 25(3)—

Add

"(3A) If a listed seller of poisons has contravened a code of practice applicable to, or a condition imposed under subsection (2A) in respect of, the listed seller of poisons, the Board may—

(a) direct the Secretary to issue a warning letter to the listed seller of poisons; or

(b) direct that variations be made to a condition imposed under that subsection in respect of the listed seller of poisons.

(3B) The Board may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a direction made under subsection (3) so that the direction takes effect only if a condition so imposed is contravened during the suspension period, and in the case of such a contravention, the direction takes effect on the date specified by the Board having regard to all the circumstances of the case.".

(7) Section 25(5)—

Repeal

everything after "by a" and before "to the"

Substitute

"decision or direction made in respect of the person under subsection (2A), (3), (3A) or (3B) may, in the prescribed manner, appeal against the decision or direction".

21. Section 27 amended (poisons to be labelled, etc.)

Section 27—

Repeal paragraph (c)

Substitute

"(c) for a medicine, the text prescribed in respect of the medicine or the class to which the medicine belongs;

(ca) for a substance or mixture of substances that is not a medicine—

(i) the text prescribed in respect of the substance or mixture or the class to which the substance or mixture belongs; or

(ii) if no text is prescribed, "Poison 毒藥"; and".

22. Section 28A substituted

Section 28A—

Repeal the section

Substitute

"**28A. Restriction on import and export of pharmaceutical products**

(1) A person must not carry on business as an importer of pharmaceutical products unless—

(a) the person is a licensed wholesale dealer; or

(b) the person is a licensed manufacturer and the products are imported by the person for the purpose of manufacturing the person's own pharmaceutical products.

(2) A person must not carry on business as an exporter of pharmaceutical products unless—

(a) the person is a licensed wholesale dealer; or

(b) the person is a licensed manufacturer and the products to be exported are manufactured by the person.

(3) If—

(a) a person was registered under this section, as in force before the commencement date of the Pharmacy and Poisons (Amendment) Ordinance 2015 (2 of 2015) (***amending Ordinance***), to carry on business as an importer or exporter of pharmaceutical products; and

(b) that registration was in force immediately before that date,

then, for the remainder of the period for which that registration would have continued to be valid had section 22 of the amending Ordinance not been enacted, the person is to be regarded as a licensed wholesale dealer and this Ordinance applies to the person accordingly.".

23. Section 29 amended (power to make regulations)

(1) Section 29(1)(aa)—

Repeal

everything after "prescribing"

Substitute

"the fees payable on the issue of a practising certificate for a registered pharmacist;".

(2) Section 29(1)(b)—

Repeal

everything after "prescribing" and before "and for"

Substitute

"the fees payable on the issue of a certificate of registration as a pharmacist".

(3) Section 29(1)(c)—

Repeal

everything after "of premises"

Substitute

"and providing for appeals;".

(4) Section 29(1)(ca)—

Repeal

everything after "the registration" and before "a change"

Substitute

"and renewal of registration of premises under section 13 and for".

(5) Section 29(1)—

Repeal paragraph (f)

Substitute

"(f) prescribing the manner of a certification for the purposes of section 22(1)(a) and specifying the class of persons authorized to give a certificate for the purposes of that section;".

(6) Section 29(1)—

Repeal paragraph (g).

(7) Section 29(1)(h)—

Repeal

everything after "of wholesale dealers in poisons"

Substitute

"or pharmaceutical products, for the revocation, suspension or variation of conditions of a wholesale dealer licence, for the issue of warning letters to licensed wholesale dealers, and for appeals against a refusal, revocation, suspension or variation of conditions of a wholesale dealer licence or issue of warning letters;".

(8) Section 29(1)(ha)—

Repeal

"wholesale dealers in poison"

Substitute

"licensed wholesale dealers or licensed manufacturers".

(9) Section 29(1)(j)—

Repeal

everything after "of manufacturers"

Substitute

"of poisons or pharmaceutical products, for the revocation, suspension or variation of conditions of a licence for manufacturers on the ground of a contravention of the principles and guidelines referred to in paragraph (ja)(ii) or any other ground, for the issue of warning letters to licensed manufacturers, and for appeals against a refusal, revocation, suspension or variation of conditions of such a licence or issue of warning letters;".

(10) Section 29(1)(ja)—

Repeal

"pharmaceutical products and poisons;"

Substitute

"poisons or pharmaceutical products including—

(i) the qualifications, experience, appointment, duties and responsibilities of persons to be employed or engaged for the purpose of the manufacture and the number of persons to be so employed or engaged; and

(ii) the establishment and issue of the principles and guidelines of good manufacturing practice in respect of pharmaceutical products;".

(11) After section 29(1)(ja)—

Add

"(jb) providing for the registration and renewal of registration of any person or class of persons referred to in paragraph (ja)(i), for the cancellation, suspension or variation of conditions of the registration, for the

issue of warning letters to any such person, and for appeals against a refusal, cancellation, suspension or variation of conditions of the registration or issue of warning letters, and prescribing the fees payable on the issue of a certificate of registration or renewed certificate of registration;

(jc) providing for the keeping of a register of the persons referred to in paragraph (ja)(i) and for the alteration to the register;".

(12) Section 29(1)(k), after "poisons" (wherever appearing)—

Add

"or pharmaceutical products".

(13) Section 29(1)(m), after "poisons"—

Add

"or pharmaceutical products".

(14) Section 29(1)(q), after "the registration"—

Add

"and renewal of registration".

(15) Section 29(1)(q)—

Repeal

everything after "thereof"

Substitute

"(including the fees payable for carrying out inspections for determining an application for such registration and renewal of registration), for the deregistration, suspension or variation of conditions of such registration, for the issue of warning letters to holders of registration certificates, and for appeals against a refusal, deregistration, suspension or variation of conditions of such registration or issue of warning letters;".

(16) Section 29(1)(qa)—

Repeal

"and the conduct of clinical trials on human beings and medicinal tests on animals,".

(17) Section 29(1)—

Repeal paragraph (qb)

Substitute

"(qb) providing for the control of the conduct of clinical trials on human beings and medicinal tests on animals, for the issue of clinical trial certificates and medicinal test certificates, for the cancellation, suspension or variation of conditions of such certificates, for the issue of warning letters to holders of such certificates, for appeals against a refusal, cancellation, suspension or variation of conditions of such certificates or issue of warning letters, and for the payment of fees in respect of the application for conducting such trials or tests and the issue of such certificates;".

(18) Section 29(1)(r)—

Repeal the full stop

Substitute a semicolon.

(19) After section 29(1)(r)—

Add

"(s) prescribing matters required or permitted to be prescribed by this Ordinance;

(t) providing for the specification of forms for the purposes of the regulations;

(u) making the incidental, consequential, evidential, transitional, savings and supplemental provisions necessary or expedient for giving full effect to the provisions of this Ordinance; and

(v) generally providing for the better carrying out of the provisions and purposes of this Ordinance.".

(20) After section 29(1A)—

Add

"(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

(b) any list, in a regulation made under subsection (1), of any substances or articles—

(i) to which a provision in this Ordinance applies; or

(ii) which are exempt from any such provision.".

24. Section 29A added

After section 29—

Add

"**29A. Power of Board to specify forms**

(1) The Board may specify forms to be used for any provision of this Ordinance.

(2) If a form is specified under this section, the Board must make copies of the form available for inspection by the public free of charge—

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

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

25. Section 30 amended (Pharmacy and Poisons Appeal Tribunal)

(1) Section 30(1)(aa)—

Repeal

"direction of the Board under section 25(3)"

Substitute

"decision or direction of the Board under section 25(2A), (3), (3A) or (3B)".

(2) After section 30(1)(aa)—

Add

"(ab) any appeal against a decision of the Board under any regulations made under section 29; and".

26. Section 31 amended (Poisons Committee)

(1) Section 31(1), Chinese text—

Repeal

"分銷"

Substitute

"分發".

(2) Section 31(1)(a)—

Repeal

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

Substitute

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

27. Section 32 amended (exemption with respect to sales wholesale and sales to certain persons)

Section 32(b)—

Repeal

everything after "a person" and before "to purchasers"

Substitute

"referred to in section 28A(2)".

28. Section 33 amended (offences)

Section 33(1)—

Repeal

"or 28"

Substitute

", 28 or 28A".

29. Section 34 amended (penalty)

Section 34—

Repeal

"of $100,000"

Substitute

"at level 6".

30. Section 34A added

After section 34—

Add

"**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 as a 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).".

Part 3

Amendments to Pharmacy and Poisons Regulations

31. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 32 to 71.

32. Regulation 2 amended (interpretation)

Regulation 2(1)—

Add in alphabetical order

"***authorized person*** (獲授權人) means a person whose name is entered in the register of authorized persons;

GMP Guide (《指引》) means the Good Manufacturing Practice Guide issued under regulation 28A as revised from time to time under that regulation;

register of authorized persons (獲授權人名冊) means the register of authorized persons kept under regulation 30B;

specified form (指明格式), in relation to a purpose under these regulations, means the form specified for that purpose under regulation 38B;".

33. Regulation 2A added

After regulation 2—

Add

"**2A. Poisons List**

The Poisons List is set out in Schedule 10.".

34. Regulation 3 amended (application of section 22 restricted to the First Schedule)

Regulation 3—

Repeal

"as set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B)".

35. Regulation 5 amended (extension of section 22 to sales wholesale etc. and relaxation of the section)

(1) Regulation 5(1), proviso, before "manufacturer"—

Add

"licensed".

(2) Regulation 5(5)—

Repeal

"of $10,000"

Substitute

"at level 3".

36. Regulation 8 amended (complete exemption for articles and substances in the Second Schedule)

Regulation 8(2)—

Repeal

"Parts VII, VIII, VIIIA,"

Substitute

"Parts VI, VII, VIII,".

37. Regulation 15 substituted

Regulation 15—

Repeal the regulation

Substitute

"**15. Poisons to be labelled "Poison 毒藥" or other bilingual text specified in Fifth Schedule etc.**

(1) For the purposes of section 27(c), a container of a medicine must be labelled in clear print with the text in both English and Chinese as specified in the Fifth Schedule in respect of the medicine or the class to which the medicine belongs.

(2) For the purposes of section 27(ca), a container of a substance or mixture of substances that is not a medicine must be labelled with the following text in clear print—

(a) the text in both English and Chinese as specified in the Fifth Schedule in respect of the substance or mixture or the class to which the substance or mixture belongs; or

(b) if no text is so specified, "Poison 毒藥".

(3) The text referred to in paragraph (1) or (2) must not be modified in meaning by the addition of any other texts or marks.".

38. Regulation 19 amended (storage of poisons)

(1) Regulation 19(2)—

Repeal

"substance included in the First Schedule"

Substitute

"poison included in Part I of the Poisons List".

(2) Regulation 19(2)—

Repeal

"the substance"

Substitute

"the poison".

(3) Regulation 19(3)—

Repeal

"or substance".

39. Regulation 22 amended (supply of medicines to out-patients from certain institutions, etc.)

(1) Regulation 22(4)(a), after "supplied;"—

Add

"and".

(2) Regulation 22(4)—

Repeal subparagraph (b).

(3) Regulation 22(5)—

Repeal

"English and in"

Substitute

"either English or".

40. Regulation 23 amended (supply of medicines for use in institutions, etc.)

Regulation 23(3)—

Repeal

everything after "labelled"

Substitute

"with words describing its contents.".

41. Regulation 24 amended (storage of poisons in institutions)

(1) Regulation 24(2)(b)—

Repeal

"solely".

(2) Regulation 24—

Repeal paragraph (3).

(3) Regulation 24—

Repeal paragraph (4).

42. Regulation 24A amended (applications to be entered on list under section 25)

Regulation 24A(4)—

Repeal

"person aggrieved by a decision of the Committee"

Substitute

"applicant aggrieved by a decision made in respect of the applicant".

43. Regulation 24B amended (applications to register premises under section 13)

(1) Regulation 24B—

Repeal paragraph (a).

(2) Regulation 24B(b)—

Repeal

"in whose presence or under whose supervision"

Substitute

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

44. Regulation 24C repealed (certificate of registration under section 13)

Regulation 24C—

Repeal the regulation.

45. Regulation 25 substituted

Regulation 25—

Repeal the regulation

Substitute

"**25. Sale and supply of poisons or pharmaceutical products wholesale**

A person must not, by way of wholesale dealing, sell or supply at or from any premises a pharmaceutical product, or a substance or article consisting of or containing any poison, unless the person—

(a) holds a wholesale dealer licence issued to the person by the Committee in respect of those premises;

(b) is an authorized seller of poisons; or

(c) is a licensed manufacturer selling or supplying only pharmaceutical products manufactured by the licensed manufacturer.".

46. Regulation 26 amended (Pharmacy and Poisons (Wholesale Licences) Committee)

(1) Regulation 26(3)—

Repeal

"issue a wholesale poisons"

Substitute

", subject to any conditions it thinks fit to impose, issue a wholesale dealer".

(2) Regulation 26(4)—

Repeal

"poisons"

Substitute

"dealer".

(3) Regulation 26(4)—

Repeal

everything after "be in"

Substitute

"the specified form.".

(4) Regulation 26—

Repeal paragraph (5)

Substitute

"(5) In any of the circumstances specified in paragraph (5A), the Committee may—

(a) revoke a wholesale dealer licence or suspend it for a period it thinks fit;

(b) issue a warning letter to the licensed wholesale dealer; or

(c) vary a condition of the licence imposed under paragraph (3).

(5A) The circumstances are—

(a) that, in the Committee's opinion, the licensed wholesale dealer has contravened—

(i) a condition of the licence; or

(ii) any of these regulations or a code of practice applicable to the licensed wholesale dealer; or

(b) that the licensed wholesale dealer has been convicted of—

(i) an offence under the Ordinance or any of the regulations made under section 29, the Dangerous Drugs Ordinance (Cap. 134), the Antibiotics Ordinance (Cap. 137) or the Undesirable Medical Advertisements Ordinance (Cap. 231); or

(ii) an offence under section 6C or 6D of the Import and Export Ordinance (Cap. 60), section 52, 54 or 61 of the Public Health and Municipal Services Ordinance (Cap. 132) or section 7, 7A or 9 of the Trade Descriptions Ordinance (Cap. 362).

(5B) The Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a decision made under paragraph (5)(a) so that the decision takes effect only if a condition so imposed is contravened during the suspension period, and in the case of such a contravention, the decision takes effect on the date specified by the Committee having regard to all the circumstances of the case.".

(5) Regulation 26(6)—

Repeal

"person"

Substitute

"applicant or licensed wholesale dealer".

(6) Regulation 26(8)—

Repeal

"poisons licence"

Substitute

"dealer licence".

(7) Regulation 26(8)(a)—

Repeal

"poisons"

Substitute

"the poisons or pharmaceutical products".

(8) Regulation 26(8)(b)—

Repeal

"a deputy"

Substitute

"one or more deputies".

(9) Regulation 26(9)—

Repeal

"of the Board".

(10) After regulation 26(9)—

Add

"(10) If—

(a) a person was issued with a wholesale poisons licence under this regulation, as in force before the commencement date of the Pharmacy and Poisons (Amendment) Ordinance 2015 (2 of 2015) (***amending Ordinance***); and

(b) that licence was in force immediately before that date,

then, for the remainder of the period for which that licence would have continued to be valid had section 46 of the amending Ordinance not been enacted, the person is to be regarded as a licensed wholesale dealer, and the Ordinance and regulations made under section 29 apply to the person accordingly.".

47. Regulation 27 amended (sales by wholesale dealers)

(1) Regulation 27, heading—

Repeal

"**Sales by wholesale dealers**"

Substitute

"**Sales of poisons by licensed wholesale dealers or licensed manufacturers**".

(2) Regulation 27—

Repeal everything before paragraph (a)

Substitute

"A licensed wholesale dealer or licensed manufacturer must not sell or supply a poison to any person other than the following—".

(3) Regulation 27—

Repeal paragraph (a)

Substitute

"(a) a licensed wholesale dealer;

(ab) a licensed manufacturer;".

(4) Regulation 27—

Repeal paragraph (j)

Substitute

"(j) a listed seller of poisons, if the poison is included in the classes of poisons in Part II of the Poisons List that the listed seller is licensed to sell.".

48. Regulation 28 amended (records to be kept by wholesale dealer)

(1) Regulation 28, heading—

Repeal

"**wholesale dealer**"

Substitute

"**licensed wholesale dealers or licensed manufacturers**".

(2) Regulation 28(1)—

Repeal

everything before "acquired by"

Substitute

"(1) A licensed wholesale dealer or licensed manufacturer must record the following particulars for each transaction by which any poison included in Part I of the Poisons List or any pharmaceutical product is".

(3) Regulation 28(1)(c)—

Repeal

"and unit of quantity"

Substitute

"or pharmaceutical product".

(4) After regulation 28(1)(c)—

Add

"(ca) the batch number, pack size and unit of quantity of the poison or pharmaceutical product;".

(5) Regulation 28(1)(d), after "poison"—

Add

"or pharmaceutical product".

(6) Regulation 28(2)—

Repeal

everything before "disposition is"

Substitute

"(2) A licensed wholesale dealer or licensed manufacturer must record the following particulars for each transaction by which any poison included in Part I of the Poisons List or any pharmaceutical product is disposed of, whether the".

(7) Regulation 28(2)(c), after "poison"—

Add

"or pharmaceutical product".

(8) Regulation 28(2)(d)—

Repeal

"quantity of the poison or pharmaceutical product, as the case may be"

Substitute

"total quantity of the poison or pharmaceutical product".

(9) Regulation 28(2)(f)—

Repeal

everything after "product"

Substitute a semicolon.

(10) After regulation 28(2)(f)—

Add

"(fa) the batch number, pack size and unit of quantity of the poison or pharmaceutical product;".

(11) Regulation 28(2)(g), after "poison"—

Add

"or pharmaceutical product".

(12) Regulation 28(3), after "Poisons List"—

Add

"or pharmaceutical product".

(13) Regulation 28(3), after "that poison" (wherever appearing)—

Add

"or pharmaceutical product".

(14) Regulation 28(4)—

Repeal

everything after "transactions"

Substitute

"must be in the specified form.".

(15) Regulation 28(7)—

Repeal

everything after "of an" and before "retain"

Substitute

"import or export transaction, the licensed wholesale dealer or licensed manufacturer must".

(16) Regulation 28(8)—

Repeal

everything before "set up"

Substitute

"(8) A licensed wholesale dealer must".

49. Regulation 28A added

Part VII, before regulation 29—

Add

"**28A. Good Manufacturing Practice Guide**

(1) The Board may issue a Good Manufacturing Practice Guide providing for the principles and guidelines of good manufacturing practice in respect of pharmaceutical products.

(2) The GMP Guide—

(a) may consist of a code, standard, rule, specification or any other documentary form of practical guidance prepared by the Board or any other body or authority; and

(b) may apply, incorporate or refer to a document that has been formulated or published by a body or authority either as in force at the time when the document is so applied, incorporated or referred to or as amended, formulated or published from time to time.

(3) If the GMP Guide is issued, the Board must by notice published in the Gazette—

(a) identify the Guide; and

(b) specify the date on which the Guide is to take effect.

(4) The Board may from time to time revise the whole or any part of the GMP Guide.

(5) If the GMP Guide is revised, the Board must by notice published in the Gazette—

(a) identify the Guide or part revised; and

(b) specify the date on which the revision is to take effect.

(6) The Board must make a copy of the GMP Guide available for inspection by the public free of charge—

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

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

(7) The GMP Guide, and a notice published under paragraph (3) or (5), are not subsidiary legislation.".

50. Regulation 29 amended (licensing of manufacturers)

(1) Regulation 29(1)—

Repeal

"Subject to paragraph (2), no person shall"

Substitute

"A person must not".

(2) After regulation 29(1)—

Add

"(1A) For the purposes of paragraph (1), a person is not regarded as manufacturing a pharmaceutical product only by affixing to the container of the product a label—

(a) that does not state any of the following particulars—

(i) particulars mentioned in regulation 31(1)(a), (b), (e) or (f);

(ii) particulars regarding the dosage, route or frequency of administration of the product;

(iii) the name of the product; and

(b) that does not obscure, change or obliterate any of the following particulars labelled on the container—

(i) particulars mentioned in subparagraph (a);

(ii) particulars mentioned in regulation 31(1)(c).".

(3) Regulation 29—

Repeal paragraph (2).

(4) Regulation 29(3)—

Repeal

everything after "Committee may" and before "on payment"

Substitute

", subject to any conditions it thinks fit to impose, issue a licence to manufacture pharmaceutical products in the specified form".

(5) Regulation 29—

Repeal paragraph (4)

Substitute

"(4) In any of the circumstances specified in paragraph (4A), the Committee may—

(a) revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit;

(b) issue a warning letter to the licensed manufacturer; or

(c) vary a condition of the licence imposed under paragraph (3).

(4A) The circumstances are—

(a) that, in the Committee's opinion, the licensed manufacturer has contravened—

(i) a condition of the licence or any of these regulations; or

(ii) a code of practice applicable to the licensed manufacturer or the GMP Guide; or

(b) that the licensed manufacturer has been convicted of—

(i) an offence under the Ordinance or any of the regulations made under section 29, the Dangerous Drugs Ordinance (Cap. 134), the Antibiotics Ordinance (Cap. 137) or the Undesirable Medical Advertisements Ordinance (Cap. 231); or

(ii) an offence under section 6C or 6D of the Import and Export Ordinance (Cap. 60), section 52, 54 or 61 of the Public Health and Municipal Services Ordinance (Cap. 132) or section 7, 7A or 9 of the Trade Descriptions Ordinance (Cap. 362).

(4B) The Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a decision made under paragraph (4)(a) so that the decision takes effect only if a condition so imposed is contravened during the suspension period, and in the case of such a contravention, the decision takes effect on the date specified by the Committee having regard to all the circumstances of the case.".

(6) Regulation 29(5)—

Repeal

"forms prescribed in the Eighth Schedule. *(See Eighth Schedule, Forms 3 & 4)*"

Substitute

"specified forms.".

(7) Regulation 29(6)—

Repeal

"manufacturer licensed under this regulation"

Substitute

"licensed manufacturer".

(8) Regulation 29(6)—

Repeal

"forms prescribed in the Eighth Schedule. *(See Eighth Schedule, Forms 5 & 5A)*"

Substitute

"specified forms.".

(9) Regulation 29(7)—

Repeal

"person"

Substitute

"applicant or licensed manufacturer".

51. Regulation 30 amended (manufacture to be under supervision of a registered pharmacist)

(1) Regulation 30(1)(a), after "pharmacist;"—

Add

"or".

(2) Regulation 30(1)—

Repeal subparagraph (b).

52. Regulations 30A to 30F added

After regulation 30—

Add

"**30A. Authorized person to certify compliance with GMP Guide etc.**

(1) A licensed manufacturer must ensure that at least one authorized person is employed to be responsible for carrying out, in relation to the pharmaceutical products manufactured under the licence, the duties specified in paragraph (2).

(2) An authorized person is responsible for ensuring and certifying that—

(a) each batch of the pharmaceutical products has been manufactured and checked in accordance with the GMP Guide; and

(b) the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products.

(3) In this regulation—

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.

30B. Register of authorized persons

(1) The Board must cause the Secretary to keep a register of authorized persons for the purposes of these regulations.

(2) The register may be kept in a form the Board thinks fit.

(3) The register must contain, for each person who is registered as an authorized person under this Part—

(a) the name and address of the person; and

(b) any other particulars of the person the Board thinks fit.

(4) The Board may amend the register as to the name, address or any other particulars relating to an authorized person whose name appears in the register on being satisfied that the amendment is necessary for preserving the accuracy of the register.

(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, 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.

30C. Application for registration as authorized person

(1) A person who satisfies the requirements specified in paragraph (2) may apply to the Committee for registration as an authorized person.

(2) The requirements are that—

(a) the person—

(i) is a registered pharmacist; or

(ii) holds a qualification awarded on completion of a course recognized by the Committee; and

(b) the person—

(i) has at least 3 years' relevant experience in Hong Kong or a place outside Hong Kong in manufacturing pharmaceutical products in accordance with the GMP Guide or a document similar or equivalent to that Guide issued or adopted by a competent authority of a place outside Hong Kong; or

(ii) meets any other criteria that the Committee may specify.

(3) The application must be in the specified form.

(4) The Committee may require the applicant to provide any information or document that the Committee considers reasonably necessary for determining the application.

30D. Registration as authorized person

(1) The Committee must decide whether to grant or refuse an application for registration made under regulation 30C.

(2) The Committee may grant an application on being satisfied that the applicant is a fit and proper person to be registered as an authorized person.

(3) A registration under this regulation is subject to any conditions the Committee thinks fit to impose.

(4) On registration, the Committee must issue to the applicant a certificate of registration in the specified form on payment of the fee prescribed in the Ninth Schedule.

(5) Subject to regulation 30F, a registration has effect from the date on which the certificate of registration is issued until the end of the year in which the date falls.

(6) An applicant aggrieved by a decision made in respect of the applicant under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

30E. Renewal of registration of authorized person

(1) The Committee may, on an application, renew the registration of an authorized person.

(2) An application for renewal of registration must be in the specified form.

(3) The Committee may require the applicant to provide any information or document that the Committee considers reasonably necessary for determining the application.

(4) A registration renewed under this regulation is subject to any conditions the Committee thinks fit to impose.

(5) On renewal of registration, the Committee must issue to the applicant a renewed certificate of registration in the specified form on payment of the fee prescribed in the Ninth Schedule.

(6) Subject to regulation 30F, a renewed registration has effect from the date on which the renewed certificate of registration is issued until the end of the year in which the date falls.

(7) An applicant aggrieved by a decision made in respect of the applicant under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

30F. Cancellation or suspension etc. of registration as authorized person

(1) The Committee may exercise any one or more of the following powers in any of the circumstances specified in paragraph (2) in respect of a person registered as an authorized person under this Part—

(a) cancel the registration;

(b) suspend the registration for a period specified by the Committee;

(c) issue a warning letter to the person;

(d) vary a condition of the registration imposed under regulation 30D(3) or 30E(4).

(2) The circumstances are—

(a) that the Committee is satisfied that the person is no longer a fit and proper person to be registered as an authorized person;

(b) that in the Committee's opinion, the person has contravened—

(i) a condition of the registration; or

(ii) any of these regulations or a code of practice applicable to the person as an authorized person; or

(c) that the person has been convicted of—

(i) an offence under the Ordinance or any of the regulations made under section 29, the Dangerous Drugs Ordinance (Cap. 134), the Antibiotics Ordinance (Cap. 137) or the Undesirable Medical Advertisements Ordinance (Cap. 231); or

(ii) an offence under section 52, 54 or 61 of the Public Health and Municipal Services Ordinance (Cap. 132) or section 7, 7A or 9 of the Trade Descriptions Ordinance (Cap. 362).

(3) The Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a decision made under paragraph (1)(a) or (b) so that the decision takes effect only if a condition so imposed is contravened during the suspension period, and in the case of such a contravention, the decision takes effect on the date specified by the Committee having regard to all the circumstances of the case.

(4) The Committee must cause the Secretary to—

(a) as soon as practicable after cancelling a person's registration under paragraph (1)(a), remove the entries relating to the person from the register of authorized persons; or

(b) as soon as practicable after suspending a person's registration under paragraph (1)(b), remove the entries relating to the person from the register of authorized persons, and restore those entries to the register as soon as practicable after the period of suspension expires.

(5) A person whose registration as an authorized person is cancelled must immediately return to the Committee the certificate of registration or renewed certificate of registration issued to the person under regulation 30D or 30E.

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

53. Regulation 31 amended (labelling by manufacturers)

(1) Regulation 31, heading, after "**by**"—

Add

"**licensed**".

(2) Regulation 31(1)—

Repeal

"manufacturer or authorized seller of poisons, supplying for distribution under regulation 29(2),"

Substitute

"licensed manufacturer".

(3) Regulation 31(1)(c)—

Repeal

"manufacturer; and"

Substitute

"manufacturer;".

(4) Regulation 31(1)(d)—

Repeal

"Board."

Substitute

"Board;".

(5) After regulation 31(1)(d)—

Add

"(e) the batch number of the pharmaceutical product; and

(f) the expiry date of the pharmaceutical product.".

(6) Regulation 31(2)(b)(ii)—

Repeal

"article."

Substitute

"article;".

(7) After regulation 31(2)(b)—

Add

"(c) ***batch number*** (批次編號), in relation to a pharmaceutical product, means a unique combination of numbers, letters or other symbols from which—

(i) the batch or lot to which the product belongs can be identified; and

(ii) the production and distribution history of the product can be determined;

(d) ***expiry date*** (使用期限), in relation to a pharmaceutical product, means the date determined, on the basis of the product's specifications registered under regulation 36(3)(a)(ii), by the manufacturer as the date after which the product should not be used, assuming that the product is stored under conditions suitable to the product.".

(8) Regulation 31(3), Chinese text—

Repeal

"分銷"

Substitute

"分發".

54. Regulation 32 amended (manufacturing workers not to infect products)

(1) Regulation 32—

Repeal

"manufacturer shall"

Substitute

"licensed manufacturer must".

(2) Regulation 32—

Repeal

"or packing".

55. Regulation 33 amended (duties of manufacturers)

(1) Regulation 33, heading—

Repeal

"**manufacturers**"

Substitute

"**licensed manufacturers regarding identity, purity, safety, etc.**".

(2) Regulation 33(1)—

Repeal

"a manufacturer shall"

Substitute

"a licensed manufacturer must".

(3) Regulation 33(1A)—

Repeal

"a manufacturer"

Substitute

"a licensed manufacturer".

(4) Regulation 33—

Repeal paragraph (2)

Substitute

"(2) A licensed manufacturer must ensure that the registrable particulars of each batch of pharmaceutical products in a finished form correspond exactly with the registered particulars of the products.".

(5) Regulation 33(4)—

Repeal

"A manufacturer shall maintain"

Substitute

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

(6) Regulation 33(4)—

Repeal

everything after "less than"

Substitute

"1 year after the expiry date of the product.".

(7) 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.".

(8) Regulation 33(5)—

Repeal

"A manufacturer shall"

Substitute

"A licensed manufacturer must".

(9) 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.".

56. Regulation 34 amended (manufacturer's premises)

(1) Regulation 34, heading—

Repeal

"**Manufacturer's**"

Substitute

"**Licensed manufacturer's**".

(2) Regulation 34(1)—

Repeal

"and packaging".

(3) Regulation 34(1)(b)—

Repeal

"and packing".

(4) Regulation 34(2)—

Repeal

", packing".

(5) Regulation 34(5)—

Repeal

"and packing".

57. Regulation 35 amended (records to be kept by manufacturers)

(1) Regulation 35, heading—

Repeal

"**manufacturers**"

Substitute

"**licensed manufacturers**".

(2) Regulation 35(1)—

Repeal

"A manufacturer shall"

Substitute

"A licensed manufacturer must".

(3) Regulation 35—

Repeal paragraph (2)

Substitute

"(2) A record showing the matters mentioned in paragraph (1)(a), (b), (d), (e) or (g) must be completed when the manufacturing process or test concerned is being carried out.

(3) A record showing the matters mentioned in paragraph (1)(c) must be completed within 72 hours after the transaction concerned takes place.

(4) For the purposes of paragraph (1)(f)—

(a) a record showing a complaint must be completed within 72 hours after the complaint is received by the licensed manufacturer; and

(b) a record showing an action taken in respect of a complaint must be completed within 72 hours after the action is taken.".

58. Regulation 36 amended (registration of pharmaceutical products and substances)

(1) Regulation 36(1), Chinese text—

Repeal

"分銷，或為銷售、分銷"

Substitute

"分發，或為銷售、分發".

(2) Regulation 36(1)(a)—

Repeal

"manufacturer,"

Substitute

"licensed manufacturer, or a licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance,".

(3) Regulation 36(1)(b)—

Repeal

"the importer"

Substitute

"a person referred to in section 28A(1) or (3) who imports the pharmaceutical product or substance into Hong Kong".

(4) Regulation 36(1)(c), Chinese text—

Repeal

"分銷"

Substitute

"分發".

(5) Regulation 36(1A)(a)(i), after "Kong;"—

Add

"or".

(6) Regulation 36(1A)(a)(ii)—

Repeal

"pharmaceutical manufacturer"

Substitute

"licensed manufacturer".

(7) Regulation 36(1A)(a)—

Repeal sub-subparagraph (iii).

(8) After regulation 36(1A)(a)—

Add

"(ab) is possessed or is to be used for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient or for the purpose of treatment by a registered veterinary surgeon of a particular animal;".

(9) Regulation 36(1A)(b)—

Repeal

"Kong."

Substitute

"Kong;".

(10) After regulation 36(1A)(b)—

Add

"(c) is to be administered for the purposes of a clinical trial that is to be conducted in accordance with a clinical trial certificate issued under regulation 36B(3); or

(d) is to be administered for the purposes of a medicinal test that is to be conducted in accordance with a medicinal test certificate issued under regulation 36B(3).".

(11) Regulation 36(2)—

Repeal

"form prescribed in the Eighth Schedule"

Substitute

"specified form".

(12) Regulation 36(2)—

Repeal

"*(See Eighth Schedule, Form 6)*".

(13) Regulation 36(5)—

Repeal

everything after "may" and before "valid"

Substitute

", subject to any conditions it thinks fit to impose, register a pharmaceutical product or substance by issuing to the applicant a registration certificate in the specified form and the certificate is".

(14) Regulation 36(5)—

Repeal

"*(See Eighth Schedule, Form 7)*".

(15) Regulation 36(7)—

Repeal

everything after "renewable on"

Substitute

"—

(a) payment of the fee prescribed in the Ninth Schedule; and

(b) providing the Committee with the up-to-date information specified by the Committee regarding the pharmaceutical product or substance.".

(16) After regulation 36(7)—

Add

"(7A) A renewal under paragraph (7) is subject to any conditions the Committee thinks fit to impose.

(7B) The Committee may vary a condition imposed under paragraph (5) or (7A) if it thinks fit to do so.".

(17) Regulation 36(8), after "substance"—

Add

", suspend the registration of a pharmaceutical product or substance for a period specified by the Committee, or issue a warning letter to the holder of a registration certificate, if it is of the opinion that a condition of the registration is contravened or".

(18) Regulation 36(9)—

Repeal

"person"

Substitute

"applicant or holder of a registration certificate".

59. Regulation 36B amended (clinical trials and medicinal tests)

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

Repeal

"床"

Substitute

"牀".

(2) Regulation 36B—

Renumber paragraph (1) as paragraph (1C).

(3) Before regulation 36B(1C)—

Add

"(1) A person must not conduct a clinical trial on human beings, or cause or permit such a trial to be conducted, except in accordance with a clinical trial certificate issued to the person under paragraph (3).

(1A) A person must not conduct a medicinal test on animals, or cause or permit such a test to be conducted, except in accordance with a medicinal test certificate issued to the person under paragraph (3).

(1B) A person who contravenes paragraph (1) or (1A) commits an offence and is liable to a fine at level 2.".

(4) Regulation 36B(1C), Chinese text—

Repeal

"床"

Substitute

"牀".

(5) Regulation 36B(2)—

Repeal

"sample of the product or substance and a".

(6) Regulation 36B(3)—

Repeal

everything after "may" and before "years"

Substitute

", subject to any conditions it thinks fit to impose, issue a clinical trial certificate or medicinal test certificate in the specified form and the certificate is valid for a period not exceeding 5".

(7) Regulation 36B(3)—

Repeal

"*(See Eighth Schedule, Form 12)*".

(8) After regulation 36B(3)—

Add

"(3A) The Committee may vary a condition imposed under paragraph (3) if it thinks fit to do so.

(3B) The Committee may cancel a clinical trial certificate or medicinal test certificate, suspend it for a period specified by the Committee, or issue a warning letter to the holder of the certificate, if—

(a) it is of the opinion that the holder of the certificate has contravened a condition of the certificate; or

(b) it considers it to be in the public interest to do so.

(3C) If the Committee refuses an application under paragraph (1C), the Committee must give the applicant a notice of refusal and state in the notice the reasons for refusal.

(3D) If the Committee decides to cancel or suspend a certificate under paragraph (3B), the Committee must give the holder of the certificate a notice of cancellation or suspension (as the case may be) and state in the notice the reasons for its decision.".

(9) Regulation 36B(4)—

Repeal

"person"

Substitute

"applicant or holder of a clinical trial certificate or medicinal test certificate".

60. Regulation 37 amended (factors relevant to determination of application for registration)

(1) Regulation 37(3)—

Repeal

"by an importer"

Substitute

"made in respect of a pharmaceutical product or substance manufactured outside Hong Kong,".

(2) Regulation 37(3)—

Repeal

"the production by the applicant of one or both of the following"

Substitute

"the applicant to take any or all of the following actions".

(3) Regulation 37(3)(a), before "an undertaking"—

Add

"produce".

(4) Regulation 37(3)(b), before "a declaration"—

Add

"produce".

(5) Regulation 37(3)(b)—

Repeal

"with."

Substitute

"with;".

(6) After regulation 37(3)(b)—

Add

"(c) pay a fee determined by the Committee as representing the expenditure incurred, or likely to be incurred, by or on behalf of the Committee in carrying out an inspection mentioned in subparagraph (a).".

61. Part VIIIA repealed (registration of importers and exporters)

Part VIIIA—

Repeal the Part.

62. Regulation 38B added

Part X, before regulation 39—

Add

"**38B. Power to specify forms**

(1) An executive committee established under section 4A for a provision of these regulations may specify forms to be used for that provision.

(2) If a form is specified under this regulation, the Board must make copies of the form available for inspection by the public free of charge—

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

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

63. Regulation 39 amended (period of keeping of records)

(1) Regulation 39(d)—

Repeal

"holders of wholesale poisons licences"

Substitute

"licensed wholesale dealers or licensed manufacturers".

(2) Regulation 39(e), before "manufacturers"—

Add

"licensed".

(3) Regulation 39—

Repeal

"holder of wholesale poison licence or manufacturer"

Substitute

"licensed wholesale dealer or licensed manufacturer".

64. Regulation 40 amended (penalties)

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

Add

", (4B)".

65. Regulation 41 amended (certificates, forms and fees)

(1) Regulation 41, Chinese text, heading—

Repeal

"表格"

Substitute

"式樣".

(2) Regulation 41(1)—

Repeal

everything after "be in the"

Substitute

"specified form.".

(3) Regulation 41—

Repeal paragraph (2).

(4) Regulation 41(2A), Chinese text—

Repeal

"*表格*"

Substitute

"*式樣*".

(5) Regulation 41—

Repeal paragraph (3).

66. First Schedule amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 15, 19, 22, 23 and 24)

(1) First Schedule, heading—

Repeal

"**15, 19, 22, 23**"

Substitute

"**22**".

(2) First Schedule—

Repeal

"[regs. 3, 5(1), 6, 7, 15(3), 17(3), 19(2), 22(3), 23(3)(b), 24(2)(b), (4)]"

Substitute

"[regs. 3, 5, 6, 7, 17, 22 & 24 & 5th Sch.]".

(3) First Schedule, Division A, item relating to "Alkaloids"—

Repeal

"Colchicum, alkaloids of"

Substitute

"Colchicum, alkaloids of; their salts".

(4) First Schedule, English text, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (a)—

Repeal

"Bacillus Calmette-Guerin"

Substitute

"Bacillus Calmette-Guérin".

(5) First Schedule, English text, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b)—

(a) **Repeal item "Japanese encephalitis";**

(b) **Add in alphabetical order**

"Japanese encephalitis".

(6) First Schedule, English text, Division A, item "Atracurium Besylate"—

Repeal

"Besylate"

Substitute

"besylate".

(7) First Schedule, English text, Division A—

(a) **Repeal item "Benzquinamide";**

(b) After item "Benzoylmorphine; its salts"—

Add

"Benzquinamide".

(8) First Schedule, English text, Division A, item relating to "Contrast media"—

Repeal

"Sulphur Hexafluoride"

Substitute

"Sulphur hexafluoride".

(9) First Schedule, English text, Division A, item "Dihydrallazine; its salts"—

Repeal

"Dihydrallazine"

Substitute

"Dihydralazine".

(10) First Schedule, English text, Division A, item "Foscarnet Trisodium Hexahydrate"—

Repeal

"Trisodium Hexahydrate"

Substitute

"trisodium hexahydrate".

(11) First Schedule, English text, Division A, item relating to "Guanidines"—

Repeal

"Polymethylene diguanidines; di-para-anisyl-para-phenetylguanidine;"

Substitute

"Polymethylene diguanidines; di-para-anisyl-para-phenethylguanidine;".

(12) First Schedule, English text, Division A, item "Haloperidol and other 4-substituted derivatives of N-(3-parafluorobenzoyl-propyl) piperidine"—

Repeal

"N-(3-parafluorobenzoyl-propyl)"

Substitute

"N-(3-para-fluorobenzoylpropyl)".

(13) First Schedule, English text, Division A, item relating to "Hydiazines"—

Repeal

"Hydiazines"

Substitute

"Hydrazines".

(14) First Schedule, English text, Division A—

(a) **Repeal item "Hydrallazine; its salts";**

(b) After item "Hexobendine; its salts"—

Add

"Hydralazine; its salts".

(15) First Schedule, English text, Division A, item "Ketanserine; its salts"—

Repeal

"Ketanserine"

Substitute

"Ketanserin".

(16) First Schedule, English text, Division A, item relating to "Ketoconazole"—

Repeal

"Ketoconazole"

Substitute

"Ketoconazole,".

(17) First Schedule, English text, Division A, item "Lithium Sulphate"—

Repeal

"Sulphate"

Substitute

"sulphate".

(18) First Schedule, English text, Division A—

(a) **Repeal item "Meclobemide; its salts";**

(b) After item "Mizolastine; its salts"—

Add

"Moclobemide; its salts".

(19) First Schedule, English text, Division A, item "Meclofenamic Acid; its salts"—

Repeal

"Acid"

Substitute

"acid".

(20) First Schedule, Division A, item "Mepirizole", after "Mepirizole"—

Add

"; its salts".

(21) First Schedule, English text, Division A, item relating to "2-Methyl-3-morpholino-1,1-diphenylpropanecarboxylic acid"—

Repeal

"1-diphenylpropanecarboxylic"

Substitute

"1-diphenylpropane carboxylic".

(22) First Schedule, English text, Division A, item relating to "Minoxidil"—

Repeal

"Minoxidil except"

Substitute

"Minoxidil, except".

(23) First Schedule, English text, Division A, item "Niflumic Acid; its salts"—

Repeal

"Acid"

Substitute

"acid".

(24) First Schedule, English text, Division A, item relating to "Piroxicam"—

Repeal

"Piroxicam"

Substitute

"Piroxicam,".

(25) First Schedule, English text, Division A, item relating to "Salbutamol and its salts"—

Repeal

"salts"

Substitute

"salts,".

(26) First Schedule, Division A, item "Sunitinib; its salts; their salts"—

Repeal

"; their salts".

(27) First Schedule, English text, Division A, item "Tetracosatrin; its salts"—

Repeal

"Tetracosatrin"

Substitute

"Tetracosactide".

(28) First Schedule, English text, Division A, item "Tolfenamic Acid; its salts"—

Repeal

"Acid"

Substitute

"acid".

(29) First Schedule, English text, Division A, item relating to "Tranexamic acid"—

Repeal

"acid"

Substitute

"acid,".

(30) First Schedule, English text, Division A—

(a) **Repeal item "Vencuronium; its salts";**

(b) After item "Vasopressins"—

Add

"Vecuronium; its salts".

(31) First Schedule, Division A, item "Warfarin salts"—

Repeal

"Warfarin"

Substitute

"Warfarin; its".

(32) First Schedule, Chinese text, Division A—

(a) **Repeal item "乙丙氨酯";**

(b) Before item "大麻；大麻的樹脂；大麻浸膏；大麻酊劑；鞣酸大麻素"—

Add

"己丙氨酯".

(33) First Schedule, Chinese text, Division A, item "乙酰苯胺；烷基乙苯胺類"—

Repeal

"苯胺類"

Substitute

"酰苯胺類".

(34) First Schedule, Chinese text, Division A, item "六甲嘧胺"—

Repeal

"嘧"

Substitute

"蜜".

(35) First Schedule, Chinese text, Division A, item "扎西他賓；其鹽類"—

Repeal

"賓"

Substitute

"濱".

(36) First Schedule, Chinese text, Division A, item "扎那米偉；其鹽類"—

Repeal

"偉"

Substitute

"韋".

(37) First Schedule, Chinese text, Division A—

(a) **Repeal item "甲納曲酮；其鹽類";**

(b) Before item "甲氯芬那酸；其鹽類"—

Add

"甲鈉曲酮；其鹽類".

(38) First Schedule, Chinese text, Division A, item "丙呱維林；其鹽類"—

Repeal

"呱"

Substitute

"哌".

(39) First Schedule, Chinese text, Division A, item "卡馬西泮"—

Repeal

"泮"

Substitute

"平".

(40) First Schedule, Chinese text, Division A—

(a) **Repeal item "代昔洛韋；其鹽類";**

(b) After item "伐地昔布；其鹽類"—

Add

"伐昔洛韋；其鹽類".

(41) First Schedule, Chinese text, Division A, item relating to "安定及具有雙氫-1"—

Repeal

"具有雙氫-1，4-苯二氮䓬的化學結構在任何程度上被取代"

Substitute

"含有雙氫-1，4-苯二氮䓬的化學結構(在任何程度上被取代者)".

(42) First Schedule, Chinese text, Division A, item "米貝地爾；其鹽類"—

Repeal

"米貝"

Substitute

"米貝拉".

(43) First Schedule, Chinese text, Division A, item "沙美物羅及其鹽類，載於噴霧器時"—

Repeal

"物"

Substitute

"特".

(44) First Schedule, Chinese text, Division A, item "那格列奈；其鹽類；其酯類"—

Repeal

"奈"

Substitute

"胺".

(45) First Schedule, Chinese text, Division A, item relating to "抗血清、抗毒素、免疫球蛋白與疫苗", paragraph (b)—

Repeal

"乙型流感嗜血杆菌"

Substitute

"乙型流感嗜血桿菌".

(46) First Schedule, Chinese text, Division A, item relating to "抗組胺物質"—

Repeal

"安他唑林"

Substitute

"安他唑啉".

(47) First Schedule, Chinese text, Division A, item "炔已蟻胺"—

Repeal

"已"

Substitute

"己".

(48) First Schedule, Chinese text, Division A, item "阿夫唑秦；其鹽類"—

Repeal

"秦"

Substitute

"嗪".

(49) First Schedule, Chinese text, Division A—

(a) **Repeal item "阿伐他汀；其鹽類";**

(b) Before item "阿托伐醌"—

Add

"阿托伐他汀；其鹽類".

(50) First Schedule, Chinese text, Division A, item relating to "阿法甲基苯乙胺(苯丙胺)", after "代及"—

Add

"上述".

(51) First Schedule, Chinese text, Division A—

(a) **Repeal item "阿紮胞苷；其鹽類";**

(b) After item "阿扎那韋；其鹽類"—

Add

"阿扎胞苷；其鹽類".

(52) First Schedule, Chinese text, Division A, item "阿撲嗎啡；其鹽類；其四級化合物，但含有少於 0.2% 阿撲嗎啡的物質除外"—

Repeal

"其四級化合物，"

Substitute

"其四級化合物；".

(53) First Schedule, Chinese text, Division A, item "依托泊甙；其酯類"—

Repeal

"甙"

Substitute

"苷".

(54) First Schedule, Chinese text, Division A, item "依米氨脂"—

Repeal

"脂"

Substitute

"酯".

(55) First Schedule, Chinese text, Division A, item "奈非那書；其鹽類"—

Repeal

"書"

Substitute

"韋".

(56) First Schedule, Chinese text, Division A, item "泮庫溴銨；其鹽類"—

Repeal

"溴".

(57) First Schedule, Chinese text, Division A, item relating to "胍類物"—

Repeal the colon.

(58) First Schedule, Chinese text, Division A—

(a) **Repeal item "苯甲酸利扎曲普坦；其鹽類";**

(b) Before item "利匹韋林；其鹽類"—

Add

"利扎曲坦；其鹽類".

(59) First Schedule, Chinese text, Division A, item "美芬噁酮"—

Repeal

"噁"

Substitute

"諾".

(60) First Schedule, Chinese text, Division A, item "氟哌啶醇(氟哌丁苯)及N-(3-對氟苯甲酰丙基)哌啶於千位被取代的其他衍生物"—

Repeal

"千"

Substitute

"4".

(61) First Schedule, Chinese text, Division A, item relating to "前列腺素類"—

Repeal

"地諾前列素(前列腺素F_2a)"

Substitute

"地諾前列素(前列腺素$F_{2\alpha}$)".

(62) First Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Bimatoprost";**

(b) **Add according to the number of strokes**

"貝美前列素".

(63) First Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Travoprost";**

(b) **Add according to the number of strokes**

"曲伏前列素".

(64) First Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Unoprostone";**

(b) **Add according to the number of strokes**

"烏諾前列酮".

(65) First Schedule, Chinese text, Division A, item "咪喹莫特；其鹽類"—

Repeal

"特"

Substitute

"德".

(66) First Schedule, Chinese text, Division A, item "氨己稀酸"—

Repeal

"稀"

Substitute

"烯".

(67) First Schedule, Chinese text, Division A, item "唑吡坦；其鹽類"—

Repeal

"咀"

Substitute

"坦".

(68) First Schedule, Chinese text, Division A, item "唑來磷酸；其鹽類"—

Repeal

"磷"

Substitute

"膦".

(69) First Schedule, Chinese text, Division A, item "胸腺肽a1"—

Repeal

"a"

Substitute

"α".

(70) First Schedule, Chinese text, Division A—

(a) **Repeal item "6-烟鹼可待因；其鹽類";**

(b) After item relating to "煙酸及其鹽類"—

Add

"6-煙鹼可待因；其鹽類".

(71) First Schedule, Chinese text, Division A—

(a) **Repeal item "培哚普利拉；其鹽類；其酯類；它們的鹽類";**

(b) After item "培氟沙星；其鹽類；其酯類"—

Add

"培哚普利拉；其鹽類；其酯類；它們的鹽類".

(72) First Schedule, Chinese text, Division A—

(a) **Repeal item "斑布特羅及其鹽類，載於噴霧器時";**

(b) After item "索拉非尼；其鹽類"—

Add

"班布特羅及其鹽類，載於噴霧器時".

(73) First Schedule, Chinese text, Division A, item "替尼泊甙"—

Repeal

"甙"

Substitute

"苷".

(74) First Schedule, Chinese text, Division A—

(a) **Repeal item "普芦沙星；其鹽類；其酯類；它們的鹽類";**

(b) After item "普蘆卡必利；其鹽類"—

Add

"普蘆沙星；其鹽類；其酯類；它們的鹽類".

(75) First Schedule, Chinese text, Division A—

(a) **Repeal item "富馬酸喹硫平；其鹽類";**

(b) After item "喹高利特；其鹽類"—

Add

"喹硫平；其鹽類".

(76) First Schedule, Chinese text, Division A, item "硼替左米"—

Repeal

"左"

Substitute

"佐".

(77) First Schedule, Chinese text, Division A—

(a) **Repeal item "噻萘普汀；其鹽類；其酯類；它們的鹽類";**

(b) After item "噻托；其鹽類"—

Add

"噻奈普汀；其鹽類；其酯類；它們的鹽類".

(78) First Schedule, Chinese text, Division A—

(a) **Repeal item "Anagrelide；其鹽類";**

(b) After item "阿那曲唑；其鹽類"—

Add

"阿那格雷；其鹽類".

(79) First Schedule, Chinese text, Division A—

(a) **Repeal item "Brinzolamide；其鹽類";**

(b) After item "布托啡諾；其鹽類"—

Add

"布林佐胺；其鹽類".

(80) First Schedule, Chinese text, Division A—

(a) **Repeal item "Candesartan；其鹽類；其酯類；它們的鹽類";**

(b) Before item "吩那多松；其鹽類"—

Add

"坎地沙坦；其鹽類；其酯類；它們的鹽類".

(81) First Schedule, Chinese text, Division A—

(a) **Repeal item "Celecoxib；其鹽類";**

(b) After item "塞利洛爾；其鹽類"—

Add

"塞來考昔；其鹽類".

(82) First Schedule, Chinese text, Division A—

(a) **Repeal item "Cidofovir；其鹽類";**

(b) After item "西曲瑞克；其鹽類；其酯類；它們的鹽類"—

Add

"西多福韋；其鹽類".

(83) First Schedule, Chinese text, Division A—

(a) **Repeal item "Darbepoetin alfa";**

(b) After item "達非那新；其鹽類"—

Add

"達促紅素 α".

(84) First Schedule, Chinese text, Division A—

(a) **Repeal item "Eletriptan；其鹽類";**

(b) After item "依泊丁"—

Add

"依來曲坦；其鹽類".

(85) First Schedule, Chinese text, Division A—

(a) **Repeal item "Eprosartan；其鹽類";**

(b) After item "依普利酮"—

Add

"依普羅沙坦；其鹽類".

(86) First Schedule, Chinese text, Division A—

(a) **Repeal item "Eptifibatide；其鹽類";**

(b) Before item "依替福林；其鹽類"—

Add

"依替巴肽；其鹽類".

(87) First Schedule, Chinese text, Division A—

(a) **Repeal item "Etanercept";**

(b) Before item "依那普利；其鹽類"—

Add

"依那西普".

(88) First Schedule, Chinese text, Division A—

(a) **Repeal item "Fondaparinux；其鹽類";**

(b) After item "縮宮素類 (催產素類)"—

Add

"磺達肝素 (癸)；其鹽類".

(89) First Schedule, Chinese text, Division A—

(a) **Repeal item "Ibandronic acid；其鹽類";**

(b) Before item "伊普吲哚；其鹽類"—

Add

"伊班膦酸；其鹽類".

(90) First Schedule, Chinese text, Division A—

(a) **Repeal item "Imatinib；其鹽類";**

(b) After item "伊索昔康；其鹽類"—

Add

"伊馬替尼；其鹽類".

(91) First Schedule, Chinese text, Division A—

(a) **Repeal item "Imiglucerase";**

(b) After item "伊立替康；其鹽類"—

Add

"伊米苷酶".

(92) First Schedule, Chinese text, Division A—

(a) **Repeal item "Indinavir；其鹽類";**

(b) Before item "茚達特羅；其鹽類；其酯類；它們的鹽類"—

Add

"茚地那韋；其鹽類".

(93) First Schedule, Chinese text, Division A—

(a) **Repeal item "Lepirudin；其鹽類";**

(b) Before item "來曲唑"—

Add

"來匹蘆定；其鹽類".

(94) First Schedule, Chinese text, Division A—

(a) **Repeal item "Levosimendan；其鹽類";**

(b) After item "左乙拉西坦；其鹽類"—

Add

"左西孟旦；其鹽類".

(95) First Schedule, Chinese text, Division A—

(a) **Repeal item "Mangafodipir；其鹽類";**

(b) After item "諾氟沙星；其鹽類；其酯類"—

Add

"錳福地吡；其鹽類".

(96) First Schedule, Chinese text, Division A—

(a) **Repeal item "Metaflumizone；其鹽類";**

(b) After item "琥珀膽鹼；其鹽類"—

Add

"氰氟蟲腙；其鹽類".

(97) First Schedule, Chinese text, Division A—

(a) **Repeal item "Palivizumab";**

(b) After item "帕利哌酮；其鹽類"—

Add

"帕利珠單抗".

(98) First Schedule, Chinese text, Division A—

(a) **Repeal item "Pimecrolimus";**

(b) After item "吡洛芬；其鹽類"—

Add

"吡美莫司".

(99) First Schedule, Chinese text, Division A—

(a) **Repeal item "Rasburicase；其鹽類";**

(b) Before item "拉米夫定；其鹽類"—

Add

"拉布立酶；其鹽類".

(100) First Schedule, Chinese text, Division A—

(a) **Repeal item "Ritonavir；其鹽類";**

(b) After item "利托君；其鹽類"—

Add

"利托那韋；其鹽類".

(101) First Schedule, Chinese text, Division A—

(a) **Repeal item "Sevelamer；其鹽類";**

(b) After item "司替氨酯"—

Add

"司維拉姆；其鹽類".

(102) First Schedule, Chinese text, Division A—

(a) **Repeal item "Stavudine；其鹽類";**

(b) After item "司巴丁(金雀花鹼)；其鹽類"—

Add

"司他夫定；其鹽類".

(103) First Schedule, Chinese text, Division A—

(a) **Repeal item relating to "Tadalafil";**

(b) After item "他莫昔芬；其鹽類"—

Add

"他達拉非；其鹽類；任何含有6-(5-苯并[1,3]二噁茂基)-2,3,6,7,12,12a-六氫吡嗪并[1',2':1,6]吡啶并[3,4-*b*]吲哚-1,4-二酮的化學結構 (在任何程度上被取代或沒有被取代者)的化合物；其鹽類".

(104) First Schedule, Chinese text, Division A—

(a) **Repeal item "Tenecteplase；其鹽類";**

(b) After item "替拉曲考；其鹽類"—

Add

"替奈普酶；其鹽類".

(105) First Schedule, Chinese text, Division A—

(a) **Repeal item "Topotecan；其鹽類";**

(b) Before item "托屈嗪；其鹽類"—

Add

"托泊替康；其鹽類".

(106) First Schedule, Chinese text, Division A—

(a) **Repeal item "Ustekinumab";**

(b) Before item "烏拉地爾；其鹽類"—

Add

"烏司奴單抗".

(107) First Schedule, Chinese text, Division A—

(a) **Repeal item "Valganciclovir；其鹽類";**

(b) After item "纈沙坦；其鹽類"—

Add

"纈更昔洛韋；其鹽類".

(108) First Schedule, Chinese text, Division A—

(a) **Repeal item "Verteporfin；其鹽類";**

(b) After item "維莫非尼；其鹽類"—

Add

"維替泊芬；其鹽類".

(109) First Schedule, Chinese text, Division A—

(a) **Repeal item "Voriconazole；其鹽類";**

(b) After item "曲普瑞林；其鹽類"—

Add

"伏立康唑；其鹽類".

(110) First Schedule, Chinese text, Division A—

(a) **Repeal item "Ziprasidone；其鹽類";**

(b) After item "齊多夫定"—

Add

"齊拉西酮；其鹽類".

(111) First Schedule, Chinese text, Division B, item "鋇鹽類，硫酸鋇除外"—

Repeal

"鋇鹽類"

Substitute

"鋇的鹽類".

67. Third Schedule amended

(1) Third Schedule—

Repeal

"[reg. 9(1)]"

Substitute

"[regs. 3 & 9 & 5th Sch. & Sch. 10]".

(2) Third Schedule, Division A, item relating to "Alkaloids"—

Add in alphabetical order

"Colchicum, alkaloids of; their salts

Ephedrine; its optical isomers; their salts; when contained in aerosol dispensers

Rauwolfia, alkaloids of; their salts; derivatives of the alkaloids of rauwolfia; their salts

Vinca, alkaloids of".

(3) Third Schedule, English text, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (a)—

Repeal

"Bacillus Calmette-Guerin"

Substitute

"Bacillus Calmette-Guérin".

(4) Third Schedule, English text, Division A, item "Antisera, antitoxins, immunoglobulins and vaccines", paragraph (b)—

(a) **Repeal item "Japanese encephalitis";**

(b) **Add in alphabetical order**

"Japanese encephalitis".

(5) Third Schedule, English text, Division A, item "Atracurium Besylate"—

Repeal

"Besylate"

Substitute

"besylate".

(6) Third Schedule, English text, Division A, item relating to "Contrast media"—

Repeal

"Sulphur Hexafluoride"

Substitute

"Sulphur hexafluoride".

(7) Third Schedule, English text, Division A—

(a) **Repeal item "3-(3,4-Dihydroxyphenyl)alanine; its salts";**

(b) After item "Dihydroetorphine; its salts"—

Add

"3-(3,4-Dihydroxyphenyl)alanine; its salts".

(8) Third Schedule, English text, Division A, item "Dihydrallazine; its salts"—

Repeal

"Dihydrallazine"

Substitute

"Dihydralazine".

(9) Third Schedule, English text, Division A, item "Foscarnet Trisodium Hexahydrate"—

Repeal

"Trisodium Hexahydrate"

Substitute

"trisodium hexahydrate".

(10) Third Schedule, English text, Division A, item "Haloperidol and other 4-substituted derivatives of N-(3-para-fluoro-benzoyl-propyl) piperidine"—

Repeal

"N-(3-para-fluoro-benzoyl-propyl)"

Substitute

"N-(3-para-fluorobenzoylpropyl)".

(11) Third Schedule, English text, Division A, item "Hydrallazine; its salts"—

Repeal

"Hydrallazine"

Substitute

"Hydralazine".

(12) Third Schedule, English text, Division A, item "Ketanserine; its salts"—

Repeal

"Ketanserine"

Substitute

"Ketanserin".

(13) Third Schedule, English text, Division A, item relating to "Ketoconazole"—

Repeal

"Ketoconazole"

Substitute

"Ketoconazole,".

(14) Third Schedule, English text, Division A, item "Lithium Sulphate"—

Repeal

"Sulphate"

Substitute

"sulphate".

(15) Third Schedule, English text, Division A—

(a) **Repeal item "Meclobemide; its salts";**

(b) After item "Mizolastine; its salts"—

Add

"Moclobemide; its salts".

(16) Third Schedule, English text, Division A, item relating to "Minoxidil"—

Repeal

"Minoxidil except"

Substitute

"Minoxidil, except".

(17) Third Schedule, English text, Division A, item relating to "Piroxicam"—

Repeal

"Piroxicam"

Substitute

"Piroxicam,".

(18) Third Schedule, English text, Division A, item relating to "Salbutamol and its salts"—

Repeal

"salts"

Substitute

"salts,".

(19) Third Schedule, Division A, item "Sunitinib; its salts; their salts"—

Repeal

"; their salts".

(20) Third Schedule, English text, Division A, item "Tetracosatrin; its salts"—

Repeal

"Tetracosatrin"

Substitute

"Tetracosactide".

(21) Third Schedule, English text, Division A, item relating to "Tranexamic acid"—

Repeal

"acid"

Substitute

"acid,".

(22) Third Schedule, English text, Division A—

(a) **Repeal item "Vencuronium; its salts";**

(b) After item "Vasopressins"—

Add

"Vecuronium; its salts".

(23) Third Schedule, Division A, item "Warfarin salts"—

Repeal

"Warfarin"

Substitute

"Warfarin; its".

(24) Third Schedule, Chinese text, Division A—

(a) **Repeal item "乙丙氨酯";**

(b) Before item "干擾素"—

Add

"己丙氨酯".

(25) Third Schedule, Chinese text, Division A, item "乙色胺，其鹽類"—

Repeal

"胺，"

Substitute

"胺；".

(26) Third Schedule, Chinese text, Division A, item "乙胺丁醇，其鹽類"—

Repeal

"醇，"

Substitute

"醇；".

(27) Third Schedule, Chinese text, Division A, item "六甲嘧胺"—

Repeal

"嗖"

Substitute

"蜜".

(28) Third Schedule, Chinese text, Division A, item "扎西他賓；其鹽類"—

Repeal

"賓"

Substitute

"濱".

(29) Third Schedule, Chinese text, Division A, item "扎那米偉；其鹽類"—

Repeal

"偉"

Substitute

"韋".

(30) Third Schedule, Chinese text, Division A—

(a) **Repeal item "甲納曲酮；其鹽類";**

(b) After item "甲麥角林"—

Add

"甲鈉曲酮；其鹽類".

(31) Third Schedule, Chinese text, Division A, item "丙呱維林；其鹽類"—

Repeal

"呱"

Substitute

"哌".

(32) Third Schedule, Chinese text, Division A, item "卡馬西泮"—

Repeal

"泮"

Substitute

"平".

(33) Third Schedule, Chinese text, Division A—

(a) **Repeal item "代昔洛韋；其鹽類";**

(b) After item "伐地昔布；其鹽類"—

Add

"伐昔洛韋；其鹽類".

(34) Third Schedule, Chinese text, Division A, item relating to "安定及具有雙氫-1"—

Repeal

"具有雙氫-1，4-苯二氮䓬的化學結構在任何程度上被取代"

Substitute

"含有雙氫-1，4-苯二氮䓬的化學結構(在任何程度上被取代者)".

(35) Third Schedule, Chinese text, Division A, item "米貝地爾；其鹽類"—

Repeal

"米貝"

Substitute

"米貝拉".

(36) Third Schedule, Chinese text, Division A, item "沙美物羅及其鹽類，載於噴霧器時"—

Repeal

"物"

Substitute

"特".

(37) Third Schedule, Chinese text, Division A, item "那格列奈；其鹽類；其酯類"—

Repeal

"奈"

Substitute

"胺".

(38) Third Schedule, Chinese text, Division A, item relating to "抗血清、抗毒素、免疫球蛋白與疫苗", paragraph (b)—

Repeal

"乙型流感嗜血杆菌"

Substitute

"乙型流感嗜血桿菌".

(39) Third Schedule, Chinese text, Division A, item relating to "抗組胺物質"—

Repeal

"安他唑林"

Substitute

"安他唑啉".

(40) Third Schedule, Chinese text, Division A, item "炔已蟻胺"—

Repeal

"已"

Substitute

"己".

(41) Third Schedule, Chinese text, Division A, item "阿夫唑秦；其鹽類"—

Repeal

"秦"

Substitute

"嗪".

(42) Third Schedule, Chinese text, Division A—

(a) **Repeal item "阿伐他汀；其鹽類";**

(b) Before item "阿托伐醌"—

Add

"阿托伐他汀；其鹽類".

(43) Third Schedule, Chinese text, Division A—

(a) **Repeal item "阿紮胞苷；其鹽類";**

(b) After item "阿扎那韋；其鹽類"—

Add

"阿扎胞苷；其鹽類".

(44) Third Schedule, Chinese text, Division A, item "阿維A脂"—

Repeal

"脂"

Substitute

"酯".

(45) Third Schedule, Chinese text, Division A, item "依托泊甙；其酯類"—

Repeal

"甙"

Substitute

"苷".

(46) Third Schedule, Chinese text, Division A, item "依米氨脂"—

Repeal

"脂"

Substitute

"酯".

(47) Third Schedule, Chinese text, Division A, item "奈非那書；其鹽類"—

Repeal

"書"

Substitute

"韋".

(48) Third Schedule, Chinese text, Division A, item "泮庫溴銨；其鹽類"—

Repeal

"溴".

(49) Third Schedule, Chinese text, Division A, item relating to "肼(聯胺)類"—

Repeal

"它們的鹽類；它們的其酰基衍生物；它們的鹽類"

Substitute

"它們的鹽類；它們的酰基衍生物；它們的鹽類".

(50) Third Schedule, Chinese text, Division A, item "苯扎托品與其同系物；它們的鹽類"—

Repeal

"與"

Substitute

"及".

(51) Third Schedule, Chinese text, Division A—

(a) **Repeal item "苯甲酸利扎曲普坦；其鹽類";**

(b) Before item "利匹韋林；其鹽類"—

Add

"利扎曲坦；其鹽類".

(52) Third Schedule, Chinese text, Division A, item "美芬噁酮"—

Repeal

"噁"

Substitute

"諾".

(53) Third Schedule, Chinese text, Division A, item relating to "前列腺素類"—

Repeal

"地諾前列素(前列腺素F_{2a})"

Substitute

"地諾前列素(前列腺素$F_{2\alpha}$)".

(54) Third Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Bimatoprost";**

(b) **Add according to the number of strokes**

"貝美前列素".

(55) Third Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Travoprost";**

(b) **Add according to the number of strokes**

"曲伏前列素".

(56) Third Schedule, Chinese text, Division A, item relating to "前列腺素類"—

(a) **Repeal item "Unoprostone";**

(b) **Add according to the number of strokes**

"烏諾前列酮".

(57) Third Schedule, Chinese text, Division A, item "咪喹莫特；其鹽類"—

Repeal

"特"

Substitute

"德".

(58) Third Schedule, Chinese text, Division A—

(a) **Repeal item "香酰化纖溶酶原溶栓酶化劑複合物";**

(b) After item "氧烯洛爾；其鹽類"—

Add

"茴香酰化纖溶酶原溶栓酶活化劑複合物".

(59) Third Schedule, Chinese text, Division A, item "氨己稀酸"—

Repeal

"稀"

Substitute

"烯".

(60) Third Schedule, Chinese text, Division A, item "唑吡坦；其鹽類"—

Repeal

"咀"

Substitute

"坦".

(61) Third Schedule, Chinese text, Division A, item "唑來磷酸；其鹽類"—

Repeal

"磷"

Substitute

"膦".

(62) Third Schedule, Chinese text, Division A, item "胸腺肽a1"—

Repeal

"a"

Substitute

"α".

(63) Third Schedule, Chinese text, Division A—

(a) **Repeal item "6-烟鹼可待因；其鹽類";**

(b) After item relating to "煙酸及其鹽類"—

Add

"6-煙鹼可待因；其鹽類".

(64) Third Schedule, Chinese text, Division A—

(a) **Repeal item "培哚普利拉；其鹽類；其酯類；它們的鹽類";**

(b) After item "培氟沙星；其鹽類；其酯類"—

Add

"培哚普利拉；其鹽類；其酯類；它們的鹽類".

(65) Third Schedule, Chinese text, Division A, item "替尼泊甙"—

Repeal

"甙"

Substitute

"苷".

(66) Third Schedule, Chinese text, Division A, item relating to "氯醛"—

Repeal

"物，"

Substitute

"物；".

(67) Third Schedule, Chinese text, Division A—

(a) **Repeal item "普芦沙星；其鹽類；其酯類；它們的鹽類";**

(b) After item "普蘆卡必利；其鹽類"—

Add

"普蘆沙星；其鹽類；其酯類；它們的鹽類".

(68) Third Schedule, Chinese text, Division A—

(a) **Repeal item "斑布特羅及其鹽類，載於噴霧器時";**

(b) After item "索拉非尼；其鹽類"—

Add

"班布特羅及其鹽類，載於噴霧器時".

(69) Third Schedule, Chinese text, Division A—

(a) **Repeal item "富馬酸喹硫平；其鹽類";**

(b) After item "喹高利特；其鹽類"—

Add

"喹硫平；其鹽類".

(70) Third Schedule, Chinese text, Division A, item relating to "雄激素、雌激素與孕激素物質"—

Repeal

"具有雄激素或孕激素作用的類固醇化合物；它們的酯類茴"

Substitute

"具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類".

(71) Third Schedule, Chinese text, Division A, item "硼替左米"—

Repeal

"左"

Substitute

"佐".

(72) Third Schedule, Chinese text, Division A—

(a) **Repeal item "噻萘普汀；其鹽類；其酯類；它們的鹽類";**

(b) After item "噻托；其鹽類"—

Add

"噻奈普汀；其鹽類；其酯類；它們的鹽類".

(73) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Anagrelide；其鹽類";**

(b) After item "阿那曲唑；其鹽類"—

Add

"阿那格雷；其鹽類".

(74) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Brinzolamide；其鹽類";**

(b) After item "布托啡諾；其鹽類"—

Add

"布林佐胺；其鹽類".

(75) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Candesartan；其鹽類；其酯類；它們的鹽類";**

(b) Before item "克拉屈濱"—

Add

"坎地沙坦；其鹽類；其酯類；它們的鹽類".

(76) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Celecoxib；其鹽類";**

(b) After item "塞利洛爾；其鹽類"—

Add

"塞來考昔；其鹽類".

(77) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Cidofovir；其鹽類";**

(b) After item "西曲瑞克；其鹽類；其酯類；它們的鹽類"—

Add

"西多福韋；其鹽類".

(78) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Darbepoetin alfa";**

(b) After item "達非那新；其鹽類"—

Add

"達促紅素 α".

(79) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Eletriptan；其鹽類";**

(b) After item "依泊丁"—

Add

"依來曲坦；其鹽類".

(80) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Eprosartan；其鹽類";**

(b) After item "依普利酮"—

Add

"依普羅沙坦；其鹽類".

(81) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Eptifibatide；其鹽類";**

(b) Before item "依替福林；其鹽類"—

Add

"依替巴肽；其鹽類".

(82) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Etanercept";**

(b) Before item "依那普利；其鹽類"—

Add

"依那西普".

(83) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Fondaparinux；其鹽類";**

(b) After item "縮宮素類(催產素類)"—

Add

"磺達肝素(癸)；其鹽類".

(84) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Ibandronic acid；其鹽類";**

(b) Before item "伊普吲哚；其鹽類"—

Add

"伊班膦酸；其鹽類".

(85) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Imatinib；其鹽類";**

(b) After item "伊索昔康；其鹽類"—

Add

"伊馬替尼；其鹽類".

(86) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Imiglucerase";**

(b) After item "伊立替康；其鹽類"—

Add

"伊米苷酶".

(87) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Indinavir；其鹽類";**

(b) Before item "茚達特羅；其鹽類；其酯類；它們的鹽類"—

Add

"茚地那韋；其鹽類".

(88) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Lepirudin；其鹽類";**

(b) Before item "來曲唑"—

Add

"來匹蘆定；其鹽類".

(89) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Levosimendan；其鹽類";**

(b) After item "左乙拉西坦；其鹽類"—

Add

"左西孟旦；其鹽類".

(90) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Mangafodipir；其鹽類";**

(b) After item "諾氟沙星；其鹽類；其酯類"—

Add

"錳福地吡；其鹽類".

(91) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Metaflumizone；其鹽類";**

(b) After item "琥珀膽鹼；其鹽類"—

Add

"氰氟蟲腙；其鹽類".

(92) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Palivizumab";**

(b) After item "帕利哌酮；其鹽類"—

Add

"帕利珠單抗".

(93) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Pimecrolimus";**

(b) After item "吡洛芬；其鹽類"—

Add

"吡美莫司".

(94) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Rasburicase；其鹽類";**

(b) Before item "拉米夫定；其鹽類"—

Add

"拉布立酶；其鹽類".

(95) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Ritonavir；其鹽類";**

(b) After item "利托君；其鹽類"—

Add

"利托那韋；其鹽類".

(96) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Sevelamer；其鹽類";**

(b) After item "司替氨酯"—

Add

"司維拉姆；其鹽類".

(97) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Stavudine；其鹽類";**

(b) After item "司巴丁(金雀花鹼)；其鹽類"—

Add

"司他夫定；其鹽類".

(98) Third Schedule, Chinese text, Division A—

(a) **Repeal item relating to "Tadalafil";**

(b) After item "他莫昔芬；其鹽類"—

Add

"他達拉非；其鹽類；任何含有6-(5-苯并[1,3]二噁茂基)-2,3,6,7,12,12a-六氫吡嗪并[1',2':1,6]吡啶并[3,4-*b*]吲哚-1,4-二酮的化學結構(在任何程度上被取代或沒有被取代者)的化合物；其鹽類".

(99) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Tenecteplase；其鹽類";**

(b) After item "替拉曲考；其鹽類"—

Add

"替奈普酶；其鹽類".

(100) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Topotecan；其鹽類";**

(b) Before item "托哌酮；其鹽類"—

Add

"托泊替康；其鹽類".

(101) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Ustekinumab";**

(b) Before item "烏拉地爾；其鹽類"—

Add

"烏司奴單抗".

(102) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Valganciclovir；其鹽類";**

(b) After item "纈沙坦；其鹽類"—

Add

"纈更昔洛韋；其鹽類".

(103) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Verteporfin；其鹽類";**

(b) After item "維莫非尼；其鹽類"—

Add

"維替泊芬；其鹽類".

(104) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Voriconazole；其鹽類";**

(b) After item "曲普瑞林；其鹽類"—

Add

"伏立康唑；其鹽類".

(105) Third Schedule, Chinese text, Division A—

(a) **Repeal item "Ziprasidone；其鹽類";**

(b) After item "齊多夫定"—

Add

"齊拉西酮；其鹽類".

(106) Third Schedule, Division A—

(a) item "Colchicum, alkaloids of; their salts";

(b) item "Ephedrine; its optical isomers; their salts; when contained in aerosol dispensers";

(c) item "Rauwolfia, alkaloids of; their salts; derivatives of the alkaloids of rauwolfia; their salts";

(d) item "Vinca, alkaloids of"—

Repeal the items.

68. Fifth Schedule amended (indication of statement prescribed by regulation 15 for the purposes of section 27(c) of the Ordinance)

(1) Fifth Schedule, heading—

Repeal

"**INDICATION OF STATEMENT PRESCRIBED BY REGULATION 15 FOR THE PURPOSES OF SECTION 27(c) OF THE ORDINANCE**"

Substitute

"**TEXTS PRESCRIBED BY REGULATION 15 FOR PURPOSES OF SECTION 27(c) OR (ca)**".

(2) Fifth Schedule—

Repeal

"[reg. 15(2)]"

Substitute

"[reg. 15]".

(3) Fifth Schedule, English text—

(a) Paragraph 1;

(b) Paragraph 2;

(c) Paragraph 3;

(d) Paragraph 4;

(e) Paragraph 5;

(f) Paragraph 6;

(g) Paragraph 7;

(h) Paragraph 8;

(i) Paragraph 9;

(j) Paragraph 10—

Repeal

"words" (wherever appearing)

Substitute

"text".

(4) Fifth Schedule—

Add

"12. To be labelled with the text "Prescription Drug 處方藥物"—

Medicine containing a poison included in the Third Schedule

13. To be labelled with the text "Drug under Supervised Sales 監督售賣藥物"—

Medicine containing a poison included in Part I of the Poisons List but not containing a poison included in the Third Schedule".

69. Eighth Schedule amended

(1) Eighth Schedule—

(a) Form 1;

(b) Form 2;

(c) Form 3;

(d) Form 4;

(e) Form 5;

(f) Form 5A;

(g) Form 6;

(h) Form 7;

(i) Form 8;

(j) Form 9;

(k) Form 10;

(l) Form 12;

(m) Form 13;

(n) Form 14;

(o) Form 15;

(p) Form 16—

Repeal the Forms.

(2) Eighth Schedule—

Repeal Form 17

Substitute

"**Form 17** [reg. 41]

Form of Logo Prescribed for Section 13A

".

70. Ninth Schedule amended (fees)

(1) Ninth Schedule—

Repeal

"[regs. 26, 29, 36, 36B, 36D, 37A & 41]"

Substitute

"[regs. 24A, 26, 29, 30D, 30E, 36, 36B, 36D & 41]".

(2) Ninth Schedule, item 5—

Repeal

"Retention of premises on the register of premises, each year"

Substitute

"Renewal of registration of premises of an authorized seller of poisons".

(3) Ninth Schedule, item 9—

Repeal

"licence for wholesale dealers in poisons"

Substitute

"wholesale dealer licence".

(4) Ninth Schedule, after item 10—

Add

"10A.	Certificate of registration of an authorized person	1,420
10B.	Renewed certificate of registration of an authorized person	1,420".

(5) Ninth Schedule—

Repeal item 20.

71. Schedule 10 added

After the Ninth Schedule—

Add

"Schedule 10 [reg. 2A]

Poisons List

1. Interpretation

(1) In the Poisons List, a reference to a substance includes—

(a) that substance prepared either from natural sources or artificially; and

(b) that substance when contained as such in a preparation, solution, mixture or natural substance.

(2) In the Poisons List—

derivative (衍生物) means an organic compound of the following descriptions—

(a) it is related to another organic compound (***parent compound***) because it has—

(i) the same elemental ring, chain, nucleus or skeleton; and

(ii) similar pharmaceutical activity;

(b) it may have a molecular weight which may be the same as, or higher or lower (for example, after formation of a derivative by the process commonly known as dehydrogenation) than that of the parent compound; and

(c) its preparation may or may not require the presence of the parent compound.

(3) In the Poisons List—

(a) substances listed in Divisions A are those whose uses are essentially medicinal; and

(b) substances listed in Divisions B are not normally used medicinally.

2. Poisons List

The Poisons List is set out in the Table.

Table

Part I

Division A

Abacavir; its salts
Abatacept
Abciximab
Abiraterone; its salts
Acamprosate; its salts
Acarbose; its salts
Acebutolol; its salts
Acemetacin; its salts
Acetanilide; alkyl acetanilides
Acetazolamide; its salts
Acetohexamide
Acetorphine; its salts; its esters and ethers; their salts
Acetylcarbromal
Acetyldihydrocodeine; its salts
Aciclovir; its salts
Acipimox; its salts
Acitretin; its salts; its esters
Adalimumab
Adapalene; its salts; its esters
Adefovir; its salts; its esters; their salts

Aflibercept

Agalsidase beta

Agomelatine; its salts

Alclofenac; its complexes

Alcuronium; its salts

Aldesleukin

Alefacept

Alemtuzumab

Alendronic acid; its salts

Alfuzosin; its salts

Alglucosidase alfa

Aliskiren; its salts; its esters; their salts

Alizapride; its salts

Alkaloids, the following; their quaternary compounds; any salt, simple or complex, of any substance falling within the following—

Aconite, alkaloids of

Atropine

Belladonna, alkaloids of

Brucine

Calabar bean, alkaloids of

Coca, alkaloids of

Cocaine

Codeine; its esters and ethers

Colchicum, alkaloids of; their salts

Coniine

Cotarnine

Curare, alkaloids of; curare bases

Ecgonine; its esters and ethers

Emetine

Ephedra, alkaloids of

Ergot, alkaloids of

Galantamine

Gelsemium, alkaloids of

Homatropine

Hyoscine

Hyoscyamine

Lobelia, alkaloids of

Morphine; its esters and ethers

Nicotine (except when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy)

Nux Vomica, alkaloids of

Papaverine

Pilocarpus, alkaloids of

Pomegranate, alkaloids of

Quebracho, alkaloids of

Rauwolfia, alkaloids of; their derivatives

Sabadilla, alkaloids of

Stavesacre, alkaloids of

Strychnine

Thebaine

Veratrum, alkaloids of

Vinca, alkaloids of

Yohimba, alkaloids of

Allergen extract of Dermatophagoides pteronyssinus

Allopurinol

Allylisopropylacetylurea

Allylprodine; its salts

Almitrine; its salts

Alphadolone; its esters

Alphaxalone

Alprenolol; its salts

Alteplase

Alufibrate

Amantadine; its salts

Amidopyrine; its salts

Amifostine; its salts

Amiloride; its salts

Amineptine; its salts

Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids; their salts (except procaine when in a preparation containing any substance to which the Antibiotics Ordinance (Cap. 137) for the time being applies)

para-Aminobenzenesulphonamide; its salts; derivatives of para-aminobenzenesulphonamide having any of the hydrogen atoms of the para-amino group or of the sulphonamide group substituted by another radical; their salts

para-Aminobenzoic acid, esters of; their salts; except benzocaine when contained in condoms

Aminoglutethimide

5-Aminolevulinic acid; its salts; its derivatives; their salts

Aminophylline; its salts

Aminopterin; its derivatives

Aminorex; its salts

para-Aminosalicylic acid; its salts; its derivatives; their salts; any compound with any substance falling within this item

Amiodarone; its salts

Amisulpride; its salts

Amitriptyline; its salts

Amlodipine; its salts

Amrinone

Amsacrine; its salts

Amyl nitrite

Amylene hydrate

Anagrelide; its salts

Anastrozole; its salts

Androgenic, oestrogenic and progestational substances, the following—

Benzoestrol

Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their esters

Steroid compounds with androgenic or oestrogenic or progestational activity; their esters

Anidulafungin; its salts; its esters; their salts

Anileridine; its salts

Anistreplase

Antihistamine substances, the following; their salts; any compound with any substance falling within this item—

Acrivastine

Antazoline

Astemizole

Azelastine

Bromodiphenhydramine

Buclizine

Chlorcyclizine

Cyclizine

Desloratadine

3-Di-n-butylaminomethyl-4,5,6-trihydroxyphthalide

Dimethothiazine

Diphenhydramine

Doxylamine

Ebastine

Fexofenadine

Isothipendyl

Ketotifen

Loratadine (except Loratadine; its salts; when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis only)

Mebhydrolin

Meclozine

Methdilazine

Phenindamine

Promethazine

Terfenadine

Thenalidine

Trimeprazine

Tripelennamine

Substances being tetra-substituted N derivatives of ethylene-diamine or propylenediamine

Antihistamine substances other than the above; their salts; any compounds with such substances; when contained in preparations for parenteral use

Antilymphocyte Immunoglobulins

Antimony, chlorides of; organic compounds of; antimonates; antimonites

Antisera, antitoxins, immunoglobulins and vaccines—

(a) the following—

Bacillus Calmette-Guérin (BCG)

Meningococcal vaccines

Normal immunoglobulins

Pneumococcal vaccines

Rotavirus vaccines

Snake venom antisera

Staphylococcal vaccines

Streptococcal vaccines;

(b) directed against the following diseases, viruses or organisms—

Bordetella species

Botulism

Canine infectious disease
Cholera
Diphtheria
Feline calicivirus
Feline Chlamydia psittaci
Feline immunodeficiency virus
Feline leukemia virus
Feline panleukopenia virus
Feline rhinotracheitis virus
Haemophilus influenzae type b
Hepatitis A
Hepatitis B
Herpes simplex
Herpes zoster
Human papillomavirus
Influenza
Japanese encephalitis
Measles
Mumps
Pertussis
Plague
Poliomyelitis
Rabies
Rubella
Tetanus
Typhoid
Varicella

Yellow fever

Antithymocyte Immunoglobulin

Apixaban; its salts

Apomorphine; its salts; its quaternary compounds

Apraclonidine; its salts

Aprepitant; its salts

Aprindine; its salts

Aripiprazole

Arsenic trioxide when contained in pharmaceutical products

Arsenical substances, the following: halides of arsenic; organic compounds of arsenic; oxides of arsenic; sulphides of arsenic; arsenates; arsenites; thioarsenates

Artemether; its salts

Articaine; its salts

Asenapine; its salts; its isomers

Atazanavir; its salts

Atenolol; its salts

Atomoxetine; its salts

Atorvastatin; its salts

Atosiban; its salts

Atovaquone

Atracurium besylate

Auranofin

Axitinib; its salts

Azacitidine; its salts

Azacyclonol; its salts

Azapropazone

Azauridine; its derivatives

Azilsartan; its salts; its esters; their salts

Aziridine; its derivatives

Baclofen

Bambuterol; its salts

Barbituric acid; its salts; its derivatives; their salts; any compound with any substance falling within this item

Basiliximab; its salts

Becaplermin; its salts

Befunolol; its salts

Belimumab

Bemiparin; its salts

Benactyzine; its salts

Benazepril; its salts

Benoxaprofen; its salts

Benserazide; its salts

Benzbromarone

Benzethidine; its salts

Benzhexol; its salts

Benzoylmorphine; its salts

Benzquinamide

Benztropine and its homologues; their salts

Benzydamine; its salts

Benzylmorphine; its salts

Besifloxacin; its salts; its esters; their salts

Betaxolol; its salts

Bethanidine; its salts

Bevacizumab

Bezafibrate

Bezitramide; its salts

Bicalutamide; its salts

Bifonazole; its salts

Biperiden; its salts

Biphenylacetic acid; its salts; its esters

N-[4,4-Bis(para-fluorophenyl)butyl]piperidine,4-substituted derivatives of; their salts

Bisoprolol; its salts

Bitolterol; its salts

Blood products derived from human blood or manufactured by biotechnology, the following—

- Albumin
- Antithrombins
- Blood clotting factors
- Fibrin
- Fibrinogen
- Plasma protein fractions
- Thrombin

Boceprevir; its salts

Bortezomib

Bosentan; its salts

Botulinum toxin complexes

Bretylium tosylate

Brimonidine; its salts

Brinzolamide; its salts

Bromocriptine; its salts

Bromvaletone

Broncho-Vaxom

Brotizolam

Bucolome

Bufexamac

Buformin; its salts

Bumadizone; its salts

Bumetanide; its salts; its derivatives; their salts

Bupivacaine; its salts

Bupranolol; its salts

Buprenorphine; its salts

Bupropion; its salts

Buserelin; its salts

Buspirone; its salts

Busulphan; its salts

Butorphanol; its salts

Butylchloral hydrate

Cabazitaxel; its salts; its esters; their salts

Cabergoline; its salts

Calcipotriol; its salts

Canakinumab

Candesartan; its salts; its esters; their salts

Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item

Cannabis; the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tannate

Cantharidin; cantharidates

Capecitabine; its salts

Captodiamine; its salts

Captopril

Caramiphen; its salts

Carbachol

Carbamazepine

Carbidopa; its salts

Carbimazole; its salts

Carboplatin

Carbromal

Carbutamide

Carisoprodol

Carmustine

Carperidine; its salts

Carprofen; its salts

Carteolol; its salts

Carvedilol; its salts

Caspofungin; its salts

Celecoxib; its salts

Celiprolol; its salts

Cerivastatin; its salts

Certolizumab pegol

Cetrorelix; its salts; its esters; their salts

Cetuximab

Chlofenamic acid; its salts

Chloral; its addition and its condensation products; any compound with any substance falling within this item

Chlordiazepoxide; its salts

Chlormethiazole; its salts

Chlormezanone

Chloroform

Chloroquine; its salts; its derivatives; their salts

Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide 1,1-dioxide, whether hydrogenated or not; their salts

Chlorphenoxamine; its salts

Chlorphentermine; its salts

Chlorpropamide; its salts

Chlorprothixene and other derivatives of 9-methylenethiaxanthen; their salts

Chlorthalidone and other derivatives of ortho-chlorobenzenesulphonamide

Chlorzoxazone

Chorionic Gonadotrophin

Chymopapain

Cicletanine; its salts

Cidofovir; its salts

Cilazapril; its salts

Cilostazol; its salts

Cinacalcet; its salts

Cinepazide; its salts

Ciprofibrate; its salts

Ciprofloxacin; its salts; its esters
Cisapride
Cisatracurium besylate
Cisplatin
Citalopram; its salts
Cladribine
Clioquinol
Clobazam
Clodronic acid; its salts; its esters
Clofarabine; its salts; its esters; their salts
Clofazimine; its salts
Clofibrate
Clomiphene; its salts
Clomipramine; its salts; its derivatives; their salts
Clonidine; its salts
Clonitazene; its salts
Clopidogrel; its salts
Clorexolone
Cloridarol
Clorprenaline; its salts
Clothiapine
Clotrimazole; its salts
Clozapine; its salts
Cobicistat; its salts
Colaspase
Colfosceril; its salts
Collagen, purified

Contrast media, the following; their salts; any compound with any substance falling within this item; when contained in preparations for parenteral use—

Acetrizoic acid

Diatrizoic acid

Ferucarbotran

Gadobenic acid

Gadobutrol

Gadodiamide

Gadopentetic acid

Gadoteric acid

Iobitridol

Iocarmic acid

Iocetamic acid

Iodamide

Iodipamide

Iodised oil

Iodixanol

Iodoxamic acid

Ioglicic acid

Ioglycamic acid

Iohexol

Iomeprol

Iopamidol

Iopanoic acid

Iophendylate

Iopromide

Iothalamic acid
Iotrolan
Iotroxic acid
Ioversol
Ioxaglic acid
Ioxitalamic acid
Ipodic acid
Metrizamide
Propyliodone
Sulphur hexafluoride
Tyropanoic acid

Corifollitropin alfa
Corticorelin; its salts
Corticotrophins
Corynebacterium parvum
Creosote obtained from wood
Crizotinib; its salts
Croton, oil of
4-Cyano-2-dimethylamino-4,4-diphenylbutane; its salts
4-Cyano-1-methyl-4-phenylpiperidine; its salts
Cyclarbamate
Cyclobenzaprine; its salts
Cyclofenil
1-Cyclohexyl-3-para-toluenesulphonylurea (tolcyclamide)
Cyclosporin A
Cycrimine; its salts
Cytarabine; its salts

Dabigatran etexilate; its salts
Dacarbazine
Daclizumab
Dalteparin; its salts
Dapagliflozin; its salts
Dapoxetine; its salts
Dapsone
Darbepoetin alfa
Darifenacin; its salts
Darunavir; its salts
Dasatinib; its salts
Deanol acetamidobenzoate
Debrisoquine; its salts
Deferasirox; its salts; its esters; their salts
Deferiprone; its salts
Degarelix; its salts
Dehydroemetine; its salts
Demecarium bromide
Denosumab
Desferrioxamine; its salts
Desipramine; its salts
Desomorphine; its salts; its esters and ethers; their salts
Desvenlafaxine; its salts
Dexketoprofen; its salts
Dexlansoprazole; its salts
Dexmedetomidine; its salts
Dexrazoxane; its salts

Diacerein; its salts; its esters

Diacetylnalorphine; its salts

Diampromide; its salts

Diazepam and other compounds containing the chemical structure of dihydro-1,4-benzodiazepine substituted to any degree; their salts

Diazoxide

Diclofenac; its salts

Didanosine; its salts

Diethylaminoethylephedrine; its salts

Diethyl para-nitrophenyl phosphate

Difenoxin; its salts

Diflunisal

Digitalis, glycosides of; other active principles of digitalis

Dihydralazine; its salts

Dihydrocodeine; its salts; its esters and ethers; their salts

Dihydrocodeinone; its salts

Dihydrocodeinone O-carboxymethyloxime; its salts; its esters; their salts

Dihydrocodeinone enol acetate; its salts

Dihydroergotamine; its salts, simple or complex

Dihydroetorphine; its salts

Dihydromorphine; its salts; its esters and ethers; their salts

3-(3,4-Dihydroxyphenyl)alanine; its salts

Diltiazem; its salts

Dimefline; its salts

Dimenoxadole; its salts

Dimepheptanol; its salts; its esters and ethers; their salts
Dioxaphetyl butyrate; its salts
Diperodon; its salts
Diphenoxylate; its salts
Dipipanone; its salts
Diprenorphine; its salts
Dipyridamole
Disopyramide; its salts
Distigmine; its salts
Disulfiram
Dithienylallylamines; dithienylalkylallylamines; their salts
Dobutamine; its salts
Docetaxel; its salts
Domperidone; its salts
Donepezil; its salts
Dopamine; its salts
Dornase alfa
Dorzolamide; its salts
Dothiepin; its salts
Doxapram; its salts
Doxazosin; its salts
Doxepin; its salts; its derivatives; their salts
Dronedarone; its salts
Droperidol
Drotrecogin alfa
Duloxetine; its salts
Dutasteride

Dyflos
Econazole; its salts
Ecothiopate iodide
Ectylurea
Eculizumab
Efalizumab
Efavirenz; its salts
Elaterin
Eletriptan; its salts
Eltrombopag; its salts; its esters; their salts
Elvitegravir; its salts
Embutramide
Emtricitabine; its salts
Emylcamate
Enalapril; its salts
Enalaprilat; its salts
Enfuvirtide
Enoxacin; its salts; its esters
Enoxaparin; its salts
Enoximone
Enrofloxacin; its salts; its esters
Entacapone; its salts
Entecavir; its salts; its esters; their salts
Eplerenone
Epoetin beta
Eprosartan; its salts
Eptifibatide; its salts

Eribulin; its salts
Erlotinib; its salts
Erythrityl tetranitrate
Esmolol; its salts
Esomeprazole; its salts
Etafedrine; its salts
Etafenone; its salts
Etamivan; its salts
Etanercept
Ethacrynic acid; its salts
Ethambutol; its salts
Ethchlorvynol
Ethinamate
Ethionamide
Ethoglucid
Ethoheptazine; its salts
Ethosuximide; its salts
Ethylmorphine; its salts; its esters and ethers; their salts
Ethylnoradrenaline; its salts
Etidronic acid; its salts
Etilefrine; its salts
Etodolac
Etofibrate
Etomidate; its salts
Etonitazene; its salts
Etoposide; its esters
Etoricoxib; its salts

Etorphine; its salts; its esters and ethers; their salts
Etoxeridine; its salts
Etravirine
Etretinate
Etryptamine; its salts
Everolimus; its salts; its esters; their salts
Exemestane; its salts
Exenatide
Ezetimibe
Famciclovir; its salts
Fampridine; its salts
Febuxostat; its salts; its esters; their salts
Felodipine
Fenbufen
Fencamfamin; its salts
Fenclofenac; its salts
Fendiline; its salts
Fenfluramine; its salts
Fenofibrate
Fenoprofen; its salts
Fenoterol; its salts
Fenoxazoline; its salts
Fentanyl; its salts
Fentiazac; its salts
Fenticonazole; its salts
Feprazone
Fesoterodine; its salts; its esters; their salts

Filgrastim
Finasteride
Fingolimod; its salts; its esters; their salts
Flavoxate; its salts
Flecainide; its salts
Fleroxacin; its salts; its esters
Fluanisone
Fluconazole; its salts
Flucytosine
Fludarabine; its salts
Flufenamic acid; its salts; its esters; their salts
Flumazenil
Flumethrin; its salts
Fluorouracil; its derivatives
Fluoxetine; its salts
Flupenthixol; its salts
Flurbiprofen
Fluspirilene
Flutamide
Fluvastatin
Fluvoxamine; its salts
Folinic acid; its salts
Fondaparinux; its salts
Formestane
Formoterol; its salts
Fosaprepitant; its salts
Foscarnet trisodium hexahydrate

Fosinopril; its salts
Fosphenytoin; its salts
Fotemustine; its salts
Frusemide
Fulvestrant
Furethidine; its salts
Gabapentin; its salts
Gadoxetic acid; its salts
Gallamine; its salts; its quaternary compounds
Gallopamil; its salts
Galsulfase
Ganciclovir; its salts
Ganirelix; its salts
Gatifloxacin; its salts; its esters
Gefitinib; its salts
Gemcitabine; its salts
Gemfibrozil
Gimeracil; its salts
Glibenclamide
Glibornuride
Gliclazide
Glimepiride; its salts
Glipizide
Gliquidone
Glucagon; its salts
Glutethimide; its salts
Glyceryl trinitrate

Glycopyrronium; its salts

Glymidine

Golimumab

Gonadorelin; its salts

Goserelin; its salts

Granisetron; its salts

Grepafloxacin; its salts; its esters

Guanabenz; its salts

Guanethidine; its salts

Guanfacine; its salts

Guanidines, the following—

Polymethylene diguanidines; di-para-anisyl-para-phenethylguanidine; their salts

Halofantrine; its salts

Halofuginone; its salts

Haloperidol and other 4-substituted derivatives of N-(3-para-fluorobenzoylpropyl) piperidine

Hexamethylmelamine

Hexapropymate

Hexobendine; its salts

Hydralazine; its salts

Hydrazines, the following and their alpha-methyl derivatives—

Benzyl hydrazine

Phenethyl hydrazine

Phenoxyethyl hydrazine

their salts; their acyl derivatives; their salts

Hydrocyanic acid; cyanides, other than ferrocyanides and ferricyanides

Hydromorphinol; its salts; its esters and ethers; their salts

Hydromorphone; its salts; its esters and ethers; their salts

Hydroxycinchoninic acids; derivatives of; their salts; their esters

Hydroxy-N,N-dimethyltryptamines; their esters and ethers; any salt of any substance falling within this item

3-Hydroxy-N-methylmorphinan; its salts; its optical isomers; their salts

3-Hydroxymorphinan; its salts; its optical isomers; their salts; their esters and ethers; their salts

3-Hydroxy-N-phenacylmorphinan; its salts; its optical isomers; their salts; their esters and ethers; their salts

Hydroxypethidine; its salts; its esters and ethers; their salts

Hydroxyphenamate

Hydroxyurea

Hydroxyzine; its salts

Ibandronic acid; its salts

Ibritumomab tiuxetan

Ibuprofen; its salts

Idursulfase

Ifosfamide

Iloprost; its salts

Imatinib; its salts

Imidapril; its salts

Imiglucerase

Imipramine; its salts

Imiquimod; its salts

Indacaterol; its salts; its esters; their salts

Indinavir; its salts

Indomethacin; its salts

Indoprofen; its salts

Indoramin; its salts

Infliximab

Inosine

Inosine pranobex

Insulin

Interferons

Iprindole; its salts

Irbesartan; its salts

Irinotecan; its salts

Isoaminile; its salts

Isoconazole; its salts

Isoetharine; its salts

Isomethadone; its salts

Isoniazid; its salts; its derivatives; their salts; any compound with any substance falling within this item

Isoprenaline; its salts

Isopyrin; its salts

Isosorbide; its nitrates

Isotretinoin

Isoxicam; its salts

Isradipine

Itraconazole; its salts

Ivabradine; its salts

Ketamine; its salts

Ketanserin; its salts

Ketobemidone; its salts; its esters and ethers; their salts

Ketoconazole

Ketophenylbutazone

Ketoprofen; its salts

Ketorolac; its salts; its esters

Labetalol; its salts

Lacidipine; its salts

Lacosamide; its salts

Lamivudine; its salts

Lamotrigine; its salts

Lanreotide; its salts

Lansoprazole

Lanthanum carbonate

Lapatinib; its salts

Laronidase

Laropiprant; its salts

Laudexium; its salts

Lead acetates; compounds of lead with acids from fixed oils

Leflunomide; its salts

Lenalidomide; its salts

Lepirudin; its salts

Lercanidipine; its salts

Letrozole

Leuprorelin; its salts

Levallorphan; its salts

Levetiracetam; its salts

Levodropropizine; its salts

Levosimendan; its salts

Lidoflazine

Lignocaine; its salts

Linagliptin; its salts

Linezolid; its salts

Liraglutide

Lisinopril; its salts

Lithium carbonate

Lithium sulphate

Lixisenatide

Lodoxamide tromethamine

Lomefloxacin; its salts; its esters

Lomustine

Lonazolac; its salts

Lopinavir; its salts

Loracarbef; its salts

Lorcainide; its salts

Losartan; its salts

Lovastatin

Loxapine; its salts

Lumefantrine; its salts

Lysergamide; its salts, simple or complex; its quaternary compounds

Lysergic acid; its salts, simple or complex; its quaternary compounds

Lysergide; its salts, simple or complex; its quaternary compounds

Lysuride; its salts

Mangafodipir; its salts

Mannityl hexanitrate

Mannomustine; its salts

Maprotiline; its salts

Maraviroc; its salts

Marbofloxacin; its salts

Mazindol

Mebezonium iodide

Mebutamate

Mecamylamine; its salts

Meclofenamic acid; its salts

Meclofenoxate; its salts

Medigoxin

Mefenamic acid; its salts; its esters; their salts

Mefloquine; its salts

Mefruside

Melagatran; its salts; its derivatives; their salts

Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia

Melitracen; its salts

Meloxicam; its salts

Memantine; its salts

Mephenesin; its esters; their salts

Mephenoxalone

Mepirizole; its salts

Mepivacaine; its salts

Meprobamate

alpha-Meprodine; its salts

beta-Meprodine; its salts

Mercaptopurine; its salts; its derivatives; their salts

Mercury, nitrates of; organic compounds of; oxides of; mercuric ammonium chloride; mercuric chloride; mercuric iodide; mercuric oxycyanide; mercuric thiocyanate; potassiomercuric iodides

Meropenem; its salts

Mertiatide; its salts; its esters; their salts

Mesalazine; its salts

Mescaline; its salts; other derivatives of phenethylamine formed by substitution in the aromatic ring; their salts

Mesocarb; its salts

Metaflumizone; its salts

Metaraminol; its salts

Metaxalone

Metazocine; its salts; its esters and ethers; their salts

Metergoline

Metformin; its salts

Methadone; its salts

Methadyl acetate; its salts

Methaqualone; its salts

Methimazole; its salts

Methixene; its salts

Methocarbamol

Methorphan; its salts; its optical isomers; their salts

Methoxsalen

Methoxyphenamine; its salts

Methylaminoheptane; its salts

Methyldesorphine; its salts; its esters and ethers; their salts

Methyldihydromorphine; its salts; its esters and ethers; their salts

Methyldopa; its esters; their salts

2-Methyl-3-morpholino-1,1-diphenylpropane carboxylic acid; its salts; its esters; their salts

Methylnaltrexone; its salts

Methylpentynol; its derivatives

alpha-Methylphenethylamine; beta-methylphenethylamine; alpha-ethylphenethylamine; beta-ethylphenethylamine; their optical isomers; any synthetic compound structurally derived from any of those substances by substitution in the aliphatic part or by ring closure therein (or by both such substitution and such closure) or by substitution in the aromatic ring (with or without substitution at the nitrogen atom), except hydroxyamphetamine, methoxyphenamine, pholedrine and N-substituted derivatives of ephedrine; any salt of any substance falling within this item

Methylphenidate; its salts

1-Methyl-4-phenylpiperidine-4-carboxylic acid; its salts; its esters; their salts

Methyprylone

Metipranolol; its salts

Metoclopramide; its salts
Metolazone
Metopon; its salts; its esters and ethers; their salts
Metoprolol; its salts
Metronidazole; its salts
Metyrapone; its salts
Mexiletine; its salts
Mianserin; its salts
Mibefradil; its salts
Micafungin; its salts; its esters
Miconazole; its salts
Midodrine; its salts
Mifepristone; its salts; its esters; their salts
Miglitol; its salts
Milnacipran; its salts
Milrinone; its salts
Minoxidil
Mirabegron; its salts; its esters; their salts
Mirtazapine; its salts
Mitobronitol
Mitopodozide; its salts
Mitotane
Mitoxantrone; its salts
Mivacurium; its salts
Mizolastine; its salts
Moclobemide; its salts
Moexipril; its salts

Mofebutazone; its salts

Molgramostim

Molindone; its salts

Montelukast; its salts

Moracizine; its salts

Moramide; its salts; its optical isomers; their salts

Moroxydine; its salts

Morpheridine; its salts

Moxifloxacin; its salts

Moxonidine; its salts

Muromonab-CD3

Mustine and any other N-substituted derivative of di-(2-chloroethyl)amine; their salts

Muzolimine

Mycophenolic acid; its salts; its esters

Myrophine; its salts

Myrtecaine; its salts

Nabumetone

Nadolol; its salts

Nadroparin; its salts

Nafarelin; its salts

Naftidrofuryl; its salts

Nalbuphine; its salts

Nalidixic acid

Nalorphine; its salts

Naloxone; its salts

Naltrexone; its salts

alpha-Naphthylacetic acid; its salts

Naproxen; its salts

Naratriptan; its salts

Natalizumab

Nateglinide; its salts; its esters

Nebivolol; its salts

Nedocromil; its salts

Nefazodone; its salts

Nefopam; its salts

Nelfinavir; its salts

Neostigmine; its salts

Nepafenac; its salts

Nesiritide

Nevirapine; its salts

Nicergoline

Niclofolan

Nicocodine; its salts

Nicotinic acid and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 200 mg of nicotinic acid

Nifedipine

Nifenazone

Niflumic acid; its salts

Nilotinib; its salts

Nilvadipine

Nimesulide; its salts

Nimodipine

Nisoldipine
Nitrendipine
Nitromethaqualone; its salts
Nomifensine; its salts
Noracymethadol; its salts
Noramidopyrine methanesulphonate; its salts
Norcodeine; its salts; its esters and ethers; their salts
Norfloxacin; its salts; its esters
Normethadone; its salts
Normorphine; its salts; its esters and ethers; their salts
Norpipanone; its salts
Nortriptyline; its salts
Octreotide; its salts
Ofloxacin; its salts; its esters
Olanzapine; its salts
Olmesartan; its salts; its esters; their salts
Olsalazine; its salts
Omalizumab
Omeprazole; its salts
Omoconazole; its salts
Ondansetron; its salts
Opipramol; its salts; its derivatives; their salts
Opium
Orciprenaline; its salts
Orgotein
Orlistat; its salts
Orphenadrine; its salts

Orthocaine; its salts
Oseltamivir; its salts
Oteracil; its salts
Ouabain
Oxalic acid; its salts other than quadroxalates
Oxaliplatin; its salts
Oxanamide
Oxcarbazepine; its salts
Oxethazaine; its salts
Oxiconazole; its salts
Oxolamine; its salts
Oxprenolol; its salts
Oxycinchoninic acid; its derivatives; their salts; their esters
Oxycodone; its salts; its esters and ethers; their salts
Oxyfedrine; its salts
Oxymorphone; its salts; its esters and ethers; their salts
Oxypertine
Oxyphenbutazone
Oxytocins
Paclitaxel
Paliperidone; its salts
Palivizumab
Palonosetron; its salts
Pamidronate; its salts
Pancuronium; its salts
Panitumumab
Pantethine; its salts

Pantoprazole; its salts
Paraldehyde
Paramethadione
Parecoxib; its salts
Pargyline; its salts
Paricalcitol; its salts; its esters; their salts
Paroxetine; its salts
Pasireotide; its salts
Pazopanib; its salts
Pefloxacin; its salts; its esters
Pegaptanib; its salts
Pegfilgrastim
Pegvisomant; its salts
Pemetrexed; its salts; its esters; their salts
Pemirolast; its salts
Pemoline; its salts
Pempidine; its salts
Penbutolol; its salts
Penciclovir; its salts
Penicillamine; its salts
Pentaerythritol tetranitrate
Pentamidine; its salts
Pentazocine; its salts
Pentolinium; its salts
Perampanel
Pergolide; its salts
Perindoprilat; its salts; its esters; their salts

Pertuzumab

Phenacemide

Phenacetin

Phenadoxone; its salts

Phenaglycodol

Phenampromide; its salts

Phenazocine; its salts; its esters and ethers; their salts

Phenbutrazate

Phencyclidine; its salts

Phenetidylphenacetin

Phenformin; its salts

Phenindione

Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by 1 atom of carbon and 2 atoms of hydrogen) except in substances containing less than 60%, weight in weight, of phenols; compounds of phenol with a metal, except in substances containing less than the equivalent of 60%, weight in weight, of phenols

Phenomorphan; its salts; its esters and ethers; their salts

Phenoperidine; its salts; its esters and ethers; their salts

Phenothiazine; its salts; its derivatives (except dimethoxanate); their salts (except salts of dimethoxanate); any compound with any substance falling within this item

Phenoxybenzamine; its salts

Phenprenazone

Phenprobamate

Phentolamine; its salts

Phenylbutazone; its salts

2-Phenylcinchoninic acid; 2-salicylcinchoninic acid; their salts; their esters

5-Phenylhydantoin; its alkyl and aryl derivatives; their salts

4-Phenylpiperidine-4-carboxylic acid ethyl ester; its salts

Pholcodine; its salts; its esters and ethers; their salts

Picric acid

Picrotoxin

Pimecrolimus

Piminodine; its salts

Pioglitazone; its salts

Pipecuronium; its salts

Pipemidic acid

Pipobroman

Piritramide; its salts

Piromidic acid; its salts

Piroxicam

Pirprofen; its salts

Pituitary gland, the active principles of, other than corticotrophins, oxytocins and vasopressins

Pizotifen; its salts

Plerixafor; its salts

Podophyllum resin

Polymethylenebistrimethylammonium salts

Poractant alfa

Posaconazole; its salts; its esters; their salts

Pralidoxime; its salts

Pramipexole; its salts
Pramoxine; its salts
Prasugrel; its salts
Pravastatin; its salts; its esters
Prazosin; its salts
Pregabalin; its salts
Pridinol; its salts
Primaquine; its salts
Primidone
Prindolol; its salts
Probucol
Procainamide; its salts
Procarbazine; its salts
Procaterol; its salts
Procyclidine; its salts
alpha-Prodine; its salts
beta-Prodine; its salts
Proglumetacin; its salts
Proguanil; its salts
Proheptazine; its salts
Promoxolane
Propafenone; its salts
Propanidid
Propiverine; its salts
Propofol
Propoxur; its salts
Propoxyphene; its salts; its optical isomers; their salts

Propranolol; its salts; its derivatives; their salts

Propylhexedrine; its salts

Propylthiouracil; its salts

Proquazone

Prostaglandins, the following and their derivatives—

Alprostadil

Bimatoprost

Dinoprost

Dinoprostone

Latanoprost

Misoprostol

Travoprost

Unoprostone

their salts; their esters

Prothionamide

Prothipendyl; its salts

Protirelin; its salts

Protriptyline; its salts; its derivatives; their salts

Prucalopride; its salts

Prulifloxacin; its salts; its esters; their salts

Pseudoephedrine; its salts

Pyrazinamide

Pyricarbate (Pyridinolcarbamate)

Pyridostigmine; its salts

Pyrimethamine

Pyrithyldione

Quetiapine; its salts

Quinagolide; its salts
Quinapril; its salts
Quinethazone
Quinidine; its salts
Quinine; its salts; its derivatives; their salts
Rabeprazole; its salts
Racecadotril; its salts
Ractopamine; its salts
Raloxifene; its salts
Raltegravir; its salts
Raltitrexed; its salts
Ramipril; its salts
Ranibizumab
Rasagiline; its salts
Rasburicase; its salts
Reboxetine; its salts
Recombinant human erythropoietin
Regorafenib; its salts
Remifentanil; its salts
Remoxipride; its salts
Repaglinide; its salts; its esters
Reproterol; its salts
Rescinnamine
Reteplase
Retigabine; its salts
Reviparin; its salts
Ribavirin; its salts

Rilmenidine; its salts
Rilpivirine; its salts
Riluzole; its salts
Rimiterol; its salts
Rimonabant; its salts
Risedronic acid; its salts
Risperidone
Ritodrine; its salts
Ritonavir; its salts
Rituximab
Rivaroxaban; its salts
Rivastigmine; its salts
Rizatriptan; its salts
Rocuronium; its salts
Rofecoxib; its salts
Roflumilast; its salts
Romiplostim
Ropinirole; its salts
Ropivacaine; its salts
Rosiglitazone; its salts
Rosoxacin; its salts
Rosuvastatin; its salts
Rotigotine; its salts
Ruxolitinib; its salts
Salbutamol; its salts
Salmeterol; its salts
Saquinavir; its salts

Savin, oil of

Saxagliptin; its salts

Sermorelin; its salts

Sertaconazole; its salts

Sertindole; its salts

Sertraline; its salts

Sevelamer; its salts

Sibutramine; its salts; any compound containing the chemical structure of 1-[1-(4-Chlorophenyl)cyclobutyl]-3-methylbutan-1-amine substituted to any degree or without substitution; its salts

Sildenafil; its salts; any compound containing the chemical structure of 5-(2-ethoxyphenyl)-1-methyl-3-propyl-1*H*-pyrazolo[4,3-*d*]pyrimidin-7(6*H*)-one substituted to any degree or without substitution; its salts

Simvastatin

Sirolimus; its salts

Sitagliptin; its salts

Sodium aurothiomalate

Sodium cromoglycate

Sodium nitroprusside

Solifenacin; its salts; its esters; their salts

Somatostatin

Sorafenib; its salts

Sotalol; its salts

Sparfloxacin; its salts; its esters

Sparteine; its salts

Spinosad

Spironolactone

Stavudine; its salts

Streptokinase

Strontium ranelate

Strophanthus, glycosides of

Styramate

Sulconazole; its salts

Sulindac

Sulphinpyrazone

Sulphonal; alkyl sulphonals

Sulpiride

Sultopride

Sumatriptan; its salts

Sunitinib; its salts

Suprarenal gland, the active principles of; their salts; their derivatives; their salts

Sutoprofen; its salts

Suxamethonium; its salts

Syrosingopine

Tacrine; its salts

Tacrolimus

Tadalafil; its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts

Tafluprost

Tamoxifen; its salts

Tazarotene; its salts

Tegaserod; its salts

Telbivudine; its salts

Telmisartan; its salts

Temozolomide; its salts

Temsirolimus; its salts; its esters

Tenecteplase; its salts

Teniposide

Tenofovir; its salts; its esters; their salts

Tenoxicam

Terazosin; its salts

Terbinafine; its salts; except when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled for the treatment of tinea pedis and/or tinea cruris only

Terbutaline; its salts

Terconazole; its salts

Teriparatide; its salts

Terodiline; its salts

Tertatolol; its salts

Tetrabenazine; its salts

Tetracosactide; its salts

Thalidomide; its salts

Thallium, salts of

Theofibrate

Theophylline; its salts

Thiacetazone

Thiocarlide; its salts

Thioctic acid; its salts; its derivatives; when contained in pharmaceutical products

Thiotepa

Thymosin alpha 1

Thyroid gland, the active principles of; their salts

Thyrotropin alfa

Tiagabine; its salts; its esters; their salts

Tianeptine; its salts; its esters; their salts

Tiapride; its salts

Ticagrelor; its salts; its esters; their salts

Ticlopidine; its salts

Tiletamine; its salts

Tilidate; its salts

Tiludronic acid; its salts

Timolol; its salts

Tinidazole; its salts

Tinoridine; its salts

Tinzaparin; its salts

Tioconazole; its salts

Tiotropium; its salts

Tiratricol; its salts

Tirofiban; its salts

Tizanidine; its salts

Tocainide; its salts

Tocilizumab

Todralazine; its salts

Tofacitinib; its salts
Tofenacin; its salts
Tolazamide
Tolbutamide
Tolcapone; its salts
Tolfenamic acid; its salts
Tolmetin; its salts
Tolperisone; its salts
Tolterodine; its salts
Tolvaptan
para-Tolylmethylcarbinol nicotinic acid ester
Topiramate; its salts
Topotecan; its salts
Torasemide
Trabectedin; its salts; its esters
Tramadol; its salts
Trandolapril; its salts
Tranexamic acid
Tranylcypromine; its salts
Trastuzumab
Trazodone; its salts
Tretamine; its salts
Tretinoin
Tretoquinol; its salts
Triamterene; its salts
Triaziquone
Tribromoethyl alcohol

2,2,2-Trichloroethyl alcohol, esters of; their salts
Trifluridine; its salts
Trilostane
Trimeperidine; its salts
Trimetaphan; its salts
Trimetazidine; its salts
Trimethadione
Trimethoprim
Trimetozine
Trimetrexate; its salts
Trimipramine; its salts
Trioxsalen
Triptorelin; its salts
Tromantadine; its salts
Tropisetron; its salts
Trovafloxacin; its salts; its derivatives; their salts
Tulobuterol; its salts
Tybamate
Urapidil; its salts
Urethane
Urokinase
Ustekinumab
Valaciclovir; its salts
Valdecoxib; its salts
Valganciclovir; its salts
Valnoctamide
Valproic acid; its salts; its esters

Valsartan; its salts

Vandetanib; its salts

Vardenafil; its salts; any compound containing the chemical structure of 2-(2-ethoxyphenyl)-5-methyl-7-propylimidazo[5,1-*f*][1,2,4]triazin-4(3*H*)-one substituted to any degree or without substitution; its salts

Varenicline; its salts

Vasopressins

Vecuronium; its salts

Vemurafenib; its salts

Venlafaxine; its salts

Veralipride; its salts

Verapamil; its salts

Vernakalant; its salts

Verteporfin; its salts

Vidarabine; its salts

Vigabatrin

Vilanterol; its salts

Vildagliptin; its salts

Viloxazine; its salts

Vindesine; its salts

Vinorelbine; its salts

Vitamin A and its esters when contained in pharmaceutical products the recommended daily dose of which contains not less than 10 000 international units of vitamin A

Voriconazole; its salts

Warfarin; its salts

Xamoterol; its salts

Xylazine; its salts

Zafirlukast

Zalcitabine; its salts

Zaleplon; its salts

Zanamivir; its salts

Zidovudine

Zimelidine; its salts

Zipeprol; its salts

Ziprasidone; its salts

Zolazepam; its salts

Zoledronic acid; its salts

Zolmitriptan; its salts

Zolpidem; its salts

Zomepirac; its salts

Zopiclone

Zoxazolamine; its salts

Division B

Alkali fluorides other than those specified in Part II of this List

Barium, salts of, except barium sulphate

alpha-Chlorohydrin (3-chloro-1,2-Propanediol)

Dinitronaphthols; dinitrophenols; dinitrothymols

Hexachlorophane, the following—

(a) medicinal products for human use containing more than 0.1% hexachlorophane;

(b) preparations for animal use—

(i) aerosols the contents of the container of which contain more than 0.1% hexachlorophane;

(ii) soaps and shampoos containing more than 2% hexachlorophane;

(iii) other medicinal products (except those for oral administration to sheep or cattle for liver fluke disease) containing more than 0.75% hexachlorophane

meta-Nitrophenol; ortho-nitrophenol; para-nitrophenol

Phosmet

Phosphorus, yellow

Sulphuric acid, except substances containing not more than 70%, weight in weight, of sulphuric acid

Part II

Division A

Antihistamine substances not included in Part I of this List; their salts; their compounds with any other substance

Benzocaine when contained in condoms

alpha-Chloralose

Loratadine; its salts; when contained in pharmaceutical products labelled for the relief of the symptoms of allergic rhinitis only

Nicotine when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy

Pharmaceutical products retailed in the form as supplied by the manufacturer, containing a poison included in

Division A of Part I of this List, where the proportion of the poison does not exceed the equivalent of—

(a) 0.01% by weight of arsenic trioxide, cantharidin, cocaine, coniine, ecgonine, hydrocyanic acid, strychnine, alkaloids of aconite, alkaloids of coca or alkaloids of gelsemium;

(b) 2%, weight in volume, of mercurochrome when contained in solutions for external use only; and

(c) 0.1% by weight in the case of other poisons,

except pharmaceutical products containing any poison—

(d) included in the Third Schedule; or

(e) in the following list—

Acetyldihydrocodeine; its salts

Alkaloids of belladonna; their salts

Alkaloids of ephedra; their salts

Atropine; its salts

Bambuterol; its salts

Benzydamine; its salts

Butropium; its salts

Codeine; its salts

Dextromethorphan; its salts

Diclofenac; its salts

Dihydrocodeine; its salts

Ethylmorphine; its salts

Fenoterol; its salts

Formoterol; its salts

Homatropine; its salts

Hyoscine; its salts

Hyoscyamine; its salts

Ipratropium; its salts

Methylaminoheptane; its salts

Morphine; its salts

Nicocodine; its salts

Norcodeine; its salts

Orciprenaline; its salts

Papaverine; its salts

Phenylpropanolamine; its salts

Pholcodine; its salts

Procaterol; its salts

Salmeterol; its salts

Terbutaline; its salts

Tretoquinol; its salts

Phenols as defined in Part I of this List in substances containing less than 60%, weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of 60%, weight in weight, of phenols

Terbinafine; its salts; when contained in preparations for external application only with no more than 1% of Terbinafine and not to be administered as a single application and when labelled for the treatment of tinea pedis and/or tinea cruris only

Division B

Ammonia

gamma-Benzene hexachloride (1,2,3,4,5,6-hexachlorocyclohexane)

Diamines, the following; their salts—

Phenylene diamines; toluene diamines; other alkylated-benzene diamines

Formaldehyde

Formic acid

Hydrochloric acid

Hydrofluoric acid; alkali fluorides; alkali metal bifluorides; ammonium bifluorides; sodium silicofluoride

Metallic oxalates

Nitric acid

Nitrobenzene

Phosphoric acid

Potassium hydroxide

Products retailed in the form as supplied by the manufacturer, containing a poison included in Division B of Part I of this List, where the proportion of such poison does not exceed the equivalent of 0.1%

Sodium hydroxide

Sodium nitrite".

Part 4

Repeal of Poisons List Regulations

72. Poisons List Regulations repealed

The Poisons List Regulations (Cap. 138 sub. leg. B) are repealed.

Part 5

Amendments Relating to Headings of Provisions

73. Amendments relating to headings of provisions

(1) The amendments relating to headings of provisions as specified in the Schedule have effect.

(2) The enactments specified in the Schedule are amended as set out in the Schedule.

Schedule

[s. 73]

Amendments Relating to Headings of Provisions

Part 1

Pharmacy and Poisons Ordinance (Cap. 138)

1. Part 1 heading added

Before section 1—

Add

"**Part 1**

Preliminary".

2. Part 2 heading added

Before section 3—

Add

"**Part 2**

Pharmacy and Poisons Board".

3. Part 3 heading added

Before section 5—

Add

"**Part 3**

Pharmacists: Requirements for Registration and Practising Certificate".

4. Part 4 heading added

Before section 11—

Add

"**Part 4**

Retail Sale of Poisons".

5. Part 5 heading added

Before section 15—

Add

"**Part 5**

Registered Pharmacists and Authorized Sellers of Poisons: Disciplinary Proceedings and Restriction on Use of Titles".

6. Part 6 heading added

Before section 21—

Add

"**Part 6**

Sale and Possession of Poisons".

7. Part 7 heading added

Before section 28A—

Add

"**Part 7**

Import and Export of Pharmaceutical Products".

8. Part 8 heading added

Before section 29—

Add

"**Part 8**

Miscellaneous".

Part 2

Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A)

9. Part III heading amended (supplementary provisions with respect to labelling and containers)

Part III, heading, after "**Containers**"—

Add

"**of Poisons**".

10. Regulation 18 heading amended (form of containers)

Regulation 18, heading, after "**containers**"—

Add

"**of poisons**".

11. Part IV heading amended (storage and transport)

Part IV, heading, after "**Transport**"—

Add

"**of Poisons**".

12. Part VB heading amended (registration of premises)

Part VB, heading, after "**Premises**"—

Add

"**of Authorized Sellers of Poisons**".

13. Part VI heading amended (wholesale dealers)

Part VI, heading—

Repeal

"**Dealers**"

Substitute

"**Dealing in Poisons and Pharmaceutical Products**".

14. Part VII heading amended (manufacturers)

Part VII, heading—

Repeal

"**Manufacturers**"

Substitute

"**Manufacture of Pharmaceutical Products**".