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# Pharmacy and Poisons (Amendment) Ordinance 2015

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**HONG KONG SPECIAL ADMINISTRATIVE REGION**

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**ORDINANCE NO. 2 OF 2015**



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.
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## 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).

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- (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-phenethylguanidine;”

**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；大麻酞劑；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 “六甲噻胺”—

**Repeal**

“噻”

**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 “卡馬西洋”—

**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-苯二氮草的化學結構在任何程度上被取代”

**Substitute**

“含有雙氫-1，4-苯二氮草的化學結構(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**

“安他啞林”

**Substitute**

“安他啞啞”.

- (47) First Schedule, Chinese text, Division A, item “炔己蟻胺”—

**Repeal**

“己”

**Substitute**

“己”.

- (48) First Schedule, Chinese text, Division A, item “阿夫啞秦；其鹽類”—

**Repeal**

“秦”



**Substitute**

“嗉”。

- (49) First Schedule, Chinese text, Division A—
- (a) **Repeal item** “阿伐他汀；其鹽類”；
  - (b) Before item “阿托伐醜”—

**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** “阿紮胞昔；其鹽類”；
  - (b) After item “阿扎那韋；其鹽類”—

**Add**

“阿扎胞昔；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**

“昔”.

- (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 “泮庫溴鉍；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<sub>2a</sub>)”**Substitute**“地諾前列素(前列腺素F<sub>2α</sub>)”.

- (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**  
“坦”
- 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** “培哌普利拉；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**

“培哌普利拉；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**

“斑布特羅及其鹽類，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  $\alpha$ ”.
- (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 “伊普吡啉；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**

“伊米昔酶”。

(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**

“氰氟蟲脞；其鹽類”。

- (97) First Schedule, Chinese text, Division A—
- (a) **Repeal item “Palivizumab”**;
  - (b) After item “帕利脈酮；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*]喹啉-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-fluorobenzoyl-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 “六甲噻胺”—

**Repeal**

“噤”

**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**

“甲納曲酮；其鹽類”。

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

**Repeal**

“呱”

**Substitute**

“哐”。

- (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-苯二氮草的化學結構在任何程度上被取代”

**Substitute**

“含有雙氫-1，4-苯二氮草的化學結構(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**

“乙型流感嗜血桿菌”

**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**

“安他啞林”

**Substitute**

“安他啞啞”.

- (40) Third Schedule, Chinese text, Division A, item “呋已蟻胺”—

**Repeal**

“已”

**Substitute**

“己”.

- (41) Third Schedule, Chinese text, Division A, item “阿夫啞秦；其鹽類”—

**Repeal**

“秦”

**Substitute**

“嗉”。

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

(a) **Repeal item** “阿伐他汀；其鹽類”；

(b) Before item “阿托伐醜”—

**Add**

“阿托伐他汀；其鹽類”。

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

(a) **Repeal item** “阿紮胞昔；其鹽類”；

(b) After item “阿扎那韋；其鹽類”—

**Add**

“阿扎胞昔；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**

“昔”。

(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 “泮庫溴鉍；其鹽類”—

**Repeal**

“溴”。

- (49) Third Schedule, Chinese text, Division A, item relating to “肱(聯肢)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<sub>2a</sub>)”

**Substitute**

“地諾前列素(前列腺素F<sub>2α</sub>)”.

(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 “咪啞莫特；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活化劑複合物”；

(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 “氫己稀酸”—

**Repeal**

“稀”

**Substitute**

“烯”。

- (60) Third Schedule, Chinese text, Division A, item “啞吡坦；其鹽類”—

**Repeal**

“坦”

**Substitute**

“坦”。

- (61) Third Schedule, Chinese text, Division A, item “啞來磷酸；其鹽類”—

**Repeal**

“磷”

**Substitute**

“磷”。

- (62) Third Schedule, Chinese text, Division A, item “胸腺肽 a1”—

**Repeal**

“a”

**Substitute**

“ $\alpha$ ”。

- (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** “培哌普利拉；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**

“培哌普利拉；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**

“昔”。

- (66) Third Schedule, Chinese text, Division A, item relating to “氣醛”—

**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；它們的酯類苗”

**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  $\alpha$ ”.
- (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 “伊普吡啉 ; 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**

“伊米昔酶”。

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

(a) **Repeal item “Indinavir ; 其鹽類”;**

(b) Before item “茛達特羅 ; 其鹽類 ; 其酯類 ; 它們的鹽類”—

**Add**

“茛地那韋 ; 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**

“氫氟蟲脞；其鹽類”。

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

(a) **Repeal item “Palivizumab”;**

(b) After item “帕利脈酮；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*]吡啶-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 “托派酮 ; 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 “瀨沙坦 ; 其鹽類”—

**Add**

“瀨更昔洛韋 ; 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—

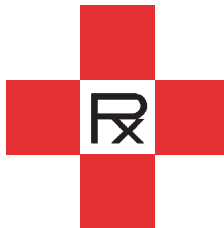
**Repeal Form 17**

**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



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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

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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
  - Amitrine; 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

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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

Cetorelix; its salts; its esters; their salts

Cetuximab

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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-methylenethioxanthen; 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

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Iothalamic acid  
Iotrolan  
Iotroxlic acid  
Ioversol  
Ioxaglic acid  
Ioxitalamic acid  
Ipodic acid  
Metrizamide  
Propyliodone  
Sulphur hexafluoride  
Tyropanoic acid  
Corifollitropin alfa  
Corticotropin; 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

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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  
Dimeflin; 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

Etoxadine; 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



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- 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

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Hydrocyanic acid; cyanides, other than ferrocyanides and ferricyanides

Hydromorphanol; 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-phenacymorphinan; 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

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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

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Mephenesin; its esters; their salts  
Mephenoxalone  
Mepirizole; its salts  
Mepivacaine; its salts  
Meproamate  
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; potassiomeric 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

Methyl-desorphine; 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

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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  
Opi Pramol; 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  
Oxycinchonic 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

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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

Phenomorphane; 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  
Polymethylenebis(trimethylammonium) 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  
Remifentanyl; 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

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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

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Spirolactone  
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

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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  
Tranlycypromine; its salts  
Trastuzumab  
Trazodone; its salts  
Tretamine; its salts  
Tretinoin  
Tretoquinol; its salts  
Triamterene; its salts  
Triaziquone  
Tribromoethyl alcohol

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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  
Trovaflouxacin; 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

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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”.

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## **Part 4**

### **Repeal of Poisons List Regulations**

**72. Poisons List Regulations repealed**

The Poisons List Regulations (Cap. 138 sub. leg. B) are repealed.

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## **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.
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**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**”.