PHARMACY AND POISONS REGULATIONS

(Cap. 138, section 29)

[1 July 1978] *L.N. 145 of 1978*

PART I

PRELIMINARY

1. Citation

These regulations may be cited as the Pharmacy and Poisons Regulations.

2. Interpretation

(1) In these regulations, unless the context otherwise requires—

"antimonial poisons" (含銻毒藥) means organic and inorganic compounds of antimony;

"arsenical poisons" (含砷毒藥) means organic and inorganic compounds of arsenic;

"British Pharmaceutical Codex" (英國藥學藥典), "British Pharmacopoeia" (英國藥典), "British National Formulary" (英國國家處方集) and "British Veterinary Codex" (英國獸醫藥方集) include the supplements thereto;

"food" (食物) includes a beverage;

"medicine for the internal treatment of human and animal ailments" (用於治療人類及動物病患的內服藥物) includes any medicine to be administered by injection, but does not include any mouth-wash, eye-drops, eye-lotion, ear-drops, nasal drops, douche or similar article;

"Tribunal" (審裁處) means the Pharmacy and Poisons Appeal Tribunal established by section 30 of the Ordinance; *(L.N. 369 of 1980)*

"veterinary institution" (獸醫機構) means a veterinary hospital, veterinary clinic or other premises where sick animals are treated.

(2) In these regulations any reference to an alkaloid shall include a reference to any salt of that alkaloid, and, in a case where the esters of an alkaloid are included in the Poisons List by virtue of the words "its esters", to any esters of that alkaloid.

(3) Any reference in the Schedules to these regulations to the percentage of a poison contained in any substance or preparation shall, unless otherwise expressly provided, be construed in the following manner, that is to say, a reference to a substance or preparation containing 1 per cent of any poison means—

(a) in the case of a solid, that 1 gramme of the poison is contained in every 100 grammes of the substance or preparation;

(b) in the case of a liquid, that 1 millilitre of the poison, or, if the poison itself is a solid, 1 gramme of the poison, is contained in every 100 millilitres of the substance or preparation,

and so in proportion for any greater or less percentage.

(4) Substances listed in Divisions A in the Schedules to these regulations are those whose uses are essentially medicinal, whilst substances listed in Divisions B are not normally used medicinally. *(L.N. 41 of 2007)*

(5) Where in these regulations reference is made to a numbered section the reference shall be a reference to that section of the Ordinance. *(L.N. 41 of 2007)*

(6) Where functions are conferred on a committee by any provision of these regulations, references in such provision to "the Committee" shall be construed as references to the executive committee established under section 4A of the Ordinance for the purpose of performing such functions. *(L.N. 369 of 1980)*

3. Application of section 22 restricted to the First Schedule

Section 22 shall only apply to those poisons included in Part I of the Poisons List as set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) which are also included in the First Schedule but not included in the Third Schedule.

4. Extension of labelling provisions and relaxation with respect to poisons in the Sixth Schedule

(1) Subject to paragraph (2), the provisions of section 27 and regulations 12 to 17 (which provisions relate to the labelling of poisons) shall apply to sales exempted by section 32, and shall also apply to the supply of poisons (otherwise than on sale) and references in those provisions to the sale and the seller of poisons shall be deemed to refer to the supply and the supplier of poisons respectively.

(2) In the case of the sale or supply of any of the poisons included in the Sixth Schedule to a person who—

(a) carries on a business in the course of which poisons are regularly sold by way of wholesale dealing or are regularly used in the manufacture of other articles; and

(b) requires the poison for the purpose of that business,

if the outside of the package in which the poison is sold or supplied is labelled conspicuously with words indicating the dangerous properties of the poison, it shall be necessary to comply only with regulation 15 and section 27(a) and section 27(d) (as modified by regulation 17).

5. Extension of section 22 to sales wholesale etc. and relaxation of the section

(1) Section 22 shall apply to sales exempted by section 32, except sales of poisons to be exported to purchasers outside Hong Kong, and shall also apply to the supply in the form of a commercial sample, otherwise than on sale, of any substance included in the First Schedule in like manner as if references in section 22 to the sale and seller of poisons respectively included references to the supply and the supplier of poisons in the form of commercial samples:
Provided that section 22 shall not apply to the sale or supply of any article by the manufacturer thereof or by a person carrying on a business in the course of which poisons are regularly sold by way of wholesale dealing, if—

(a) the article is sold or supplied to a person carrying on a business in the course of which poisons are regularly sold or are regularly used in the manufacture of other articles; and

(b) the seller or supplier is reasonably satisfied that the purchaser requires the article for the purpose of that business.

(2) Section 22(1) shall, in its application to sales exempted by section 32 and to the supply in the form of commercial samples of substances included in the First Schedule, be deemed to be satisfied if the person to whom the poison or sample is sold or supplied is known by the person in charge of the department of the business through which the sale or supply is effected to be a person to whom the poison or sample may properly be sold or supplied.

(3) Subject to paragraph (4), so much of section 22(3)(b) as requires an entry in the poisons book to be signed by the purchaser of a poison shall not, as respects the sale of a poison to a person for the purpose of his trade, business or profession, apply if the following requirements are satisfied—

(a) the seller shall obtain before the completion of the sale an order in writing signed by the purchaser stating his name and address, trade, business or profession, the name and quantity of the article to be purchased, and the purpose for which it is required;

(b) the seller shall be reasonably satisfied that the signature is that of the person purporting to have signed the order, and that that person carries on the trade, business or profession stated in the order, being one in which the poison to be purchased is used; and

(c) if the article sold is sent by post, it shall be sent by registered post.

(4) Where a person represents that he urgently requires a poison for the purpose of his trade, business or profession, the seller may, if he is reasonably satisfied that the person so requires the poison and is, by reason of some emergency, unable before delivery either to furnish to the seller an order in writing duly signed or to attend and sign the entry in the book, deliver the poison to the purchaser on an undertaking by the purchaser to furnish such an order within 48 hours next following.

(5) Any purchaser by whom an undertaking under paragraph (4) has been given who fails to deliver to the seller a signed order in accordance with the undertaking, or any person who for the purpose of obtaining delivery of any poison makes a statement which is to his knowledge false in any material particular shall be guilty of an offence and shall be liable on conviction to a fine of $10,000 and to imprisonment for 12 months.

(6) In the case of a sale or the supplying of a poison included in the First Schedule to an institution such of the provisions of this regulation as require the purchaser to state his trade, business or profession and the seller to be satisfied with respect thereto shall not apply and for the reference in paragraph (4) to the purposes of the purchaser's trade, business or profession there shall be substituted in the case of any such sale a reference to the name of the institution and the full name and rank or position held at the institution of the person making the order.

6. Relaxation of section 28(3) in the case of certain medicines

The requirements of section 28(3) (which requires particulars of medicines supplied or dispensed under that section to be entered in a book) shall be satisfied in respect of medicines included in the First Schedule, but need not be satisfied in respect of other medicines which are supplied by—

(a) a registered medical practitioner for the purposes of medical treatment; or

(b) an authorized seller of poisons on and in accordance with a prescription given by a registered medical practitioner.

7. Exemption from the provisions relating solely to the First Schedule

The provisions of these regulations and of the Ordinance (as modified by these regulations) which apply solely to the substances in the First Schedule shall not apply to—

(a) machine-spread plasters;

(b) surgical dressings;

(c) *(Repealed L.N. 262 of 1995)*

(d) corn paints in which the only poison is a poison included in the Poisons List under the heading "Cannabis".

8. Complete exemption for articles and substances in the Second Schedule

(1) Subject to paragraph (2), nothing in the Ordinance or these regulations shall apply—

(a) to any article in Group I of the Second Schedule; or

(b) to any of the articles or substances specified in the second column of Group II of the Second Schedule opposite the description of the poison specified in the first column thereof. *(L.N. 85 of 1987)*

(2) Notwithstanding paragraph (1)(b), Parts VII, VIII, VIIIA, IX and X of these regulations shall apply to every article or substance referred to in that paragraph, that is a pharmaceutical product within the meaning of the Ordinance. *(L.N. 85 of 1987)*

PART II

ADDITIONAL RESTRICTIONS ON THE SALE OF POISONS

9. Additional restriction of sale of poisons in the Third Schedule

(1) No person shall sell any poison included in the Third Schedule, except on and in accordance with a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. *(L.N. 614 of 1997)*

(2) This regulation shall apply to the sale of any such poison, including a medicine exempted by section 28, but shall not apply to any sale exempted by section 32.

(3) For the purposes of this regulation a prescription shall—

(a) be in writing and be signed by the person giving it with his usual signature and be dated by him;

(b) specify the address of the person giving it;

(c) specify the name and address of the person for whose treatment it is given or, if the prescription is given by a registered veterinary surgeon, of the person to whom the medicine is to be delivered; *(L.N. 614 of 1997)*

(d) have written thereon, if given by a dentist, the words "For dental treatment only 祇限牙科醫療用", or, if given by a registered veterinary surgeon, the words "For animal treatment only 祇限醫治禽畜用"; and *(L.N. 614 of 1997)*

(e) indicate the total amount of the medicine to be supplied and the dose to be taken or administered.

(4) The person dispensing the prescription shall comply with the following requirements—

(a) the prescription shall not be dispensed more than once unless the prescriber has directed either—

(i) that it may be dispensed a stated number of times; or

(ii) that it may be dispensed at stated intervals;

(b) if the prescription contains a direction that it may be dispensed a stated number of times or at stated intervals, it shall not be dispensed otherwise than in accordance with the direction;

(c) at the time of dispensing there shall be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed; and

(d) except in the case of a prescription which may be dispensed again, the prescription shall, for a period of 2 years, be retained and kept on the premises on which it was dispensed in such manner as to be readily available for inspection.

10. Restriction of sales by listed sellers of poisons

No listed seller of poisons shall sell any poison other than a solution of ammonia, hydrochloric acid, nitric acid, potassium quadroxalate or sulphuric acid, except in a closed container as closed by the manufacturer or other person from whom the poison was obtained.

10A. Prohibition on dispensing of prescriptions by listed sellers of poisons

No listed seller of poisons shall dispense any prescription for medicine.

(L.N. 85 of 1987)

11. Restriction of sale of strychnine

(1) No person shall sell or supply strychnine except as an ingredient in a medicine.

(2) This regulation shall extend to transactions exempted by section 32, but shall not apply to the sale of strychnine—

(a) by way of wholesale dealing;

(b) to be exported to purchasers outside Hong Kong;

(c) for the purpose of being compounded in medicines prescribed or administered by a registered medical practitioner or registered veterinary surgeon; or *(L.N. 614 of 1997)*

(d) to a person or institution concerned with education, scientific research or chemical analysis, for the purpose of that education, research or analysis.

PART III

SUPPLEMENTARY PROVISIONS WITH RESPECT TO LABELLING AND CONTAINERS

12. Manner of labelling containers

(1) Subject to paragraphs (2) and (3), the particulars with which the container of a poison is required to be labelled under section 27 and under these regulations, shall appear in a conspicuous position on the container in which the poison is sold and on every box or other covering of whatever nature enclosing the container, and the particulars shall be clearly and distinctly set out and not in any way obscured or obliterated.

(2) Where the poison is contained in a cachet or similar article it shall not be necessary to label the article itself, if every box or other covering in which the article is enclosed is labelled in accordance with paragraph (1).

(3) Nothing in section 27 or in this regulation or regulations 13 to 17 shall be deemed to require the labelling of any transparent cover or any wrapper, hamper, packing case, crate or other covering used solely for the purposes of transport or delivery.

13. Labelling of name of poison

(1) For the purposes of section 27(a) and regulation 22(3)(a), the name of a poison shall be the term under which it is included in the Poisons List:

Provided that, where the term describes a group of poisons and not the poison specifically, the name of the poison shall be—

(a) if the poison is the subject of a monograph in either the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex, one of the names or synonyms or abbreviated names set out at the head of the monograph; or

(b) in any other case, the accepted scientific name or the name descriptive of the true nature and origin of the poison.

(2) For the purposes of the proviso to paragraph (1), where—

(a) a substance is the subject of a monograph in the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex, or any dilution, concentration or admixture of such substance; or

(b) a preparation is contained in the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary or the British Veterinary Codex, or any dilution, concentration or admixture of such preparation; or

(c) a surgical dressing of a type for which a standard is prescribed in the British Pharmaceutical Codex,

it shall be sufficient to state the name, synonym or abbreviated name used to describe the substance, preparation or surgical dressing with the addition of the letters B.P., B.P.C., B.N.F. or B. Vet.C., as the case may be.

14. Labelling of particulars as to proportions of the poison

For the purpose of section 27(b) (which requires preparation containing poisons to be labelled with particulars as to the proportion of each poison therein)—

(a) in the case of a preparation containing a poison specified in the first column of the Fourth Schedule, it shall be sufficient to state on the label the particulars specified in the second column of that Schedule against the description of the poison;

(b) in the case of a substance, preparation or surgical dressing which is named in accordance with regulation 13(2), it shall not be necessary to state on the label the proportion of the poison contained in the substance, preparation or surgical dressing, and in the case of any dilution, concentration or admixture of such substance or preparation it shall be sufficient to state the proportion which the substance or preparation bears to the total ingredients of that dilution, concentration or admixture;

(c) where the poison is in tablets, pills, cachets, capsules, lozenges or similar articles, it shall be sufficient to state on the label of the box or other covering in which the articles are enclosed the number of the articles and the amount of the poison, or in the case of a preparation or substance mentioned in paragraph (b), the amount of the preparation or substance, contained in each article;

(d) where the poison is in ampoules it shall be sufficient to show the name of the poison contained in it together with, either its concentration (if in solution or in emulsified form), or the quantity (if in solid form); and

(e) where any proportion is stated as a percentage, the statement shall indicate whether the percentage is calculated on the basis of weight in weight, weight in volume, or volume in volume.

15. "Poison" to be in English and Chinese

(1) The word "poison" or other statement as specified in the Fifth Schedule with which a container of a poison is required to be labelled pursuant to section 27(c) shall be printed clearly in both English and Chinese. *(L.N. 137 of 1978)*

(2) The container of any article specified in the Fifth Schedule shall, instead of being labelled with the word "Poison 毒藥" be labelled with the words specified in that Schedule as applicable to that article.

(3) The words referred to in paragraph (2) or the word "Poison 毒藥", as the case may be, shall not be modified in meaning by the addition of any other words or marks, and—

(a) in the case of a substance included in the First Schedule, shall either be in red lettering or be set against a red background; and

(b) in all cases shall either be on a separate label or be surrounded by a line within which there shall be no other words except words with which the container of the poison is required to be labelled under the Ordinance or these regulations.

16. Special precautions in the case of certain articles

(1) No person shall sell or supply any poison—

(a) in the case of a liquid other than a medicine, in a container of a capacity of not more than 2 litres, unless the container is labelled with the words "Not to be taken 忌食"; and *(L.N. 22 of 1982)*

(b) in the case of an embrocation, liniment, lotion, liquid antiseptic, or other liquid medicine for external application, unless the container is labelled with the type of preparation and the words "For external use only 祇供外用". *(L.N. 137 of 1978)*

(2) No person shall sell or supply any compressed hydrocyanic acid, unless the container thereof is labelled with the words "Warning. This container holds poisonous gas and should only be opened and used by persons having expert knowledge of the precautions to be taken in its use. 警告：此容器內載毒氣，祇限由具有專門知識而在使用上知所提防之人士開啟及使用.".

(3) This regulation shall be in addition to the other requirements of the Ordinance and of these regulations with respect to labelling and shall apply to the transactions referred to in sections 28 and 32, but shall not apply to the sale or supply of poisons to be exported to purchasers outside Hong Kong.

17. Name of seller and address of premises

(1) Section 27(d) (which requires the container of a poison to be labelled with the name of the seller and the address of the premises on which it was sold) shall apply to the transactions referred to in section 32, but shall not apply—

(a) in the case of an article sold for the purpose of being sold again in the same container; or

(b) to poisons to be exported to purchasers outside Hong Kong.

(2) The requirements of section 27(d) shall be deemed to be satisfied, in the case of a poison supplied from a warehouse or depot, if the container of the poison is labelled with the address of the supplier's principal place of business.

(3) Where any poison (other than a substance included in the First Schedule) is sold in a container and outer covering, being the container and covering in which it was obtained by the seller, it shall be sufficient if the name of the seller and the address of the premises on which it was sold appear only on the outer covering.

(4) Where the names of more than one person or more than one address appear on any label, there shall also be words on the label indicating clearly which person is the seller and at which of the addresses the poison was sold.

18. Form of containers

(1) No person shall sell, whether wholesale or retail, or supply any poison unless—

(a) it is contained in a container impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport; and

(b) in the case of a liquid contained in a glass bottle or plastic container containing not more than 2 litres, not being a medicine made up ready to be taken for the internal treatment of human or animal ailments, the outer surface of the bottle or container is fluted vertically with ribs or grooves recognizable by touch. *(L.N. 22 of 1982)*

(2) Paragraph (1)(a) shall apply to the transactions referred to in section 28, and paragraph (1)(b) shall apply to the transactions exempted by section 32 but shall not apply to the sale or supply of poisons to be exported to purchasers outside Hong Kong.

PART IV

STORAGE AND TRANSPORT

19. Storage of poisons

(1) No person shall store any poison except in a container impervious to the poison and sufficiently stout to prevent leakage from the container arising from the ordinary risks of handling.

(2) No person shall store any substance included in the First Schedule in any retail shop or premises used in connexion therewith unless the substance is stored—

(a) in a receptacle reserved solely for the storage of poisons, which receptacle shall be locked with an adequate lock the key for which shall be retained by the registered pharmacist; and *(L.N. 197 of 1989; L.N. 366 of 1995)*

(b) in a part of the premises to which customers are not permitted to have access and which is partitioned off or otherwise separated from the remainder of the premises.

(3) No food shall be stored in the part of the premises where such poison or substance is stored.

20. Transport of poisons

No person shall consign any poison for transport unless it is sufficiently stoutly packed to avoid leakage arising from the ordinary risks of handling and transport.

21. Special provisions with respect to the transport of poisons in the Seventh Schedule

(1) No person shall consign for transport by carrier any poison included in the Seventh Schedule unless the outside of the package containing the article is labelled conspicuously with the name or description of the poison as set forth in that Schedule and a notice indicating that it is to be kept separate from food and from empty containers in which food has been contained.

(2) No person shall knowingly transport any poison included in the Seventh Schedule, either on his own behalf or for another person, in any vehicle in which food is being transported, unless the food is carried in a part of the vehicle effectively separated from that containing the poison, or is otherwise adequately protected from the risk of contamination.

(3) This regulation shall not apply to medicines.

PART V

SPECIAL PROVISIONS WITH RESPECT TO INSTITUTIONS

22. Supply of medicines to out-patients from certain institutions, etc.

(1) Nothing in the Ordinance or in these regulations, except regulation 16 and this Part, shall apply with respect to— *(L.N. 262 of 1995)*

(a) any medicine dispensed in an institution where the dispensing is under the supervision of a registered pharmacist or other person as may be approved by the Director of Health; or *(L.N. 76 of 1989)*

(b) any medicine for the treatment of animals supplied from a veterinary institution which is under the superintendence of a registered veterinary surgeon, *(L.N. 614 of 1997)*

if the requirements of this regulation are satisfied in relation thereto.

(2) The medicine shall not be supplied except by, or on and in accordance with a prescription of, a duly registered medical practitioner for the purposes of medical treatment, or a registered dentist for the purposes of dental treatment, or a registered veterinary surgeon for the purposes of animal treatment. *(L.N. 614 of 1997)*

(3) In a case where a substance included in the First Schedule is supplied, a record shall be kept on the premises in such a way that there can readily be traced at any time during a period of 2 years after the date on which the substance was supplied the following particulars—

(a) the name and quantity of the poison supplied;

(b) the date on which the poison was supplied;

(c) the name and address of the person to whom the poison was supplied; and

(d) the name of the person who supplied the poison or who gave the prescription upon which it was supplied.

(4) The container of the medicine shall be labelled—

(a) with a designation sufficient to identify the institution or veterinary institution from which it was supplied; *(L.N. 137 of 1978)*

(b) except in the case of a medicine made up ready for treatment, with the word "Poison 毒藥";

(c) in the case of a poison supplied from a veterinary institution, with the words "For animal treatment only 祇限醫治禽畜用".

(5) The medicine shall be clearly labelled with instructions for use in English and in Chinese.

(6) In the case of a medicine to which regulation 16 applies the requirements of that regulation shall be satisfied in addition to the requirements of this regulation.

23. Supply of medicines for use in institutions, etc.

(1) In any institution in which medicines are dispensed in a dispensing or pharmaceutical department in charge of a registered pharmacist or any other person approved by the Director of Health for that purpose, no medicine containing a poison shall be supplied from that department, except in cases of emergency, for use in the wards, operating theatres or other sections of the institution, except in accordance with paragraphs (2) and (3). *(L.N. 76 of 1989)*

(2) Subject to paragraph (4), the medicines shall not be supplied except upon a written order signed by a duly registered medical practitioner, registered dentist, or by a person authorized to be in charge of a ward, theatre or other section of the institution.

(3) The container of the medicine shall be labelled—

(a) with words describing its contents;

(b) in the case of substances included in the First Schedule, with a distinguishing mark or other indication indicating that the poison is to be stored in a cupboard reserved solely for the storage of poisons.

(4) In the case of an emergency, a medicine containing a poison may be supplied without a written order if the person ordering the medicine undertakes to furnish a written order in respect of that medicine within the next 24 hours.

24. Storage of poisons in institutions

(1) In any institution in which medicines are dispensed in a dispensing or pharmaceutical department in the charge of a person appointed for the purpose, all poisons other than those issued for use within the institution shall be stored in that department.

(2) In any institution to which paragraph (1) does not apply all poisons other than those issued for use within the institution shall be stored—

(a) in the charge of a person appointed for the purpose by the governing body or person in control of the institution; and

(b) in the case of substances included in the First Schedule either in a cupboard or drawer, or on a shelf, reserved solely for the storage of poisons.

(3) No poison shall be stored on an open shelf, unless the container of the poison is distinguishable by touch from the containers of any other substances stored in the same premises. *(L.N. 137 of 1978)*

(4) In every institution, every substance in the First Schedule which is stored in the wards shall be stored in a locked cupboard reserved for the storage of poisons. *(L.N. 137 of 1978)*

(5) All places in which poisons are required by this regulation to be stored shall be inspected at regular intervals of time not exceeding three months by a registered pharmacist or registered medical practitioner appointed for the purpose by the governing body of the institution and a record of all inspections shall be made in a book kept at the institution.

PART VA

LISTED SELLERS OF POISONS

24A. Applications to be entered on list under section 25

(1) Any application under section 25(1) shall be made in writing to the Committee and shall be accompanied by the fee specified in the Ninth Schedule.

(2) The Committee may grant or refuse any application under this regulation and shall notify the applicant of its decision:
Provided that if the Committee intends to refuse an application the Committee shall first notify the applicant and the applicant may, not later than 14 days after the date of such notification, submit representations in writing to the Committee in support of his application.

(3) Where the Committee grants an application under this regulation the Committee shall notify the Board of its decision and shall state whether the applicant has paid the prescribed fee.

(4) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

PART VB

REGISTRATION OF PREMISES

24B. Applications to register premises under section 13

An application to register premises under section 13 shall be—

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

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

(L.N. 85 of 1987)

24C. Certificate of registration under section 13

A certificate of registration under section 13 shall be in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 16)

(L.N. 85 of 1987)

PART VI

WHOLESALE DEALERS

25. Sale and supply of poisons wholesale

No person other than an authorized seller of poisons or a licensed manufacturer selling pharmaceutical products of his own manufacture only shall, by way of wholesale dealing, sell or supply at or from any premises any substance or article consisting of or containing any poison unless he is the holder of a wholesale poisons licence issued to him by the Committee in respect of those premises.

(L.N. 137 of 1978)

26. Pharmacy and Poisons (Wholesale Licences) Committee

(1) There shall be for the purposes of this Part a Committee to be called the Pharmacy and Poisons (Wholesale Licences) Committee.

(2) *(Repealed L.N. 369 of 1980)*

(3) The Committee may issue a wholesale poisons licence on payment of the fee prescribed in the Ninth Schedule.

(4) The issue of a wholesale poisons licence shall be at the discretion of the Committee and shall be in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 1)

(5) The Committee may revoke a wholesale poisons licence or suspend it for such period as it thinks fit, if in its opinion the holder has failed to comply with the conditions subject to which the licence was issued or with any of these regulations, or has been convicted of an offence under the Ordinance.

(6) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980)*

(7) *(Repealed L.N. 369 of 1980)*

(8) An applicant for a wholesale poisons licence—

(a) shall nominate in writing a responsible person to be in charge of poisons; and

(b) may nominate in writing a deputy to act during the temporary absence of the responsible person.

(9) An applicant shall at the time of his application submit to the Secretary of the Board the name of the person so nominated and of any deputy, and shall advise the Secretary of any change within 7 days of its occurrence.

27. Sales by wholesale dealers

No person holding a wholesale poisons licence or a licence to manufacture pharmaceutical products shall sell or supply any poisons except to—

(a) another wholesale dealer duly licensed to sell poisons wholesale;

(b) an authorized seller of poisons;

(c) a registered pharmacist;

(d) a registered medical practitioner, a registered dentist or a registered veterinary surgeon; *(L.N. 614 of 1997)*

(e) persons who require the poison for the purpose of their trade or business;

(f) a Government department or public officer requiring the article for the purposes of the public service;

(g) a person or an establishment concerned with education or scientific research, if the article is required for the purposes of such education or research;

(h) an institution;

(i) purchasers outside Hong Kong; or

(j) a listed seller of poisons:
Provided that only such poisons shall be supplied to a listed seller of poisons as are included in the classes of poisons in Part II of the Poisons List that the listed seller is licensed to sell.

(L.N. 137 of 1978)

28. Records to be kept by wholesale dealer

(1) The holder of a wholesale poisons licence or a licence to manufacture pharmaceutical products shall record the following particulars of all transactions whereby poisons included in Part I of the Poisons List are acquired by him whether by way of import, purchase, gift or otherwise—

(a) the date of the transaction;

(b) the name of the supplier;

(c) the name of the poison and unit of quantity;

(d) the total quantity of the poison;

(e) the nature of the transaction; and

(f) a reference to the invoice or other documents supporting the transaction.

(2) The holder of a wholesale poisons licence or a licence to manufacture pharmaceutical products shall record the following particulars of all transactions for the disposition of poisons included in Part I of the Poisons List, whether uncompounded or as part of a pharmaceutical product and whether such disposition is by way of export, sale, gift or otherwise—

(a) the date of the transaction;

(b) the nature of the transaction;

(c) the name of the person to whom the poison is supplied;

(d) the quantity of the poison or pharmaceutical product, as the case may be;

(e) a reference to the invoice or other documents supporting the transaction;

(f) the name of the poison or pharmaceutical product, as the case may be, and the unit of quantity;

(g) the balance of the poison remaining in his possession after the transaction. *(L.N. 137 of 1978)*

(3) For each poison in Part I of the Poisons List there shall be a separate entry in the records and all transactions involving that poison shall be entered in a part of the records reserved for that poison.

(4) Unless the Committee approves another system of recording, all records of transactions involving poisons in Part I of the Poisons List shall be made in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 2)

(5) Every transaction to which these regulations relate shall be recorded within 72 hours after the time it took place.

(6) Records of sales or supplies maintained under this regulation shall be supported by documents signed by the purchaser.

(7) In the case of an export transaction the holder of a wholesale poisons licence or a licence to manufacture pharmaceutical products shall retain all shipping and other documents supporting the transaction. *(L.N. 137 of 1978)*

(8) A holder of a wholesale poisons licence or a wholesale dealer in medicines not containing poisons shall set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any lot or batch of a pharmaceutical substance or product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health. *(L.N. 137 of 1978)*

PART VII

MANUFACTURERS

29. Licensing of manufacturers

(1) Subject to paragraph (2), no person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises.

(2) Paragraph (1) and regulations 33 and 35 shall not apply to an authorized seller of poisons, who in the course of his retail business, manufactures any pharmaceutical product at any premises registered by him under the Ordinance in quantities which in the opinion of the Board, are consistent with the scope of his business and the nature of the product.

(3) The Committee may issue a licence to manufacture pharmaceutical products in such form as it may prescribe on payment of the fee prescribed in the Ninth Schedule.

(4) The Committee may revoke the licence or suspend it for such period as it thinks fit, if, in its opinion, the licensee has failed to comply with the conditions subject to which the licence was issued or with any of these regulations.

(5) For the purpose of certifying that a manufacturer is licensed under this regulation, the Committee, subject to any conditions it may impose and to the payment of the fee prescribed in the Ninth Schedule, may issue to the manufacturer—

(a) a certificate for manufacture; or

(b) an interim-certificate for manufacture,

in the forms prescribed in the Eighth Schedule. (See Eighth Schedule Forms 3 & 4) *(L.N. 137 of 1978)*

(6) For the purpose of exporting pharmaceutical products manufactured by a manufacturer licensed under this regulation, the Committee may, subject to any conditions it may impose and to the payment of the fee prescribed in the Ninth Schedule, issue to the manufacturer—

(a) a free sale certificate of pharmaceutical product; or

(b) a certificate of pharmaceutical product,

in the forms prescribed in the Eighth Schedule. (see Eighth Schedule, Forms 5 & 5A) *(L.N. 449 of 1991)*

(7) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980)*

(L.N. 369 of 1980)

30. Manufacture to be under supervision of a registered pharmacist

(1) In all premises in which pharmaceutical products are manufactured such products shall be manufactured by or under the supervision of—

(a) a registered pharmacist;

(b) a Fellow or Associate of the Royal Institute of Chemistry; or

(c) a person having such other qualifications or sufficient experience as may be approved by the Board.

(2) For the purposes of paragraph (1), "supervision" (監督) means the exercise by any of the persons referred to in paragraph (1) of control over the process of manufacture and of the persons engaged therein. *(L.N. 137 of 1978)*

31. Labelling by manufacturers

(1) Subject to paragraph (4), a manufacturer or authorized seller of poisons, supplying for distribution under regulation 29(2), shall label or cause to be labelled the container of each pharmaceutical product, with the following particulars—

(a) the appropriate designation of—

(i) the substance or substances from which the pharmaceutical product was manufactured;

(ii) each of the active constituents of the product; or

(iii) each of the ingredients from which the product was compounded;

(b) in the case where the appropriate designation of each of the active constituents or ingredients of a product is given, the appropriate quantitative particulars of those constituents or ingredients;

(c) the name and address of the manufacturer; and

(d) the number of the certificate of drug/product registration or the provisional certificate of drug/product registration of the pharmaceutical product issued by the Board.

(2) For the purposes of paragraph (1)—

(a) the expression "appropriate designation" (適當稱號), in relation to a substance, constituent or ingredient, means —

(i) in the case of a poison included in the Poisons List, the name with which the container of the poison is for the time being required to be labelled in accordance with regulation 13;

(ii) in the case where a substance, constituent or ingredient is not a poison and is described in any of the monographs contained in the edition of the British Pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex which was last published before the date on which the article was sold or supplied, the description set out at the head of that monograph; and

(iii) in any other case the accepted scientific name or the name descriptive of the true nature and origin of the substance, constituent or ingredient;

(b) the expression "appropriate quantitative particulars" (適當數量詳情), in relation to the active constituent or ingredient of a pharmaceutical product, means—

(i) the percentage or quantity of that constituent or ingredient contained in the pharmaceutical product sold or supplied; or

(ii) in the case of a pharmaceutical product which is in pill, capsule, tablet or similar article, either the percentage or quantity of the substance or substances comprising or forming part of the pills, capsules, tablets or similar articles, or the quantity of each constituent or ingredient in each pill, capsule, tablet or article.

(3) For the purposes of paragraph (1) the container to be labelled shall, where the pharmaceutical product is packed by the manufacturer in more than one container, be the container which is likely to be sold or distributed to the ultimate user of the product.

(4) In the case of a pharmaceutical product intended for export it shall be a sufficient compliance with this regulation if the container of the product is labelled with the following particulars—

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

(b) such other details as the importing country may require. *(L.N. 137 of 1978)*

32. Manufacturing workers not to infect products

A manufacturer shall take adequate steps to ensure that every person engaged in the manufacturing or packing of pharmaceutical products does not contaminate or infect such products.

33. Duties of manufacturers

(1) Subject to paragraph (1A), a manufacturer shall test each lot or batch of raw or bulk material intended to be used in the manufacture of pharmaceutical products to ensure identity and purity.

(1A) Raw or bulk material the identity and purity of which the manufacturer thereof has certified by a certificate of analysis does not require a test by a manufacturer under paragraph (1).

(2) A manufacturer shall test each batch of pharmaceutical products in a finished form to ensure identity and potency.

(3) Every parenteral product shall be manufactured in accordance with the method of preparation of injections laid down by the British Pharmacopoeia or other Pharmacopoeia with which the particular product is intended to comply.

(4) A manufacturer shall maintain a control sample of each batch of finished products under conditions of storage suitable to that product for a period of not less than the normal shelf-life of the product or 2 years after the last transaction in that batch of products whichever is the shorter period.

(5) A manufacturer shall set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any lot or batch of a pharmaceutical substance or product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health.

(L.N. 137 of 1978)

34. Manufacturer's premises

(1) No pharmaceutical product shall be manufactured unless the premises and the fittings and machinery therein used in the manufacturing and packaging of such product are of such construction, materials and finish as to—

(a) permit the ready and efficient cleaning of all surfaces; and

(b) avoid the contamination of the product during manufacture and packing.

(2) All premises used in the manufacturing, testing, packing and despatch of pharmaceutical products shall be—

(a) suitable for the purpose; and

(b) maintained in a clean and orderly condition.

(3) The temperature and humidity of the premises shall be controlled as appropriate to the manufacture of the product or the process being carried out therein.

(4) All parenteral products shall be manufactured and put into containers in an enclosed area in which aseptic conditions can be maintained.

(5) The enclosed area referred to in paragraph (4) shall be separate from the areas used for the manufacture and packing of other pharmaceutical products.

35. Records to be kept by manufacturers

(1) A manufacturer shall maintain adequate records in respect of each pharmaceutical product prepared by him, showing—

(a) the quantities of all substances used in the manufacture of the product;

(b) the quantity of the product manufactured;

(c) the name and the address of the person to whom the pharmaceutical product was sold or supplied;

(d) the nature and results of tests made on each lot or batch of raw or bulk materials used in the product;

(e) the nature and results of tests made on each batch of finished product;

(f) any complaints received relating to the product and the action taken thereon by him; and

(g) the nature and result of any tests made on the samples retained. *(L.N. 228 of 1975)*

(2) The records required to be maintained by paragraph (1) shall be completed within 72 hours from the time the process or test was carried out or the transaction took place. *(L.N. 137 of 1978)*

PART VIII

REGISTRATION OF PHARMACEUTICAL PRODUCTS AND SUBSTANCES

35A. Interpretation (Part VIII)

In this Part, unless the context otherwise requires—

"additional particulars" (附加詳情), in relation to a pharmaceutical product or substance registered before the commencement date, means those registrable particulars of the product or substance not referred to in the repealed regulation 36(3);

"commencement date" (生效日期) means the commencement date* of section 4 of the Pharmacy and Poisons (Amendment) (No. 2) Regulation 1995 (L.N. 366 of 1995);

"registered particulars" (註冊詳情) means—

(a) in relation to a pharmaceutical product or substance registered before the commencement date—

(i) such of its particulars as are registered under the repealed regulation 36(3); and

(ii) its additional particulars as contained in or ascertainable from the application form, the relevant literature and supporting documents (if any) submitted to the Committee for the purpose of the registration of the product or substance, or as contained in or ascertainable from the specimen sales packs or samples (or prototypes of the packs and proposed wordings of the labels) made available for inspection by the Committee for the purpose of the registration of the product or substance;

(b) in relation to a pharmaceutical product or substance registered on or after the commencement date, its registrable particulars as registered under regulation 36(3), or

in either case, where from time to time any subsequent approval has been given by the Board or the Committee to change any of the registrable particulars of the product or substance as from a certain date, then as from that date, its said particulars changed in accordance with such approval;

"registered product or substance" (註冊製品或物質) means any pharmaceutical product or substance which is the subject of a valid registration certificate issued under regulation 36(5);

"registrable particulars" (須註冊詳情), in relation to a pharmaceutical substance, means the particulars referred to in regulation 36(3)(a), and, in relation to a pharmaceutical product, means all of the particulars referred to in regulation 36(3)(a) and (b);

"repealed regulation 36(3)" (已廢除的第36(3)條) means the regulation 36(3) which was in force immediately before the

commencement date.

(L.N. 366 of 1995)

Editorial Note:
* Section 4 of L.N. 366 of 1995 commenced operation on 28 July 1995.

36. Registration of pharmaceutical products and substances

(1) Subject to paragraphs (1A), (1B) and (1C), no person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product or substance unless the product or substance is registered with the Board— *(L.N. 85 of 1987; L.N. 366 of 1995)*

(a) by the manufacturer, if the pharmaceutical product or substance is manufactured in Hong Kong;

(b) by the importer, if the pharmaceutical product or substance is manufactured outside Hong Kong; or

(c) by the local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong. *(L.N. 137 of 1978; 23 of 1998 s. 2)*

(1A) Nothing in paragraph (1) shall apply in the case of possession or use where the pharmaceutical product or substance—

(a) has been imported into Hong Kong—

(i) to be exported outside Hong Kong;

(ii) by a pharmaceutical manufacturer for the purpose of manufacture or the compounding of pharmaceutical preparations;

(iii) 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; or *(L.N. 614 of 1997)*

(b) has been manufactured in Hong Kong to be exported outside Hong Kong. *(L.N. 85 of 1987)*

(1B) For the avoidance of any doubt, a pharmaceutical product or substance is registered with the Board, for the purposes of paragraph (1), if and only if its registrable particulars are those which correspond exactly with the registered particulars of a registered product or substance. *(L.N. 366 of 1995)*

(1C) It shall be a defence to a charge against any person for contravening paragraph (1) if the person proves that he did not know and could not with reasonable diligence have discovered that the product or substance was not registered with the Board. *(L.N. 366 of 1995)*

(2) Application for the initial registration of a pharmaceutical product or substance shall be made in the form prescribed in the Eighth Schedule and shall be accompanied by the fee prescribed in the Ninth Schedule. (See Eighth Schedule Form 6)

(2A) In considering an application for registration of a pharmaceutical product which contains as active ingredients any Chinese herbal medicines or proprietary Chinese medicines as defined in section 2 of the Chinese Medicine Ordinance (Cap. 549) or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Board shall seek advice from the Chinese Medicines Board established under the Chinese Medicine Ordinance (Cap. 549). *(47 of 1999 s. 175)*

(3) The particulars to be registered shall—

(a) in the case of a product or substance, be—

(i) its name;

(ii) its specifications;

(iii) its label;

(iv) its package insert, if any;

(v) the name and address of the manufacturer; and

(vi) the name and address of the applicant;

(b) in the case of a product, further be—

(i) its dose form;

(ii) the quantity or quantities of the dose form contained in its unit package or unit packages;

(iii) the name and quantity of all its active ingredients;

(iv) the name and quantity of all its excipients; and

(v) its proposed indication, dosage and route of administration. *(L.N. 366 of 1995)*

(3A) For the purposes of paragraph (3)—

"active ingredient" (有效成分) means an ingredient of the product which is not an excipient;

"excipient" (賦形劑) means an ingredient of the product which does not contribute to its pharmacological action or which so contributes only by regulating the release of an active ingredient;

"label" (標籤) means any statement forming part of or affixed to the container or package of the product or substance;

"package insert" (包裝附頁) means any leaflet, notification or other document supplied with the container or package of the product or substance, but does not include a label. *(L.N. 366 of 1995)*

(4) Representative specimen sales packs of the product or representative samples of the substance shall be made available for inspection by the Committee. In the case of products not yet marketed the Committee may accept prototypes of the packs and proposed wordings of the labels on the understanding that these will be replaced by actual sale packs not later than 6 months after registration of the product or substance.

(5) The Committee may issue to an applicant a registration certificate in the form prescribed in the Eighth Schedule valid for a period of 5 years from the date of registration on payment of the fee prescribed in the Ninth Schedule. (See Eighth Schedule Form 7)

(6) The Committee shall advise the applicant whether the pharmaceutical product or substance appears in the Poisons List and if so, under which classification.

(7) A registration certificate issued under paragraph (5) shall be renewable on payment of the fee prescribed in the Ninth Schedule.

(8) The Committee may deregister a pharmaceutical product or substance if it considers it to be in the public interest to do so.

(8A) Where the Committee refuses to register or deregisters a pharmaceutical product or substance it shall forward to the applicant or permit holder, as the case may be, a notice of refusal or of deregistration and shall state in such notice its reasons for refusal to register or for deregistration. *(L.N. 137 of 1978)*

(9) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980)*

(10) *(Repealed L.N. 369 of 1980)*

(11) *(Repealed L.N. 366 of 1995)*

(L.N. 137 of 1978; L.N. 369 of 1980)

36A. Application for approval to change the registered particulars of a registered product or substance

(1) In this regulation—

"person responsible for registering a registered product or substance" (負責將註冊製品或物質註冊的人) means a person who, in relation to the product or substance, belongs to any one of the classes of person described in regulation 36(1)(a), (b) or (c).

(2) The person responsible for registering a registered product or substance may apply in writing to the Committee for approval to change any of the registrable particulars of the product or substance except the particulars referred to in regulation 36(3)(a)(i) and (b)(i) and (iii).

(3) A person responsible for registering a registered product or substance who proposes to change the particulars referred to in regulation 36(3)(a)(i) or (b)(i) or (iii) may apply under regulation 36 for registering, as a separate product or substance, as the case may be, the product or substance with the particulars changed as proposed.

(4) In dealing with an application under paragraph (2)—

(a) the Committee shall take into consideration the safety, efficacy and quality of the pharmaceutical product or substance with its particulars changed as proposed, and in considering such safety and efficacy, the Committee shall observe the requirements of regulation 37(2); and

(b) regulation 37(3) shall apply to such application as if it were an application for initial registration of the pharmaceutical product or substance with the particulars changed as proposed.

(5) The Committee shall advise the applicant in writing whether the change is approved, and where the Committee refuses to approve a change it shall state its reasons for such refusal.

(6) Where the change is approved, it shall be approved to take effect from a certain date, and the following provisions shall apply—

(a) as from that date, and without limiting the generality of regulation 36(1B), the product or substance having as its registrable particulars the registered particulars which are to be changed (hereinafter referred to as the "product or substance to be replaced") shall not be regarded as registered with the Board;

(b) the applicant shall, prior to that date, recall or cause to be recalled any product or substance to be replaced which may still be in the possession of any person to whom he supplied the product or substance;

(c) where the product or substance to be replaced is to be recalled, the applicant shall, as soon as reasonably possible, replace or cause to be replaced such product or substance with the product or substance having the particulars changed as approved, or make such alternative arrangements as are agreed with the person to whom he supplied the product or substance.

(7) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

(L.N. 366 of 1995)

36B. Clinical trials and medicinal tests

(1) For the purpose of conducting a clinical trial on human beings or a medicinal test on animals application shall be made in writing to the Committee and shall be accompanied by the fee prescribed in the Ninth Schedule.

(2) A sample of the product or substance and a copy of the protocol for the trial or test shall accompany the application.

(3) The Committee may issue a clinical trial certificate or medicinal test certificate in the form prescribed in the Eighth Schedule valid for a period not exceeding 2 years on payments of the fee prescribed in the Ninth Schedule. (See Eighth Schedule Form 12)

(4) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980)*

(L.N. 137 of 1978; L.N. 360 of 1980)

36C. Definition of "pharmaceutical product" and "substance" for the purposes of this Part

For the purposes of this Part "pharmaceutical product" (藥劑製品) and "substance" (物質) have the meaning assigned to "pharmaceutical product" and "medicine" in the Ordinance.

(L.N. 137 of 1978)

36D. Duplicate certificates

(1) The Committee may issue a duplicate of any certificate issued under this Part if the Committee is satisfied that the original certificate has been lost or destroyed or that for other good reason such duplicate ought to be issued.

(2) A duplicate certificate issued under this regulation shall be certified in such manner as the Committee may determine.

(3) There shall be payable in respect of any duplicate certificate issued under this regulation the fee prescribed in respect thereof in the Ninth Schedule.

(L.N. 369 of 1980)

37. Factors relevant to determination of application for registration

(1) In dealing with an application for initial registration of a pharmaceutical product or substance the Committee shall in particular take into consideration—

(a) the safety of the pharmaceutical product or substance to which the application relates;

(b) the efficacy of the pharmaceutical product or substance for the purposes for which the product or substance is proposed to be administered; and

(c) the quality of the pharmaceutical product or substance according to the specification and the method or proposed method of manufacture of the product or substance, and the provisions proposed for securing that the product or substance as sold or supplied will be of that quality.

(2) In taking into consideration the efficacy for a particular purpose of a pharmaceutical product or substance to which such an application relates, the Committee shall leave out of account any question whether a pharmaceutical product or substance of another description would or might be equally or more efficacious for that purpose:
Provided that nothing in the paragraph shall be construed as requiring the Committee, in considering the safety of a pharmaceutical product or substance of a particular description, in relation to a purpose for which it is proposed to be administered, to leave out of account any question whether a pharmaceutical product or substance of another description, being equally or more efficacious for that purpose, would or might be safer in relation to that purpose.

(3) In dealing with an application by an importer the Committee shall also take into consideration in particular the methods, standards and conditions of manufacture of the pharmaceutical product or substance in respect of which application is made and may, if it thinks fit, require the production by the applicant of one or both of the following—

(a) an undertaking, given by the manufacturer of any such products or substances, to permit the premises where they are to be manufactured, and the operations carried on or to be carried on in the course of manufacturing them, to be inspected by or on behalf of the Committee;

(b) a declaration, given by or on behalf of the manufacturer of any such products or substances, that, in relation to the manufacture of these products any requirements imposed by or under the law of the country in which they are or are to be manufactured have been or will be complied with.

(4) The Committee shall make arrangements for the separate processing of an application for the registration of a new pharmaceutical product or new substance so that its registration shall not be unduly delayed. *(L.N. 137 of 1978)*

(5) For the purposes of paragraph (4) "new pharmaceutical product" (新藥劑製品) and "new substance" (新物質) mean a medicine containing an active ingredient, or a substance, having a chemical formula which has not previously been marketed or registered in Hong Kong under some other name or description. *(L.N. 137 of 1978; L.N. 235 of 1996)*

(L.N. 369 of 1980)

PART VIIIA

REGISTRATION OF IMPORTERS AND EXPORTERS

(Part VIIIA added L.N. 369 of 1980)

37A. Application for registration under section 28A

(1) Any application for registration under section 28A as an importer or exporter of pharmaceutical products shall be made to the Committee in Form 13 in the Eighth Schedule and shall be accompanied by the fee specified in the Ninth Schedule.

(2) The Committee may require any applicant under this regulation to furnish such information and to permit such inspection of premises and storage facilities used by the applicant for the purposes of his business as the Committee may specify by notice to the applicant.

(3) The Committee may grant or refuse any application under this regulation as the Committee may deem fit.

(4) The Committee shall furnish any person whose application is granted with a certificate in Form 14 in the Eighth Schedule.

(5) Any person aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision.

PART IX

SALE OF MEDICINES

38. Disclosure of composition of medicines

(1) Subject to these regulations, no person shall—

(a) sell any article consisting of or comprising a substance recommended as a medicine; or

(b) supply any such article as a sample for the purpose of inducing persons to buy the substances of which it consists or which it comprises,

unless—

(i) the article is labelled as required under regulation 31; or

(ii) the particulars specified under regulation 31(1) are printed so as to be clearly legible in English or Chinese on the article or a label affixed thereto. *(L.N. 137 of 1978)*

(2) Nothing in this regulation shall apply to any article—

(a) made up and supplied for the use of a particular person, being an article prescribed by reference to the needs of that person; or

(b) consisting wholly of either—

(i) a product resulting solely from the pharmaceutical treatment of natural products as referred to by the Chinese Herbal Materia Medica;

(ii) a mixture the sole ingredients of which are two or more of such products; or

(iii) a natural mineral water or an artificial imitation thereof.

(3) For the purposes of this regulation—

"advertisement" (廣告) includes any notice, circular, pamphlet, label, wrapper or other document, and any announcement made orally or by any means of producing or transmitting light or sound;

"proprietary designation" (所有人稱號), in relation to the sale of an article consisting of or comprising a substance recommended as a medicine, means words used or proposed to be used in connexion with the sale of articles consisting of or comprising the substance, for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale; and "proprietor" (所有人) in relation to such a designation means the person whose goods are indicated or intended to be indicated by the designation;

"substance" (物質) includes a preparation;

"substance recommended as a medicine" (建議作為藥物的物質), in relation to the sale of an article consisting or comprising a substance so recommended, means a substance which is referred to—

(a) on the article, or on any wrapper or container in which the article is sold, or on any label affixed to, or in any document enclosed in, the article or such wrapper or container; or

(b) in any placard or other document exhibited at the place where the article is sold; or

(c) in any advertisement published after the coming into operation of these regulations by or on behalf of the manufacturer of the article, or the person carrying on the business in the course of which the article was sold, or, in a case where the article was under a proprietary designation, the proprietor of the designation,

in terms which are calculated to lead to the use of the substance for the prevention or treatment of any ailment, infirmity or injury affecting the human body, not being terms which give a definite indication that the substance is intended to be used as, or as part of, a food or drink, and not as, or as part of, a medicine.

38A. Labelling of certain medicines

(1) No person shall sell or supply any medicine unless it is labelled with particulars printed so as to be clearly legible in English and Chinese, as to dosage and the route and frequency of administration.

(2) This regulation shall not apply to medicine that is included in Part I of the Poisons List or in the Schedule to the Antibiotics Regulations (Cap. 137 sub. leg. A).

(L.N. 85 of 1987)

PART X

MISCELLANEOUS

39. Period of keeping of records

All—

(a) poisons books;

(b) books kept under section 28(3);

(c) certificates given under section 22(1)(a) kept by authorized sellers of poisons;

(d) books or other form of records and documents required to be kept or retained by holders of wholesale poisons licences under regulation 28; and

(e) all records and documents required to be kept or retained by manufacturers under regulation 35,

shall be preserved by the authorized seller of poisons, holder of wholesale poison licence or manufacturer, as the case may be, in the premises in which the transaction recorded took place—

(i) for a period of 2 years from the date of the last entry therein; or

(ii) in relation to a certificate or document, for a period of 2 years from the date of the transaction.

40. Penalties

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

(L.N. 262 of 1995; L.N. 366 of 1995)

41. Certificates, forms and fees

(1) The certificate referred to in section 22(1)(a) may be given by any person known both to the intending purchaser and the intending seller and shall be in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 8)

(2) A certificate of registration issued under section 9 of the Ordinance shall be in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 9)

(2A) The logo referred to in section 13A(1) shall be in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 17) *(L.N. 85 of 1987)*

(3) The particulars of sales of poisons which are required by section 22(3) to be entered in a book shall be entered in the form prescribed in the Eighth Schedule. (See Eighth Schedule, Form 10)

(4) The fees to be paid under the Ordinance and these regulations shall be those prescribed in the Ninth Schedule.

42. *(Omitted as spent)*

FIRST SCHEDULE

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

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

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

(L.N. 41 of 2007)

DIVISION A

Abacavir; its salts	—

Abatacept
Abciximab
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; except when contained in skin creams packed in a package size of not more than 3 grams and labelled for the treatment of cold sores only
Acipimox; its salts
Acitretin; its salts; its esters
Adalimumab
Adapalene; its salts; its esters
Adefovir; its salts; its esters; their salts
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 salts, simple or complex, of any substance falling within the following—
- Calabar bean, alkaloids of
- Coca, alkaloids of, except substances containing less than 0.1% of the alkaloids of coca
- Cocaine, except substances containing less than 0.1% of cocaine
- Codeine, except substances containing not more than 0.1% of codeine
- Colchicum, alkaloids of
- Coniine, except substances containing less than 0.1% of coniine
- Cotarnine, except substances containing less than 0.2% of cotarnine
- Curare, alkaloids of; curare bases
- Ecgonine; its esters and ethers; except substances containing less than the equivalent of 0.1% of ecgonine
- Emetine, except substances containing less than 1% of emetine
- Ephedrine; its optical isomers; their salts; when contained in aerosol dispensers
- Ergot, alkaloids of
- Galantamine
- Gelsemium, alkaloids of, except substances containing less than 0.1% of the alkaloids of gelsemium
- Morphine; its esters and ethers; except substances containing less than 0.2% of morphine calculated as anhydrous morphine
- 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)
- Pilocarpus, alkaloids of, except substances containing less than 0.5% of the alkaloids of pilocarpus
- Rauwolfia, alkaloids of; their derivatives
- Sabadilla, alkaloids of, except substances containing less than 1% of the alkaloids of sabadilla
- Thebaine, except substances containing less than 1% of thebaine
- Veratrum, alkaloids of, except substances containing less than 1% of the alkaloids of veratrum
- Vinca, alkaloids of

Allergen extract of Dermatophagoides pteronyssinus
Allylisopropylacetylurea
Allylprodine; its salts
Almitrine; its salts
Alphadolone; its esters
Alphaxalone
Alprenolol; its salts
Alteplase
Alufibrate
Amantadine; its salts
Amidopyrine; its salts
Amifostine; its salts
Amiloride; its salts
Amineptine; its salts
Aminoglutethimide
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
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—
Antazoline
Astemizole
Doxylamine
Mebhydrolin
Terfenadine
Tripelennamine
Antilymphocyte Immunoglobulins
Antimonial poisons, except substances containing less than the equivalent of 1% of antimony trioxide
Antisera, antitoxins, immunoglobulins and vaccines—
(a) the following—
Bacillus Calmette-Guerin (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
Japanese encephalitis
Haemophilus influenzae type b
Hepatitis A
Hepatitis B
Herpes simplex
Herpes zoster
Human papillomavirus
Influenza
Measles
Mumps
Pertussis
Plague
Poliomyelitis
Rabies
Rubella
Tetanus
Typhoid
Varicella
Yellow fever
Antithymocyte Immunoglobulin
Apomorphine; its salts; its quaternary compounds; except substances containing less than 0.2% of apomorphine
Aprepitant; its salts
Aprindine; its salts
Aripiprazole
Arsenical poisons, except substances containing less than the equivalent of 0.01% of arsenic trioxide and except dentifrices containing less than 0.5% of acetarsol
Arsenic trioxide when contained in pharmaceutical products
Artemether; its salts
Articaine; its salts

Atazanavir; its salts
Atenolol; its salts
Atomoxetine; its salts
Atorvastatin; its salts
Atosiban; its salts
Atovaquone
Atracurium Besylate
Auranofin
Azacitidine; its salts
Azacyclonal; its salts
Azapropazone
Azauridine; its derivatives
Aziridine; its derivatives
Baclofen
Bambuterol and its salts when contained in aerosol dispensers
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
Bemiparin; its salts
Benactyzine; its salts
Benazepril, its salts
Benoxaprofen; its salts
Benserazide; its salts
Benzbromarone
Benzethidine; its salts
Benzhexol; its salts
Benzquinamide
Benzoylmorphine; its salts
Benztropine and its homologues; their 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
Biphenylacetic acid; its salts; its esters; except when contained in preparations intended for external use only
N-[4,4-Bis(para-fluorophenyl)butyl]piperidine, 4-substituted derivatives of; their salts
Bisoprolol; its salts
Bitolterol and its salts when contained in aerosol dispensers
Blood products derived from human blood or manufactured by biotechnology, the following—
    Albumin
    Antithrombins
    Blood clotting factors
    Fibrin
    Fibrinogen
    Plasma protein fractions
    Thrombin
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
Cabergoline; its salts
Calcipotriol; its salts
Canakinumab
Candesartan; its salts; its esters; their salts
Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item
Cannabis; the resin of cannabis; extracts of cannabis; tinctures of cannabis; cannabin tennate

Capecitabine; its salts
Captodiamine; its salts
Captopril
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
Cetrorelix; its salts; its esters; their salts
Cetuximab
Chlofenamic acid; its salts
Chloral; its addition and its condensation products other than alphachloralose; any compound with any substance falling within this item, except when contained, in the form of chloral hydrate, in preparations intended for external application only
Chlordiazepoxide; its salts
Chlormethiazole; its salts
Chlormezanone
Chloroform, except substances containing not more than 5% of chloroform or when in preparations not intended for the internal treatment of human ailments
Chloroquine; its salts
Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide 1,1-dioxide, whether hydrogenated or not; their salts
Chlorphenoxamine; its salts
Chlorphentermine; its salts
Chlorpropamide; its salts
Chlorprothixene and other derivatives of 9-methylenethiaxanthen; their salts
Chlorthalidone and other derivatives of ortho-chlorobenzene-sulphonamide
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
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 and its salts when contained in aerosol dispensers
Clothiapine
Colaspase
Colfosceril; its salts
Collagen, purified
Contrast media, the following; their salts; any compound with any substance falling within this item; when contained in preparations for parenteral use —

Acetrizoic acid
Diatrizoic acid
Ferucarbotran
Gadobenic acid
Gadobutrol
Gadodiamide
Gadopentetic acid
Gadoteric acid

Iobitridol
Iocarmic acid
Iocetamic acid
Iodamide
Iodipamide
Iodised oil
Iodixanol
Iodoxamic acid
Ioglicic acid
Ioglycamic acid
Iohexol
Iomeprol
Iopamidol
Iopanoic acid
Iophendylate
Iopromide
Iothalamic acid
Iotrolan
Iotroxic acid
Ioversol
Ioxaglic acid
Ioxitalamic acid
Ipodic acid
Metrizamide
Propyliodone
Sulphur Hexafluoride
Tyropanoic acid
Corticorelin; its salts
Corticotrophins
Corynebacterium parvum
4-Cyano-2-dimethylamino-4,4-diphenylbutane; its salts
4-Cyano-1-methyl-4-phenylpiperidine; its salts
Cyclarbamate
Cyclobenzaprine; its salts
Cyclofenil
Cyclosporin A
Cytarabine; its salts
Dabigatran etexilate; its salts
Dacarbazine
Daclizumab
Dalteparin; 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
Dehydroemetine; its salts
Demecarium bromide
Desferrioxamine; its salts
Desipramine; its salts
Desomorphine; its salts; its esters and ethers; their salts
Desvenlafaxine; its salts
Dexketoprofen; its salts
Dexmedetomidine; its salts
Dexrazoxane; its salts
Diacerein; its salts; its esters
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; except when contained in preparations for external application only
Didanosine; its salts
Digitalis, glycosides of; other active principles of digitalis
Dihydrallazine; its salts
Dihydrocodeine; its salts; its esters and ethers; their salts
Dihydrocodeinone; its salts
Dihydrocodeinone O-carboxymethyloxime; its salts; its esters; their salts
Dihydrocodeinone enol acetate; its salts
Dihydroergotamine; its salts, simple or complex
Dihydroetorphine; its salts
Dihydromorphine; its salts; its esters and ethers; their salts
3-(3,4-Dihydroxyphenyl)alanine; its salts
Diltiazem; its salts
Dimefline; its salts
Dimenoxadole; its salts
Dimepheptanol; its salts; its esters and ethers; their salts
Dioxaphetyl butyrate; its salts
Dipipanone; its salts
Diprenorphine; its salts

Dipyridamole
Disopyramide; its salts
Distigmine; its salts
Disulfiram
Dithienylallylamines; dithienylalkylallylamines; their salts
Dobutamine; its salts
Docetaxel; 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
Ecothiopate iodide
Ectylurea
Efalizumab
Efavirenz; its salts
Eletriptan; its salts
Eltrombopag; its salts; its esters; their 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
Erlotinib; its salts
Esmolol; its salts
Esomeprazole; 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; except substances containing less than 0.2% of ethylmorphine
Etidronic acid; its salts
Etilefrine; its salts
Etodolac
Etofibrate
Etomidate; its salts
Etonitazene; its salts
Etoposide; its esters
Etoricoxib; its salts
Etorphine; its salts; its esters and ethers; their salts
Etoxeridine; its salts
Etravirine
Etretinate
Etryptamine; its salts
Everolimus; its salts; its esters; their salts
Exemestane; its salts
Exenatide
Ezetimibe
Famciclovir; its salts
Felodipine
Fenbufen
Fencamfamin; its salts
Fenclofenac; its salts
Fendiline; its salts
Fenfluramine; its salts
Fenofibrate
Fenoprofen; its salts

Fenoterol and its salts when contained in aerosol dispensers
Fenoxazoline; its salts
Fentanyl; its salts
Fentiazac; its salts
Feprazone
Fesoterodine; its salts; its esters; their salts
Filgrastim
Finasteride
Flavoxate; its salts
Flecainide; its salts
Fleroxacin; its salts; its esters
Fluanisone
Fluconazole; its salts
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 and its salts when contained in aerosol dispensers
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
Glibenclamide
Glibornuride
Gliclazide
Glimepiride; its salts
Glipizide
Gliquidone
Glucagon; its salts
Glutethimide; 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-phenetylguanidine; their salts
Halofantrine; its salts
Haloperidol and other 4-substituted derivatives of N-(3-parafluorobenzoyl-propyl) piperidine
Hexachlorophane contained in medicinal products except (a) in the case of medicinal products for human use substances containing 0.1% or less; and (b) in the case of medicinal products for animal use (i) aerosols the contents of the container of which contain 0.1% or less; (ii) soaps and shampoos containing 2% or less; (iii) other medicinal products containing 0.75% or less; and (c) preparations for oral administration to sheep or cattle for liver fluke disease
Hexamethylmelamine
Hexapropymate
Hexobendine; its salts
Hydiazines, the following and their alpha-methyl derivatives—
Benzyl hydrazine
Phenethyl hydrazine
Phenoxyethyl hydrazine

their salts; their acyl derivatives; their salts
Hydrallazine; its salts
Hydrocyanic acid, except substances containing less than 0.15%, weight in weight, of hydrocyanic acid (HCN); cyanides, other than ferrocyanides and ferricyanides, except substances containing less than the equivalent of 0.1% weight in weight, of hydrocyanic acid (HCN)
Hydromorphinol; its salts; its esters and ethers; their salts
Hydromorphone; its salts; its esters and ethers; their salts
Hydroxychloroquine; its salts
Hydroxy-N,N-dimethyltryptamines; their esters and ethers; any salt of any substance falling within this item
3-Hydroxy-N-methylmorphinan; its salts; its optical isomers; their salts
3-Hydroxymorphinan; its salts; its optical isomers; their salts; their esters and ethers; their salts
3-Hydroxy-N-phenacylmorphinan; its salts; its optical isomers; their salts; their esters and ethers; their salts
Hydroxypethidine; its salts; its esters and ethers; their salts
Hydroxyphenamate
Hydroxyurea
Hydroxyzine; its salts
Ibandronic acid; its salts
Ibritumomab tiuxetan
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
Interferons
Iprindole; its salts
Irbesartan; its salts
Irinotecan; its salts
Isoaminile; 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
Isotretinoin
Isoxicam; its salts
Isradipine
Itraconazole; its salts
Ivabradine; its salts
Ketamine; its salts
Ketanserine; its salts
Ketobemidone; its salts; its esters and ethers; their salts
Ketoconazole except when contained in preparations for external application only
Ketophenylbutazone
Ketorolac; its salts; its esters
Labetalol; its salts
Lacidipine; its salts
Lamivudine; its salts
Lamotrigine; its salts
Lanreotide; its salts
Lansoprazole
Lanthanum carbonate
Lapatinib; its salts
Laronidase
Laropiprant; its salts
Lead, compounds of, 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
Levosimendan; its salts
Lidoflazine
Linezolid; its salts
Lisinopril; its salts
Lithium carbonate

Lithium Sulphate
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
Lysuride; its salts
Mangafodipir; its salts
Mannomustine; its salts
Maprotiline; its salts
Maraviroc; its salts
Marbofloxacin; its salts
Mazindol
Mebutamate
Mecamylamine; its salts
Meclobemide; its salts
Meclofenamic Acid; its salts
Meclofenoxate; its salts
Medigoxin
Mefenamic acid; its salts; its esters; their salts
Mefloquine; its salts
Mefruside
Melagatran; its salts; its derivatives; their salts
Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia
Melitracen; its salts
Meloxicam; its salts
Memantine; its salts
Mephenesin; its esters; their salts
Mephenoxalone
Mepirizole
Mepivacaine; its salts
Meprobamate
alpha-Meprodine; its salts
beta-Meprodine; its salts
Mercaptopurine; its salts; its derivatives; their salts
Mercuric chloride, except substances containing less than 1% of mercuric chloride; mercuric iodide, except substances containing less than 2% of mercuric iodide; nitrates of mercury, except substances containing less than the equivalent of 3%, weight in weight, of mercury (Hg); potassiomercuric iodides, except substances containing less than the equivalent of 1% of mercuric iodide; organic compounds of mercury, except substances, not being aerosols, containing less than the equivalent of 0.3%, weight in weight, of mercury (Hg)
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; except substances containing not more than 0.1% of dextromethorphan
Methoxsalen
Methyldesorphine; its salts; its esters and ethers; their salts
Methyldihydromorphine; its salts; its esters and ethers; their salts
Methyldopa; its esters; their salts
2-Methyl-3-morpholino-1,1-diphenylpropanecarboxylic acid; its salts; its esters; their salts
Methylnaltrexone; its salts
Methylphenidate; 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
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
Metyrapone; its salts
Mexiletine; its salts
Mianserin; its salts
Mibefradil; its salts
Micafungin; its salts; its esters
Midodrine; its salts
Miglitol; its salts
Milnacipran; its salts
Milrinone; its salts
Minoxidil except when contained in preparations intended for external application only and the preparations contain not more than 5% of Minoxidil
Mirtazapine; its salts
Mitobronitol
Mitopodozide; its salts
Mitotane
Mitoxantrone; its salts
Mivacurium; its salts
Mizolastine; its salts
Moexipril; its salts
Mofebutazone; its salts
Molgramostim
Molindone; its salts
Montelukast; its salts
Moracizine; its salts
Moramide; its salts; its optical isomers; their salts
Moroxydine; its salts
Morpheridine; its salts
Moxifloxacin; its salts
Moxonidine; its salts
Muromonab-CD3
Mustine and any other N-substituted derivative of di-(2-chloroethyl)amine; their salts
Muzolimine
Mycophenolic acid; its salts; its esters
Myrophine; its salts
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
Nateglinide; its salts; its esters
Nebivolol; its salts
Nefazodone; its salts
Nefopam; its salts
Nelfinavir; its salts
Neostigmine; its salts
Nepafenac; its salts
Nesiritide
Nevirapine; its salts
Nicergoline
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
Ondansetron; its salts
Opipramol; its salts; its derivatives; their salts
Opium, except substances containing less than 0.2% of morphine calculated as anhydrous morphine
Orciprenaline; its salts
Orgotein
Orlistat; its salts; except when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day
Orphenadrine; its salts
Oseltamivir; its salts
Ouabain
Oxaliplatin; its salts
Oxanamide
Oxcarbazepine; its salts
Oxprenolol; its salts
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
Pantethine; its salts
Pantoprazole; its salts
Paraldehyde
Paramethadione
Parecoxib; its salts
Pargyline; its salts
Paricalcitol; its salts; its esters; their salts
Paroxetine; 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
Pentamidine; its salts
Pentazocine; its salts
Pentolinium; its salts
Pergolide; its salts
Perindoprilat; its salts; its esters; their salts
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
Phenomorphan; its salts; its esters and ethers; their salts
Phenoperidine; its salts; its esters and ethers; their salts
Phenothiazine; its salts; its derivatives (except dimethoxanate and promethazine); their salts (except salts of dimethoxanate and promethazine); 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; except substances containing less than 1.5% of pholcodine
Picrotoxin
Pimecrolimus
Piminodine; its salts
Pioglitazone; its salts
Pipecuronium; its salts
Pipemidic acid
Pipobroman
Piritramide; its salts
Piromidic acid; its salts
Piroxicam except when contained in preparations for external application only
Pirprofen; its salts
Pituitary gland, the active principles of, other than corticotrophins, oxytocins and vasopressins
Pizotifen; its salts
Plerixafor; its salts
Polymethylenebistrimethylammonium salts
Poractant alfa
Posaconazole; its salts; its esters; their salts
Pralidoxime; its salts
Pramipexole; 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 and its salts when contained in aerosol dispensers
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
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
Rasburicase; its salts
Reboxetine; its salts
Recombinant human erythropoietin
Remifentanil; its salts
Remoxipride; its salts
Repaglinide; its salts; its esters
Reproterol and its salts when contained in aerosol dispensers
Rescinnamine
Reteplase
Reviparin; its salts
Ribavirin; its salts
Rilmenidine; its salts
Riluzole; its salts
Rimiterol and its salts when contained in aerosol dispensers
Rimonabant; its salts
Risedronic acid; its salts
Risperidone
Ritodrine; its salts
Ritonavir; its salts
Rituximab
Rivaroxaban; its slats
Rivastigmine; its salts
Rizatriptan; its salts
Rocuronium; its salts
Rofecoxib; its salts
Ropinirole; its salts
Ropivacaine; its salts
Rosiglitazone; its salts
Rosoxacin; its salts
Rosuvastatin; its salts
Rotigotine; its salts
Salbutamol and its salts except when contained in aerosol dispensers
Salmeterol and its salts when contained in aerosol dispensers
Saquinavir; its salts
Saxagliptin; its salts
Sermorelin; 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 nitroprusside
Solifenacin; its salts; its esters; their salts
Somatostatin
Sorafenib; its salts
Sotalol; its salts
Sparfloxacin; its salts; its esters
Sparteine; its salts
Spironolactone
Stavudine; its salts
Streptokinase
Strontium ranelate
Strophanthus, glycosides of
Styramate
Sulindac
Sulphinpyrazone
Sulphonal; alkyl sulphonals
Sulpiride
Sultopride
Sumatriptan; its salts
Sunitinib; its salts; their salts
Suprarenal gland, the active principles of, except adrenaline and noradrenaline (other than when contained in aerosol dispensers); their salts; except salts of adrenaline (other than when contained in aerosol dispensers); their derivatives; their salts; except hydrocortisone and its salts when contained in preparations intended for external application only at not more than 1%; except beclomethasone and its salts when contained in aerosol dispensers and except clobetasone butyrate when contained in preparations intended for external application only at not more than 0.05%
Sutoprofen; its salts
Suxamethonium; its salts

Syrosingopine
Tacrine; its salts
Tacrolimus
Tadalafil; its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12, 12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts
Tafluprost
Tamoxifen; its salts
Tazarotene; its salts
Tegaserod; its salts
Telbivudine; its salts
Telmisartan; its salts
Temozolomide; its salts
Temsirolimus; its salts; its esters
Tenecteplase; its salts
Teniposide
Tenofovir; its salts; its esters; their salts
Tenoxicam
Terazosin; its salts
Terbinafine; its salts; except when contained in preparations for external application only
Terbutaline and its salts when contained in aerosol dispensers
Teriparatide; its salts
Terodiline; its salts
Tertatolol; its salts
Tetrabenazine; its salts
Tetracosatrin; its salts
Thalidomide; its salts
Thallium, salts of
Theofibrate
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
Ticlopidine; its salts
Tiletamine; its salts
Tilidate; its salts
Tiludronic acid; its salts
Timolol; its salts
Tinoridine; its salts
Tinzaparin; its salts
Tiotropium; its salts
Tiratricol; its salts
Tirofiban; its salts
Tizanidine; its salts
Tocainide; its salts
Tocilizumab
Todralazine; 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 except when contained in toothpaste at 0.05% by weight
Tranylcypromine; its salts
Trastuzumab
Trazodone; its salts
Tretamine; its salts
Tretinoin
Triamterene; its salts
Triaziquone
Tribromoethyl alcohol
2,2,2-Trichloroethyl alcohol, esters of; their salts
Trifluridine; its salts
Trilostane
Trimeperidine; its salts

Trimetaphan; its salts
Trimetazidine; its salts
Trimethadione
Trimethoprim
Trimetozine
Trimetrexate; its salts
Trimipramine; its salts
Trioxsalen
Triptorelin; its salts
Tromantadine; its salts; except when contained in pharmaceutical products labelled for the treatment of cold sores only
Tropisetron; its salts
Trovafloxacin; its salts; its derivatives; their salts
Tulobuterol and its salts when contained in aerosol dispensers
Tybamate
Urapidil; its salts
Urethane
Urokinase
Ustekinumab
Valaciclovir; its salts
Valdecoxib; its salts
Valganciclovir; its salts
Valnoctamide
Valproic acid; its salts; its esters
Valsartan; its salts
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
Vencuronium; its salts
Venlafaxine; its salts
Veralipride; its salts
Verapamil; its salts
Verteporfin; its salts
Vidarabine; its salts
Vigabatrin
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 10000 international units of vitamin A
Voriconazole; its salts
Warfarin 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

(L.N. 137 of 1978; L.N. 369 of 1980; L.N. 415 of 1984; L.N. 129 of 1986; L.N. 130 of 1987; L.N. 197 of 1989; L.N. 128 of 1990; L.N. 384 of 1992; L.N. 262 of 1995; L.N. 130 of 1998; L.N. 22 of 1999; L.N. 202 of 1999; L.N. 30 of 2000; L.N. 138 of 2000; L.N. 235 of 2000; L.N. 296 of 2000; L.N. 51 of 2001; L.N. 143 of 2001; L.N. 173 of 2001; L.N. 287 of 2001; L.N. 56 of 2002; L.N. 112 of 2002; L.N. 132 of 2002; L.N. 170 of 2002; L.N. 237 of 2002; L.N. 73 of 2003; L.N. 179 of 2003; L.N. 181 of 2003; L.N. 273 of 2003; L.N. 276 of 2003; L.N. 74 of 2004; L.N. 135 of 2004; L.N. 191 of 2004; L.N. 11 of 2005; L.N. 72 of 2005; L.N. 114 of 2005; L.N. 212 of 2005; L.N. 25 of 2006; L.N. 122 of 2006; L.N. 178 of 2006; L.N. 223 of 2006; L.N. 277 of 2006; L.N. 41 of 2007; L.N. 98 of 2007; L.N. 143 of 2007; L.N. 208 of 2007; L.N. 239 of 2007; L.N. 61 of 2008; L.N. 113 of 2008; L.N. 197 of 2008; L.N. 234 of 2008; L.N. 282 of 2008; L.N. 90 of 2009; L.N. 147 of 2009; L.N. 199 of 2009; L.N. 258 of 2009; L.N. 11 of 2010; L.N. 32 of 2010; L.N. 81 of 2010; L.N. 104 of 2010; L.N. 140 of 2010; L.N. 23 of 2011)

DIVISION B

Barium, salts of, except barium sulphate
Dinitronaphthols; dinitrophenols; dinitrothymols
meta-Nitrophenol; ortho-nitrophenol; para-nitrophenol
—Phosmet

(L.N. 195 of 1977; L.N. 137 of 1978; L.N. 129 of 1986; L.N. 262 of 1995; L.N. 41 of 2007)

SECOND SCHEDULE

[reg. 8]

ARTICLES EXEMPTED BY REGULATION 8 FROM THE PROVISIONS OF THE ORDINANCE AND OF THESE REGULATIONS

GROUP I

GENERAL EXEMPTIONS

Adhesives; anti-fouling compositions; builders' materials; ceramics; distempers; electrical valves; enamels; explosives; fillers; fireworks; fluorescent lamps; glazes; glues; inks; lacquer solvents; loading materials; matches; motor fuels and lubricants; paints other than pharmaceutical paints; photographic paper; pigments; plastics; propellants; rubber; varnishes

(L.N. 195 of 1977; L.N. 262 of 1995)

GROUP II

SPECIAL EXEMPTIONS

DIVISION A—*(L.N. 41 of 2007)*

Poison	Substance or article in which exempted
Alkaloids, the following—	
Brucine	Surgical spirit containing not more than 0.015% of brucine
Emetine	Ipecacuanha; extracts and tinctures of ipecacuanha; substances containing less than 0.05% of emetine
Lobelia, alkaloids of	Preparations for the relief of asthma in the form of cigarettes, smoking mixtures or fumigants; substances containing less than 0.1% of the alkaloids of lobelia
Pilocarpus, alkaloids of	Substances containing less than 0.025% of the alkaloids of pilocarpus, preparations containing not more than 2%, weight of the sulphate salt of transpilosine *(L.N. 137 of 1978)*
Pomegranate, alkaloids of	Pomegranate bark
Stavesacre, alkaloids of	Soaps; ointments; lotions for external use
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	Feeding stuffs containing not more than 0.5% of total sulphonamides
Androgenic, oestrogenic and progestational substances, the following—	Preparations intended for external application only; except preparations containing more than 4 milligrammes of oestrogenic substance per 100 grammes of inert substance and preparations containing testosterone or its esters *(L.N. 90 of 2009)*
Benzoestrol	
Derivatives of stilbene, dibenzyl or naphthalene with oestrogenic activity; their esters	
Steroid compounds with androgenic or oestrogenic or progestational activity; their esters	preparations intended to be taken orally for contraceptive purposes only which contain not more than the following per dose— 0.15 milligrammes Desogestrel; 3.00 milligrammes Drospirenone; 0.05 milligrammes Ethinyloestradiol; 0.10 milligrammes Gestodene; 0.25 milligrammes Levonorgestrel; 2.50 milligrammes Lynoestrenol; 0.05 milligrammes Mestranol; 1.00 milligrammes Norethisterone; 0.25 milligrammes Norgestimate; and 0.50 milligrammes Norgestrel, multivitamin preparations with or without minerals containing not more than 0.01 mg. ethinyloestradiol or not more than 2.5 mg. Methyltestosterone or both in each dosage form *(L.N. 369 of 1980; L.N. 112 of 2002)*
Antihistamine substances; their salts; any compound with any substance falling within this item	Preparations intended for external application only and preparations containing not more than 1% of anti-histamine substances for application in the nose or eye
Arsenical poisons	Poultry or pig feeding stuffs containing not more than 0.005% of 4-hydroxy-3-nitrophenylarsonic acid and not containing any other arsenical poison; animal feeding stuffs containing not more than 0.01% of arsenilic acid and not containing any other arsenical poison; poultry feeding stuffs containing not more than 0.0375% of carbarsone and not containing any other arsenical poison; medicines containing arsenic in a non-assimilable form
Barbituric acid; its salts; its derivatives; their salts; any compound with any substance falling within this item	Self-heating preparations, in aerosol dispensers intended for external application only, containing 1, 5-diethyl-2-thio-4, 6-pyrimidine-dione and not containing any other substance mentioned opposite hereto in the first column

Chloroform	Substances containing less than 1% of chloroform; solid preparations; toothpaste
Clioquinol	Preparations intended for external application only *(L.N. 137 of 1978)*
Creosote obtained from wood	Substances containing less than 50% of creosote obtained from wood
Diperodon; its salts	Preparations intended for external application only, containing not more than 1% of diperodon, calculated as anhydrous base
Hydrocyanic acid	Preparations of wild cherry; in reagent kits supplied for medical or veterinary purposes; substances containing less than the equivalent of 0.1%, weight in weight, of hydrocyanic acid (HCN)
Lead acetate	Substances containing less than 4% of lead acetate
Lead, compounds of	Machine-spread plasters
Lignocaine; its salts	Preparations intended for external application only, containing not more than 0.7% of Lignocaine or its salts *(L.N. 369 of 1980)*
Mercury, nitrates of	Ointments containing less than the equivalent of 3%, weight in weight, of mercury (Hg)
Mescaline; its salts	Living plants
Phenols	Butylated hydroxytoluene, carvacrol, creosote obtained from coal tar; essential oils in which phenols occur naturally; medicines containing less than 1% of phenols; nasal sprays, mouth washes, pastilles, lozenges, capsules, pessaries, ointments or suppositories containing less than 2.5% of phenols, in reagent kits supplied for medical or veterinary purposes; smelling bottles; soaps for washing; solid substances, other than pastilles, lozenges, capsules, pessaries, ointments and suppositories, containing less than 60% of phenols; Tar (coal or wood), crude or refined; para-tertiary amylphenol; tertiary butylcresol; para-tertiary butylphenol; para-(1, 1, 3, 3-tetramethylbutyl) phenol; thymol
Phenyl mercuric salts	Toilet, cosmetic and therapeutic preparations containing not more than 0.01% of phenyl mercuric salts as preservative; antiseptic dressings on toothbrushes; in textiles containing not more than 0.01% of phenyl mercuric salts as a bacteriostat and fungicide
Picric acid	Substances containing less than 5% of picric acid
Podophyllum resin	Preparations containing not more than 1.5%, weight in weight, of podophyllum resin
Procaine	Feeding stuffs containing any substance to which the Antibiotics Ordinance (Cap. 137) for the time being applies
Quinine; its salts; its derivatives; their salts	Preparations containing not more than 1% of quinine, its salts, its derivatives or their salts; soft drinks, wines or tonic wines; preparations containing not more than 15% of quinine, its salts, its derivatives or their salts for use in the manufacture of soft drinks, wines, tonic wines, or confectionery *(L.N. 130 of 1987)*
Sodium ethyl mercurithio-salicylate	Therapeutic substances containing less than 0.1% of sodium ethyl mercurithiosalicylate as a preservative
Sodium fluoride	Substances containing less than 3% of sodium fluoride as a preservative; dentifrices containing not more than 0.33% of sodium fluoride; mouth wash tables containing not more than 0.2% of sodium fluoride and liquid mouth washes containing not more than 0.05% thereof; tablets containing not more than 0.016%, weight in weight, of sodium fluoride and intended, when chewed to prevent tooth decay *(L.N. 202 of 1999)*

(L.N. 138 of 2000; L.N. 41 of 2007)

DIVISION B—*(L.N. 41 of 2007)*

Acetanilide; alkyl acetanilides	Substances not being preparations for the treatment of human ailments
Ammonia	Substances not being solutions of ammonia or preparations containing solutions of ammonia; substances containing less than 5%, weight in weight, of ammonia (NH_3); refrigerators; smelling bottles
Antimony, chlorides of	Polishes
Arsenical poisons	Pyrites ores or sulphuric acid containing arsenical poisons as natural impurities
Barium, salts of	Witherite other than finely ground witherite; barium carbonate bonded to charcoal for case hardening; fire extinguishers containing barium chloride
gamma-Benzene hexachloride	Substances containing not more than 5% by weight of gamma-benzene hexachloride; when used in agriculture or horticulture *(L.N. 195 of 1977)*
Diamines, the following; their salts-phenylene diamines; toluene diamines; other alkylated-benzene diamines	Substances other than preparations for the dyeing of hair
Dinitrophenols	Substances not being preparations for the treatment of human ailments
Disulfiram	Substances not being preparations for the treatment of human ailments
Formaldehyde	Substances containing less than 5%, weight in weight, of formaldehyde (H. CHO); photographic glazing or hardening solutions
Formic acid	Substances containing less than 5%, weight in weight, of formic acid (H. COOH)
Hydrochloric acid	Substances containing less than 9%, weight in weight, of hydrochloric acid (HCl)
Mercuric chloride	Batteries
Mercuric chloride; mercuric iodide; organic compounds of mercury	Dressings on seeds or bulbs
Mercury, oxides of	Canker and wound paints (for trees) containing not more than 3%, weight in weight, of yellow mercuric oxide

Nicotine	Tobacco; preparations in aerosol dispensers containing not more than 0.2% of nicotine, weight in weight; other liquid preparations and solid preparations with a soap base, containing not more than 7.5% of nicotine, weight in weight
Nitric acid	Substances containing less than 9%, weight in weight, of nitric acid (HNO_2)
Nitrobenzene	Substances containing less than 0.1% of nitrobenzene; soaps containing less than 1 % of nitrobenzene; polishes
para-Nitrobenzyl cyanide	Photographic solutions containing less than the equivalent of 0.1%, weight in weight, of hydrocyanic acid (HCN)
para-Nitrophenol	Preparations for use in agriculture or horticulture containing not more than 0.5% of para-Nitrophenol as preservative
Oxalic acid; metallic oxalates	Laundry blue; polishes; cleaning powders or scouring products containing the equivalent of not more than 10% of oxalic acid dihydrate
Phosphoric acid	Substances containing phosphoric acid, not being descaling preparations containing more than 50%, weight in weight, of ortho-phosphoric acid *(L.N. 137 of 1978)*
Potassium hydroxide	Substances containing the equivalent of less than 17% of total caustic alkalinity expressed as potassium hydroxide; accumulators, batteries
Sodium hydroxide	Substances containing the equivalent of less than 12% of total caustic alkalinity expressed as sodium hydroxide
Sodium nitrite	Substances other than preparations containing more than 0.1% of sodium nitrite for the destruction of rats or mice
Sodium silicofluoride	Substances containing less than 3% of sodium silicofluoride as preservative
Sulphaquinoxaline; its salts	Preparations for the destruction of mice and rats containing not more than the equivalent of 0.5% of sulphaquinoxaline
Sulphuric acid	Substances containing less than 9%, weight in weight, of sulphuric acid (H_2SO_4); accumulators; batteries and sealed containers in which sulphuric acid is packed together with car batteries for use in those batteries; fire extinguishers

(L.N. 195 of 1977; L.N. 262 of 1995)

THIRD SCHEDULE

[reg. 9(1)]
(L.N. 41 of 2007)

DIVISION A

SUBSTANCES REQUIRED BY REGULATION 9 TO BE SOLD BY RETAIL ONLY UPON A PRESCRIPTION GIVEN BY A REGISTERED MEDICAL PRACTITIONER, REGISTERED DENTIST OR REGISTERED VETERINARY SURGEON

(L.N. 614 of 1997)

Abacavir; its salts
Abatacept
Abciximab
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; except when contained in skin creams packed in a package size of not more than 3 grams and labelled for the treatment of cold sores only
Acipimox; its salts
Acitretin; its salts; its esters
Adalimumab
Adapalene; its salts; its esters
Adefovir; its salts; its esters; their salts
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—

Calabar bean, alkaloids of
Codeine, except substances containing less than 0.2% of codeine
Coniine, except substances containing less than 0.1% of coniine
Cotarnine, except substances containing less than 0.2% of cotarnine
Curare, alkaloids of; curare bases
Emetine, except substances containing less than 1% of emetine
Ergot, alkaloids of
Galantamine
Gelsemium, alkaloids of, except substances containing less than 0.1% of the alkaloids of gelsemium
Pilocarpus, alkaloids of, except substances containing less than 0.5% of the alkaloids of pilocarpus
Sabadilla, alkaloids of, except substances containing less than 1% of the alkaloids of sabadilla
Veratrum, alkaloids of, except substances containing less than 1% of the alkaloids of veratrum

Allergen extract of Dermatophagoides pteronyssinus
Allylisopropylacetylurea
Almitrine; its salts
Alphadolone; its esters
Alphaxalone
Alprenolol; its salts
Alteplase
Alufibrate
Amantadine; its salts
Amidopyrine; its salts
Amifostine; its salts
Amiloride; its salts
Amineptine; its salts
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; except when contained in preparations intended for external application or surgical dressings or in preparations for the prevention and treatment of diseases in poultry
Aminoglutethimide
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
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
Anistreplase
Antihistamine substances, the following; their salts; any compound with any substance falling within this item—
Antazoline
Astemizole
Doxylamine
Mebhydrolin
Terfenadine
Tripelennamine
Antilymphocyte Immunoglobulins
Antisera, antitoxins, immunoglobulins and vaccines—
(a) the following—
Bacillus Calmette-Guerin (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
Japanese encephalitis
Haemophilus influenzae type b
Hepatitis A
Hepatitis B
Herpes simplex
Herpes zoster
Human papillomavirus
Influenza
Measles
Mumps
Pertussis
Plague
Poliomyelitis
Rabies
Rubella
Tetanus
Typhoid
Varicella
Yellow fever
Antithymocyte Immunoglobulin
Apomorphine; its salts; its quaternary compounds; except substances containing less than 0.2% of apomorphine
Aprepitant; its salts
Aprindine; its salts
Aripiprazole
Arsenic trioxide when contained in pharmaceutical products
Artemether; its salts
Articaine; its salts
Atazanavir; its salts
Atenolol; its salts
Atomoxetine; its salts
Atorvastatin; its salts
Atosiban; its salts
Atovaquone
Atracurium Besylate
Auranofin
Azacitidine; its salts
Azacyclonol; its salts
Azapropazone
Azauridine; its derivatives
Aziridine; its derivatives
Baclofen
Bambuterol and its salts when contained in aerosol dispensers
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
Bemiparin; its salts
Benactyzine; its salts
Benazepril; its salts
Benoxaprofen; its salts
Benserazide; its salts
Benzbromarone
Benzhexol; its salts
Benzquinamide
Benztropine and its homologues; their salts
Besifloxacin; its salts; its esters; their salts
Betaxolol; its salts
Bethanidine; its salts
Bevacizumab
Bezafibrate
Bicalutamide; its salts
Biphenylacetic acid; its salts; its esters; except when contained in preparations intended for external use only
N-[4,4-Bis(para-fluorophenyl)butyl]piperidine, 4-substituted derivatives of; their salts
Bisoprolol; its salts
Bitolterol and its salts when contained in aerosol dispensers
Blood products derived from human blood or manufactured by biotechnology, the following-
Albumin
Antithrombins
Blood clotting factors
Fibrin
Fibrinogen
Plasma protein fractions
Thrombin
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
Cabergoline; its salts
Calcipotriol; its salts
Canakinumab
Candesartan; its salts; its esters; their salts
Capecitabine; its salts
Captodiamine; its salts
Captopril
Caramiphen; its salts; except tablets containing not more than the equivalent of 7.5 milligrammes of caramiphen base and liquid preparations containing not more than the equivalent of 0.1% of caramiphen base
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
Cetrorelix; its salts; its esters; their salts
Cetuximab
Chlofenamic acid; its salts
Chloral; its addition and its condensation products other than alphachloralose; any compound with any substance falling within this item, except when contained, in the form of chloral hydrate, in preparations intended for external application only
Chlordiazepoxide; its salts
Chlormethiazole; its salts
Chlormezanone
Chloroquine; its salts
Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide 1, 1-dioxide, whether hydrogenated or not; their salts
Chlorphenoxamine; its salts
Chlorphentermine; its salts
Chlorpropamide; its salts
Chlorprothixene and other derivatives of 9-methylenethiaxanthen; their salts
Chlorthalidone and other derivatives of ortho-chlorobenzene sulphonamide
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
Clofazimine; its salts
Clofibrate
Clomiphene; its salts
Clomipramine; its salts; its derivatives; their salts
Clonidine; its salts
Clopidogrel; its salts
Clorexolone
Cloridarol
Clorprenaline and its salts when contained in aerosol dispensers
Clothiapine
Colaspase
Colchicum, alkaloids of, their salts
Colfosceril; its salts
Collagen, purified
Contrast media, the following; their salts; and compound with any substance falling within this item; when contained in preparations for parenteral use-
Acetrizoic acid
Diatrizoic acid
Ferucarbotran
Gadobenic acid
Gadobutrol
Gadodiamide
Gadopentetic acid
Gadoteric acid
Iobitridol
Iocarmic acid
Iocetamic acid
Iodamide
Iodipamide
Iodised oil
Iodixanol
Iodoxamic acid
Ioglicic acid
Ioglycamic acid
Iohexol
Iomeprol
Iopamidol
Iopanoic acid
Iophendylate
Iopromide
Iothalamic acid
Iotrolan
Iotroxic acid
Ioversol
Ioxaglic acid
Ioxitalamic acid
Ipodic acid
Metrizamide
Propyliodone
Sulphur Hexafluoride
Tyropanoic acid
Corticorelin; its salts
Corticotrophins
Corynebacterium parvum
Cyclarbamate
Cyclobenzaprine; its salts
Cyclofenil
Cyclosporin A
Cytarabine; its salts
Dabigatran etexilate; its salts
Dacarbazine
Daclizumab
Dalteparin; 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
Dehydroemetine; its salts
Demecarium bromide
Desferrioxamine; its salts
Desipramine; its salts
Desvenlafaxine; its salts
Dexketoprofen; its salts
Dexmedetomidine; its salts
Dexrazoxane; its salts
Diacerein; its salts; its esters

Diazepam and other compounds containing the chemical structure of dihydro-1, 4-benzodiazepine substituted to any degree; their salts
Diazoxide
Diclofenac; its salts; except when contained in preparations for external application only
Didanosine; its salts
Digitalis, glycosides of; other active principles of digitalis
3-(3,4-Dihydroxyphenyl)alanine; its salts
Dihydrallazine; its salts
Dihydroergotamine; its salts, simple or complex
Dihydroetorphine; its salts
Diltiazem; its salts
Dimefline; its salts
Diprenorphine; its salts
Dipyridamole
Disopyramide; its salts
Distigmine; its salts
Disulfiram
Dithienylallylamines; dithienylalkylallylamines; their salts; except diethylthiambutene, dimethylthiambutene and ethylmethylthiambutene
Dobutamine; its salts
Docetaxel; 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
Ecothiopate iodide
Ectylurea
Efalizumab
Efavirenz; its salts
Eletriptan; its salts
Eltrombopag; its salts; its esters; their 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
Ephedrine; its optical isomers; their salts; when contained in aerosol dispensers
Eplerenone
Epoetin beta
Eprosartan; its salts
Eptifibatide; its salts
Erlotinib; its salts
Esmolol; its salts
Esomeprazole; 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
Ethylnoradrenaline and its salts when contained in aerosol dispensers
Etidronic acid; its salts
Etilefrine; its salts
Etodolac
Etofibrate
Etomidate; its salts
Etoposide; its esters
Etoricoxib; its salts
Etravirine

Etretinate
Etryptamine; its salts
Everolimus; its salts; its esters; their salts
Exenatide
Exemestane; its salts
Ezetimibe
Famciclovir; its salts
Felodipine
Fenbufen
Fencamfamin; its salts
Fenclofenac; its salts
Fendiline; its salts
Fenfluramine; its salts
Fenofibrate
Fenoprofen; its salts
Fenoterol and its salts when contained in aerosol dispensers
Fenoxazoline; its salts
Fentiazac; its salts
Feprazone
Fesoterodine; its salts; its esters; their salts
Filgrastim
Finasteride
Flavoxate; its salts
Flecainide; its salts
Fleroxacin; its salts; its esters
Fluanisone
Fluconazole; its salts
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 and its salts when contained in aerosol dispensers
Fosaprepitant; its salts
Foscarnet Trisodium Hexahydrate
Fosinopril; its salts
Fosphenytoin; its salts
Fotemustine; its salts
Frusemide
Fulvestrant
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
Glibenclamide
Glibornuride
Gliclazide
Glimepiride; its salts
Glipizide
Gliquidone
Glucagon; its salts
Glutethimide; 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
Halofantrine; its salts
Halofuginone; its salts; except for incorporation in feed for chickens for fattening at levels not exceeding 3 parts per million
Haloperidol and other 4-substituted derivatives of N-(3-para-fluoro-benzoyl-propyl) piperidine
Hexamethylmelamine
Hexapropymate

Hexobendine; its salts
Hydrallazine; its salts
Hydrazines, the following and their alpha-methyl derivatives-
Benzyl hydrazine
Phenethyl hydrazine
Phenoxyethyl hydrazine
their salts; their acyl derivatives; their salts
Hydroxychloroquine; its salts
Hydroxy-N,N-dimethyltryptamines; their esters and ethers; any salt of any substance falling within this item
Hydroxyphenamate
Hydroxyurea
Hydroxyzine; its salts
Ibandronic acid; its salts
Ibritumomab tiuxetan
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
Interferons
Iprindole; its salts
Irbesartan; its salts
Irinotecan; its salts
Isoaminile; its salts
Isoetharine; its salts
Isoniazid; its salts; its derivatives; their salts; any compound with any substance falling within this item
Isoprenaline; its salts
Isopyrin; its salts
Isotretinoin
Isoxicam; its salts
Isradipine
Itraconazole; its salts
Ivabradine; its salts
Ketamine; its salts
Ketanserine; its salts
Ketoconazole except when contained in preparations for external application only
Ketophenylbutazone
Ketoprofen; its salts
Ketorolac; its salts; its esters
Labetalol; its salts
Lacidipine; its salts
Lamivudine; its salts
Lamotrigine; its salts
Lanreotide; its salts
Lansoprazole
Lanthanum carbonate
Lapatinib; its salts
Laronidase
Laropiprant; its salts
Leflunomide; its salts
Lenalidomide; its salts
Lepirudin; its salts
Lercanidipine; its salts
Letrozole
Leuprorelin; its salts
Levallorphan; its salts
Levetiracetam; its salts
Levosimendan; its salts
Lidoflazine
Linezolid; its salts
Lisinopril; its salts
Lithium carbonate
Lithium Sulphate
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
Lysuride; its salts
Mangafodipir; its salts
Mannomustine; its salts
Maprotiline; its salts
Maraviroc; its salts
Marbofloxacin; its salts
Mazindol
Mebutamate
Mecamylamine; its salts
Meclobemide; its salts
Meclofenamic acid; its salts
Meclofenoxate; its salts
Medigoxin
Mefenamic acid; its salts; its esters; their salts
Mefloquine; its salts
Mefruside
Melagatran; its salts; its derivatives; their salts
Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia
Melitracen; its salts
Meloxicam; its salts
Memantine; its salts
Mephenesin; its esters; their salts
Mephenoxalone
Mepirizole; its salts
Mepivacaine; its salts
Meprobamate
Mercaptopurine; its salts; its derivatives; their salts
Meropenem; it 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
Metergoline
Metformin; its salts
Methaqualone; its salts
Methimazole; its salts
Methixene; its salts
Methocarbamol
Methoxsalen
Methoxyphenamine and its salts when contained in aerosol dispensers
Methylaminoheptane and its salts when contained in aerosol dispensers
Methyldopa; its esters; their salts
Methylnaltrexone; its salts
Methylpentynol; its derivatives
alpha-Methylphenethylamine; beta-methylphenethylamine; alpha-ethylphene-thylamine; 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, methoxy-phenamine, phenylpropanolamine, pholedrine and N-substituted derivatives of ephedrine; any salt of any substance falling within this item
Methylphenidate; its salts
Methyprylone
Metipranolol; its salts
Metoclopramide; its salts
Metolazone
Metoprolol; its salts
Metyrapone; its salts
Mexiletine; its salts
Mianserin; its salts
Mibefradil; its salts
Micafungin; its salts; its esters
Midodrine; its salts
Miglitol; its salts
Milnacipran; its salts
Milrinone; its salts
Minoxidil except when contained in preparations intended for external application only and the preparations contain not more than 5% of Minoxidil
Mirtazapine; its salts
Mitobronitol
Mitopodozide; its salts
Mitotane

Mitoxantrone; its salts
Mivacurium; its salts
Mizolastine; its salts
Moexipril; its salts
Mofebutazone; its salts
Molgramostim
Molindone; its salts
Montelukast; its salts
Moracizine; its salts
Moroxydine; 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
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
Nateglinide; its salts; its esters
Nebivolol; its salts
Nefazodone; its salts
Nefopam; its salts
Nelfinavir; its salts
Neostigmine; its salts
Nepafenac; its salts
Nesiritide
Nevirapine; its salts
Nicergoline
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
Noramidopyrine methanesulphonate; its salts
Norcodeine; its salts; its esters and ethers; their salts
Norfloxacin; its salts; its esters
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
Ondansetron; its salts
Opipramol; its salts; its derivatives; their salts
Orciprenaline and its salts when contained in aerosol dispensers
Orgotein
Orlistat; its salts; except when contained in a pharmaceutical product of which the recommended dose is a quantity of the product that contains not more than 60 mg of orlistat or its salts, taken 3 times a day
Orphenadrine; its salts
Oseltamivir; its salts
Ouabain
Oxaliplatin; its salts
Oxanamide
Oxcarbazepine; its salts
Oxprenolol; its salts
Oxyfedrine; its salts
Oxypertine
Oxyphenbutazone
Oxytocins
Paclitaxel

Paliperidone; its salts
Palivizumab
Palonosetron; its salts
Pamidronate; its salts
Pancuronium; its salts
Pantethine; its salts
Pantoprazole; its salts
Paraldehyde
Paramethadione
Parecoxib; its salts
Pargyline; its salts
Paricalcitol; its salts; its esters; their salts
Paroxetine; 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
Pentamidine; its salts
Pentazocine; its salts
Pentolinium; its salts
Pergolide; its salts
Perindoprilat; its salts; its esters; their salts
Phenacemide
Phenacetin
Phenaglycodol
Phenbutrazate
Phencyclidine; its salts
Phenetidylphenacetin
Phenformin; its salts
Phenindione
Phenothiazine; its salts; its derivatives (except dimethoxanate and promethazine); their salts (except salts of dimethoxanate and promethazine); 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
Picrotoxin
Pimecrolimus
Pioglitazone; its salts
Pipecuronium; its salts
Pipemidic acid
Pipobroman
Piromidic acid; its salts
Piroxicam except when contained in preparations for external application only
Pirprofen; its salts
Pituitary gland, the active principles of, other than corticotrophins, oxytocins and vasopressins, except when contained in inhalants or in preparations intended for external application only
Pizotifen; its salts
Plerixafor; its salts
Polymethylenebistrimethylammonium salts
Poractant alfa
Posaconazole; its salts; its esters; their salts
Pralidoxime; its salts
Pramipexole; its salts
Prasugrel; its salt
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 and its salts when contained in aerosol dispensers
Proglumetacin; its salts
Proguanil; its salts

Promoxolane
Propafenone; its salts
Propanidid
Propiverine; its salts
Propofol
Propoxur; its salts
Propranolol; its salts; its derivatives; their salts
Propylhexedrine and its salts, except when contained in inhalers
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
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; except in preparations containing less than 10% of quinine, its salts, its derivatives or their salts
Rabeprazole; its salts
Racecadotril; its salts
Ractopamine; its salts
Raloxifene; its salts
Raltegravir; its salts
Raltitrexed; its salts
Ramipril; its salts
Ranibizumab
Rasburicase; its salts
Rauwolfia, alkaloids of; their salts; derivatives of the alkaloids of rauwolfia; their salts
Reboxetine; its salts
Recombinant human erythropoietin
Remifentanil; its salts
Remoxipride; its salts
Repaglinide; its salts; its esters
Reproterol and its salts when contained in aerosol dispensers
Rescinnamine
Reteplase
Reviparin; its salts
Ribavirin; its salts
Rilmenidine; its salts
Riluzole; its salts
Rimiterol and its salts when contained in aerosol dispensers
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
Ropinirole; its salts
Ropivacaine; its salts
Rosiglitazone; its salts
Rosoxacin; its salts
Rosuvastatin; its salts
Rotigotine; its salts
Salbutamol and its salts except when contained in aerosol dispensers
Salmeterol and its salts when contained in aerosol dispensers
Saquinavir; its salts
Saxagliptin; its salts
Sermorelin; 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 nitroprusside
Solifenacin; its salts; its esters; their salts
Somatostatin
Sorafenib; its salts
Sotalol; its salts
Sparfloxacin; its salts; its esters
Sparteine; its salts
Spironolactone
Stavudine; its salts
Streptokinase
Strontium ranelate
Strophanthus, glycosides of
Styramate
Sulindac
Sulphinpyrazone
Sulphonal; alkyl sulphonals
Sulpiride
Sultopride
Sumatriptan; its salts
Sunitinib; its salts; their salts
Suprarenal gland, the active principles of, except adrenaline and noradrenaline (other than when contained in aerosol dispensers); their salts; except salts of adrenaline (other than when contained in aerosol dispensers); their derivatives; their salts; except hydrocortisone and its salts when contained in preparations intended for external application only at not more than 1%; except beclomethasone and its salts when contained in aerosol dispensers and except clobetasone butyrate when contained in preparations intended for external application only at not more than 0.05%
Sutoprofen; its salts
Suxamethonium; its salts
Syrosingopine
Tacrine; its salts
Tacrolimus
Tadalafil; its salts; any compound containing the chemical structure of 6-(Benzo[1,3]dioxol-5-yl)-2,3,6,7,12,12a-hexahydropyrazino[1',2':1,6]pyrido[3,4-*b*]indole-1,4-dione substituted to any degree or without substitution; its salts
Tafluprost
Tamoxifen; its salts
Tazarotene; its salts
Tegaserod; its salts
Telbivudine; its salts
Telmisartan; its salts
Temozolomide; its salts
Temsirolimus; its salts; its esters
Tenecteplase; its salts
Teniposide
Tenofovir; its salts; its esters; their salts
Tenoxicam
Terazosin; its salts
Terbinafine; its salts; except when contained in preparations for external application only
Terbutaline and its salts when contained in aerosol dispensers
Teriparatide; its salts
Terodiline; its salts
Tertatolol; its salts
Tetrabenazine; its salts
Tetracosatrin; its salts
Thalidomide; its salts
Theofibrate
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
Ticlopidine; its salts
Tiletamine; its salts
Tilidate; its salts
Tiludronic acid; its salts
Timolol; its salts
Tinoridine; its salts
Tinzaparin; its salts
Tiotropium; its salts
Tiratricol; its salts
Tirofiban; its salts
Tizanidine; its salts
Tocainide; its salts
Tocilizumab
Todralazine; 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 except when contained in toothpaste at 0.05% by weight
Tranylcypromine; its salts
Trastuzumab
Trazodone; its salts
Tretamine; its salts
Tretinoin
Triamterene; its salts
Triaziquone
Tribromoethyl alcohol
2,2,2-Trichloroethyl alcohol, esters of; their salts
Trifluridine; its salts
Trilostane
Trimetaphan; its salts
Trimetazidine; its salts
Trimethadione
Trimethoprim
Trimetozine
Trimetrexate; its salts
Trimipramine; its salts
Trioxsalen
Triptorelin; its salts
Tromantadine; its salts; except when contained in pharmaceutical products labelled for the treatment of cold sores only
Tropisetron; its salts
Trovafloxacin; its salts; its derivatives; their salts
Tulobuterol and its salts when contained in aerosol dispensers
Tybamate
Urapidil; its salts
Urethane
Urokinase
Ustekinumab
Valaciclovir; its salts
Valdecoxib; its salts
Valganciclovir; its salts
Valnoctamide
Valproic acid; its salts; its esters
Valsartan; its salts
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
Vencuronium; its salts
Venlafaxine; its salts
Veralipride; its salts
Verapamil; its salts
Verteporfin; its salts
Vidarabine; its salts
Vigabatrin
Vildagliptin; its salts
Viloxazine; its salts
Vinca, alkaloids of

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 10000 international units of vitamin A
Voriconazole; its salts
Warfarin 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
(L.N. 137 of 1978; L.N. 369 of 1980; L.N. 415 of 1984; L.N. 129 of 1986; L.N. 130 of 1987; L.N. 197 of 1989; L.N. 128 of 1990; L.N. 262 of 1995; L.N. 130 of 1998; L.N. 22 of 1999; L.N. 202 of 1999; L.N. 30 of 2000; L.N. 138 of 2000; L.N. 235 of 2000; L.N. 296 of 2000; L.N. 51 of 2001; L.N. 143 of 2001; L.N. 173 of 2001; L.N. 287 of 2001; L.N. 56 of 2002; L.N. 112 of 2002; L.N. 132 of 2002; L.N. 170 of 2002; L.N. 237 of 2002; L.N. 73 of 2003; L.N. 179 of 2003; L.N. 181 of 2003; L.N. 273 of 2003; L.N. 276 of 2003; L.N. 74 of 2004; L.N. 135 of 2004; L.N. 191 of 2004; L.N. 11 of 2005; L.N. 72 of 2005; L.N. 114 of 2005; L.N. 212 of 2005; L.N. 25 of 2006; L.N. 122 of 2006; L.N. 178 of 2006; L.N. 223 of 2006; L.N. 277 of 2006; L.N. 41 of 2007; L.N. 98 of 2007; L.N. 143 of 2007; L.N. 208 of 2007; L.N. 239 of 2007; L.N. 61 of 2008; L.N. 113 of 2008; L.N. 197 of 2008; L.N. 234 of 2008; L.N. 282 of 2008; L.N. 90 of 2009; L.N. 147 of 2009; L.N. 199 of 2009; L.N. 258 of 2009; L.N. 11 of 2010; L.N. 32 of 2010; L.N. 81 of 2010; L.N. 104 of 2010; L.N. 140 of 2010; L.N. 23 of 2011)

DIVISION B—*(L.N. 41 of 2007)*

Dinitronaphthols; dinitrophenols; dinitrothymols
Hexachlorophane; preparations containing more than 0.1% for human or animal use in aerosol containers; preparations in the form of a cake, tablet or bar of soap for human use containing more than 2%; preparations in the form of soaps or shampoos for animal use containing more than 2%; medicinal preparations for human or animal use (except those for oral administration to sheep or cattle for liver fluke disease) containing more than 0.75%.

(L.N. 262 of 1995; L.N. 41 of 2007)

FOURTH SCHEDULE

[reg. 14]

STATEMENT OF PARTICULARS AS TO PROPORTION OF POISON IN CERTAIN CASES PERMITTED BY REGULATION 14(a)

DIVISION A

(L.N. 41 of 2007)

Name of Poison	Particulars
Alkaloids Aconite, alkaloids of	The proportion of any one alkaloid of aconite that the preparation would be calculated to contain on the assumption that all the alkaloids of aconite in the preparation were that alkaloid.

Belladonna, alkaloids of Calabar bean, alkaloids of Coca, alkaloids of Colchicum, alkaloids of Ephedra, alkaloids of Ergot, alkaloids of Gelsemium, alkaloids of Lobelia, alkaloids of Pilocarpus, alkaloids of Pomegranate, alkaloids of Quebracho, alkaloids of, other than the alkaloids of red quebracho Sabadilla, alkaloids of Stavesacre, alkaloids of Veratrum, alkaloids of Yohimba, alkaloids of	The same as above, with the substitution for the reference to aconite of a reference to balladonna, calabar bean or such other of the said poisons as the case may require. *(L.N. 137 of 1978)*
Antimonial poisons	The proportion of antimony trioxide (Sb_2O_3) or antimony pentoxide (Sb_2O_5) that the preparation would be calculated to contain on the assumption that the antimony (Sb) in the poison had been wholly converted into antimony trioxide or antimony pentoxide as the case may be.
Arsenical poisons	The proportion of arsenic trioxide (As_2O_3) or arsenic pentoxide (As_2O_5) that the preparation would be calculated to contain on the assumption that the arsenic (As) in the poison had been wholly converted into arsenic trioxide or arsenic pentoxide as the case may be.
Digitalis, glycosides of; other active principles of digitalis	The number of units of activity as defined in the British Pharmacopoeia contained in a specified quantity of the preparation.
Hydrocyanic acid ; cyanides other than ferrocyanides and ferricyanides	The proportion of hydrocyanic acid (HCN) that the preparation would be calculated to contain on the assumption that the cyanides in the poison had been wholly converted into hydrocyanic acid.
Insulin	The number of units of activity as defined in the British Pharmacopoeia contained in a specified quantity of the preparation.
Lead, compounds of, with acids from fixed oils	The proportion of lead oxide (PbO) that the preparation would be calculated to contain on the assumption that the lead in the poison had been wholly converted into lead oxide.
Mercury, organic compounds of	The proportion of organically-combined mercury (Hg) contained in the preparation.
Nux Vomica	The proportion of strychnine contained in the preparation.
Opium	The proportion of morphine contained in the preparation.
Phenols	The proportion of phenols (added together) contained in the preparation.
Compounds of a phenol with a metal	The proportion of phenols (added together) that the preparation would be calculated to contain on the assumption that the compounds of phenols with a metal had been wholly converted into the corresponding phenols.
Pituitary gland, the active principles of	Either— (a) The number of units of activity as defined in the British Pharmacopoeia contained in a specified quantity of the preparation; or

	(b) the proportion of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, contained in the preparation; or (c) the amount of pituitary gland, or of anterior or of posterior lobe of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.
Strophanthus, glycosides of	The amount of Standard Tincture of Strophanthus as defined in the British Pharmacopoeia 1948 which possesses the same activity as a specified quantity of the preparation when assayed by the method described in the said Pharmacopoeia.
Suprarenal gland, the active principles of; their salts; their derivatives; their salts	Either— (a) the proportion of Suprarenal gland or of the cortex or of the medulla of the gland, as the case may be, contained in the preparation; or (b) the amount of Suprarenal gland, or of the cortex or of the medulla of the gland, as the case may be, from which a specified quantity of the preparation was obtained, together with an indication whether the amount relates to fresh or to dried gland substance.
Thyroid gland, the active principles of; their salts	Either— (a) the proportion of thyroid gland contained in the preparation; or (b) the amount of thyroid gland from which a specified quantity of the preparation was obtained together with an indication whether the amount relates to fresh or to dried gland.

DIVISION B

(L.N. 41 of 2007)

Name of Poison	Particulars
Barium, salts of	The proportion of one particular barium salt which the preparation would be calculated to contain on the assumption that the barium (Ba) in the preparation had been wholly converted into that salt.
Potassium hydroxide	The proportion of potassium monoxide (K_2O) which the preparation would be calculated to contain on the assumption that the potassium hydroxide in the preparation had been wholly converted into potassium monoxide.
Sodium hydroxide	The proportion of sodium monoxide (Na_2O) which the preparation would be calculated to contain on the assumption that the sodium hydroxide in the preparation had been wholly converted into sodium monoxide.

FIFTH SCHEDULE

[reg. 15(2)]

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

1. To be labelled with the words "Caution. It is dangerous to take this preparation except under medical supervision." 「注意：非經醫生指示，服食此藥有危險。」—

Medicines made up ready for the internal treatment of human ailments and containing insulin

2. To be labelled with the words "Caution. It is dangerous to exceed the stated dose." 「注意：服食過量有危險。」—

Medicines (other than medicines containing insulin and medicines mentioned in paragraph 8 of this Schedule) made up ready for the internal treatment of human ailments except in the case of a substance included in the First Schedule

3. To be labelled with the words "Poison. For animal treatment only." 「毒藥：祇限醫治禽畜用。」—

Medicines made up ready for the treatment of animals

4. To be labelled with the words "Caution. This preparation may cause serious inflammation of the skin in certain persons and should be used only in accordance with expert advice." 「注意：此藥可使某些人士皮膚嚴重發炎，須照專家指示使用。」—

Preparations for the dyeing of hair containing phenylene diamines, toluene diamines or other alkylated-benzene diamines or their salts

5. To be labelled with the words "Caution. This substance is caustic." 「注意：此物質有腐蝕作用。」—

Potassium hydroxide, sodium hydroxide, and articles containing either of those substances

6. To be labelled with the words "Caution. This substance is poisonous. The inhalation of its vapour, mist, spray or dust may have harmful consequences. It may also be dangerous to let it contact the skin or clothing." 「注意：此物質有毒。吸入其蒸氣、煙霧、噴霧或粉末，可能有害。如觸及皮膚或衣服，亦可能有危險。」—

Diethyl para-nitrophenyl phosphate

Organic compounds of mercury in aerosols *(L.N. 195 of 1977; L.N. 262 of 1995)*

7. To be labelled with the words "Caution. This preparation should be administered only under medical supervision. The vapour is dangerous." 「注意：此藥之蒸氣有危險，須經醫生指示，方可使用。」—

Medicines made up ready for the internal or external treatment of human ailments and containing dyflos

8. To be labelled with the words "Caution. This may cause drowsiness. If affected, do not drive or operate machinery." 「注意：此藥可使人昏昏欲睡，服後如有此情形，不得駕駛或動用機械。」—

Medicines made up ready for the internal treatment of human ailments containing any of the antihistamine substances (except Astemizole, Cetirizine, Desloratadine, Fexofenadine, Loratadine and Terfenadine), their salts or their compounds with any other substance *(L.N. 262 of 1995; L.N. 202 of 1999; L.N. 132 of 2002)*

9. To be labelled with the words "Caution. Not to be taken internally." 「注意：忌食。」—

Preparations for external use containing mercuric ammonium chlorides

10. (a) To be labelled with the words "Not to be used for babies" 「嬰兒禁用。」 or "This preparation should not be administered, except on medical advice, to a child under 2 years of age." 「非經醫生指示，此藥不可用於兩歲以下兒童。」—

Hexachlorophane

(b) To be labelled with the words "Not to be used for whole body bathing except on medical advice." 「非經醫生指示不可用作全身沐浴。」—

Soap for human use containing 2% or more of hexachlorophane

(c) To be labelled with the words "For animal treatment only." 「祇限醫治禽畜用。」—

Medicine containing hexachlorophane for the treatment of animal

(d) To be labelled with the words "Not for use for lactating cattle." 「不得用於授乳牛隻。」—

Medicine containing hexachlorophane for oral administration for the prevention or treatment of liver fluke disease in cattle

(e) To be labelled with the words "Protective clothing must be worn by the operator when this product is being administered." 「使用此藥之人員必須穿着防護性衣服。」—

Medicine containing hexachlorophane for oral administration for the prevention or treatment of liver fluke disease in sheep or cattle

11. *(Repealed L.N. 262 of 1995)*

SIXTH SCHEDULE

[reg. 4(2)]

POISONS EXEMPTED BY REGULATION 4 FROM LABELLING PROVISIONS WHEN SOLD OR SUPPLIED IN CERTAIN CIRCUMSTANCES

DIVISION A

(L.N. 41 of 2007)

Antimony, chlorides of; oxides of; sulphides of; antimonates; antimonites

Chloroform

Glyceryl trinitrate

Lead acetates; compounds of lead with acids from fixed oils

Mercuric chloride; mercuric iodide; organic compounds of mercury

Mercury, nitrates of; oxides of

Oxalic acid; metallic oxalates

Phenols; compounds of phenol with a metal

Picric acid

DIVISION B

(L.N. 41 of 2007)

Ammonia

Alkali fluorides

Dinitronaphthols; dinitrophenols; dinitrothymols

Formaldehyde

Formic acid

Hydrochloric acid

Hydrofluoric acid; sodium silicofluoride

Nitric acid

Nitrobenzene

meta-Nitrophenol; ortho-nitrophenol; para-nitrophenol

Phosphorus, yellow

Potassium hydroxide

Sodium hydroxide

Sulphuric acid

(L.N. 262 of 1995)

SEVENTH SCHEDULE

[reg. 21]

POISONS REQUIRED BY REGULATION 21 TO BE SPECIALLY LABELLED FOR TRANSPORT

DIVISION A

(L.N. 41 of 2007)

Arsenical poisons

Diethyl para-nitrophenyl phosphate

Hydrocyanic acid; cyanides, other than ferrocyanides and ferricyanides, except preparations containing less than the equivalent of 0.1%, weight in weight, of hydrocyanic acid (HCN)

Nicotine

Strychnine; its salts

Thallium, salts of

(L.N. 195 of 1977)

DIVISION B

(L.N. 41 of 2007)

Barium, salts of, except barium sulphate

(L.N. 137 of 1978; L.N. 262 of 1995)

EIGHTH SCHEDULE

FORM 1 [reg. 26(4)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

WHOLESALE POISONS LICENCE

..... of .....
is hereby licensed to deal in wholesale poisons at .....
..... until the ..... day of .....
..... 19 ....., inclusive, subject to the conditions endorsed hereon.

Dated this ..... day of ..... 19.....

.....
for Pharmacy and Poisons Board.

CONDITIONS

.....
.....
.....

(L.N. 85 of 1987; L.N. 63 of 1997)

FORM 2 [reg. 28(4)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

FORM OF RECORDS OF TRANSACTIONS INVOLVING POISONS IN PART I OF THE POISONS LIST TO BE KEPT BY WHOLESALE DEALERS

Name of Poisons			Unit of Quantity		
Date	Nature of transaction	Supplier or to whom supplied	Invoice No.	Quantity	Balance after transaction

(L.N. 63 of 1997)

FORM 3 [reg. 29(5)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE FOR MANUFACTURER

It is hereby certified that .....

.....

(Name of the pharmaceutical firm)

(1) is authorized to manufacture and market drugs and pharmaceutical products;

(2) is subject to regular inspections which have shown that it follows the requirements of good practices in manufacture and quality control of drugs and pharmaceutical products as recommended by the World Health Organization, and is included in the list established for that purpose.

HONG KONG. ..... (Date)

.....

for *Pharmacy and Poisons Board.*

(L.N. 63 of 1997)

FORM 4 [reg. 29(5)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

INTERIM CERTIFICATE FOR MANUFACTURER

It is hereby certified that .....

.....

(Name and address of manufacturer)

(1) is authorized to manufacture and market drugs and pharmaceutical products;

(2) is subject to regular inspections in respect of the manufacture of drugs and pharmaceutical products in accordance with the requirements recommended by the World Health Organization.

This certificate shall expire on .....

Subject to the Pharmacy and Poisons Board being satisfied that the manufacturer complies with the requirements of good practices in manufacture and quality control of drugs and pharmaceutical products as recommended by the World Health Organization, a Certificate for Manufacturer may be issued on or before the expiry of this certificate.

HONG KONG. ..... (Date)

.....

for *Pharmacy and Poisons Board.*

(L.N. 63 of 1997)

FORM 5 [reg. 29(6)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

FREE SALE CERTIFICATE OF PHARMACEUTICAL PRODUCT

Name and dosage form of product (specify strength): .....

Name and amount of each active ingredient (as provided by manufacturer):

.....

.....

.....

.....

.....

Manufacturer, and/or when applicable, the person responsible for placing the product on the market: .....

.....

.....

Address(es): .....

It is certified that:

* This product has been authorized to be placed on the market for use in Hong Kong.
  Number of permit and date of issue .....

  .....

* This product has not been authorized to be placed on the market for use in Hong Kong for the following reasons: .....

  .....

  .....

* It is also certified that (a) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals, and (b) the manufacturer conforms to requirements for good practices in the manufacture and quality control, as recommended by the World Health Organization, in respect of products to be sold or distributed within the country of origin or to be exported.

HONG KONG. ..... (Date)

.....

for *Pharmacy and Poisons Board.*

(L.N. 137 of 1978; L.N. 449 of 1991; L.N. 63 of 1997)

FORM 5A [reg. 29(6)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE OF PHARMACEUTICAL PRODUCT

Name and dosage form of product (specify strength):

.....

.....

.....

.....

.....

Name and amount of each active ingredient (as provided by manufacturer):

.....

.....

.....

.....

.....

Manufacturer, and/or when applicable, the person responsible for placing the product on the market:

.....

.....

.....

.....

Address(es):

.....

.....

.....

.....

It is certified that—

(a) this product has been registered with the Pharmacy and Poisons Board;

(b) this product has been authorized to be placed on the market for use in Hong Kong—

Number of permit: .....

Date of issue: .....

(c) the manufacturing plant in which the product is produced is subject to inspection at suitable intervals.

This certificate is valid for one year from the date of issue.

.....(Date)

HONG KONG.

.....

for *Pharmacy and Poisons Board.*

(L.N. 449 of 1991; L.N. 63 of 1997)

FORM 6 [reg. 36(2)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

APPLICATION FOR REGISTRATION OF A DRUG/ PHARMACEUTICAL PRODUCT/SUBSTANCE

Note: A specimen sales pack of the drug/product or sample of the substance and the relevant literature must be submitted together with the application. Supplementary documentation and supporting documents issued by the health authority in the Country of origin should be submitted if required.

Name of Drug/Product/Substance*:
(*Delete as appropriate)

Dose Form/Package Size(s):

Detailed Qualitative and Quantitative Composition:

Indications:

Names of Countries in which registered/marketed:

Name of Applicant:

Business Address of Applicant: Tel. No.

Name of Manufacturer:

Address of Manufacturer:

DECLARATION OF APPLICANT

I hereby declare that to the best of my knowledge and belief the information given in this application is correct.

Date : ..... *Signature :* .....

For Office Use Only

Date Rec'd	Forensic Classification	Fees Paid	Registration Approved	Certificate Issued	Registration

(L.N. 137 of 1978; L.N. 63 of 1997)

FORM 7 [reg. 36(5)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE OF DRUG/PRODUCT REGISTRATION

It is hereby certified that .....
.....
(*Name and address*)

has been issued with a permit No. ..... authorizing .....(Name of drug/product) to be marketed for use within Hong Kong.

2. This certificate will be valid until ..... 19 ..... , and thereafter for periods of 5 years at a time on renewal and subject to the payment of the registration fee.

3. No change in the formulation and commercial presentation of this product shall be made during the effectivity of this registration without the approval of the Pharmacy and Poisons Board.

HONG KONG. ..... (Date)

.....
for *Pharmacy and Poisons Board.*

(L.N. 137 of 1978; L.N. 63 of 1997)

FORM 8 [reg. 41(1)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE

For the purposes of section 22(1)(a) of the Pharmacy and Poisons Ordinance, I, the undersigned, occupying[(a)] .....
.....
hereby certify that I am acquainted with[(b)] .....
..... and with[(c)] .....
..... and that[(b)] .....
is a fit and proper person to whom [(d)] .....
.....may properly be supplied by[(c)] .....
I further certify that[(e)] .....
..... is the signature of the said(e) .....

.....

.....
Signature of person giving certificate

(Name in block letters) .....

Date .....

(a) Insert full postal address.
(b) Insert full name of intending purchaser.
(c) Insert full name of intending seller.
(d) Insert name of poison.
(e) Intending purchaser to sign here.

(L.N. 63 of 1997)

FORM 9 [reg. 41(2)]

PHARMACY AND POISONS BOARD

HONG KONG

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE OF REGISTRATION
(Section 9(1))

Number on Register.....

This is to certify that .....
whose address is .....
.....
and whose photograph appears hereon was on the ..... day of ..... 19..... admitted to the register of pharmacists.
Dated this ..... day of ..... 19.....

.....
Secretary,
Pharmacy and Poisons Board.

(L.N. 63 of 1997)

FORM 10 [reg. 42(3)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

FORM OF ENTRY TO BE MADE IN THE BOOK TO BE KEPT BY SELLERS OF POISONS IN ACCORDANCE WITH SECTION 22(3)

Date of Sale	Name and quantity of poison supplied	Purchaser's			Purpose for which stated to be required	Date of certificate (if any)	Name and address of person giving certificate (if any)	Signature purchaser reference nun Signed order of wholes
		Name and number of identity card	Address	Business, trade or occupation				

(L.N. 366 of 1995; L.N. 63 of 1997)

FORM 11

(Spent)

FORM 12 [reg. 36B(3)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE FOR CLINICAL TRIAL/MEDICINAL TEST*

It is hereby certified that .....
.....
(*Name and address*)
is authorized to establish a clinical trial on human beings/medicinal test on animals* in respect of .....
.....
(*Name of Product or substance*)
to be conducted by .....
(*Name(s) of person(s) concerned*)
at .....
(*Name and address of institution where applicable*)
.....

2. This certificate will be valid until .....
.....

HONG KONG. ..... (Date)

.....
for *Pharmacy and Poisons Board.*

(L.N. 63 of 1997)

FORM 13 [reg. 37A]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

APPLICATION FOR REGISTRATION AS AN IMPORTER/EXPORTER OF PHARMACEUTICAL PRODUCTS

We wish to apply for registration as an importer and exporter of pharmaceutical products under the Pharmacy and Poisons Ordinance, Cap. 138.

Name of pharmaceutical product(s) registered by Applicant:

Name of manufacturer(s) represented by Applicant, if any:

Description of storage room/cubicle/receptacle* :
(* Delete as appropriate)

Name of Applicant:

Business Address of Applicant: Tel. No.

Name of person in charge:

Date ..... *Signature* .....

(L.N. 369 of 1980; L.N. 63 of 1997)

FORM 14 [reg. 37A]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE OF REGISTRATION AS AN IMPORTER AND EXPORTER

It is hereby certified that .....
.....
(*Name and Address of pharmaceutical firm*)
.....
has been registered as an importer and exporter of pharmaceutical products and is entitled to import and export pharmaceutical products subject to the conditions endorsed hereon.

Dated this ..... day of ..... 19.....

.....
for *Pharmacy and Poisons Board.*

CONDITIONS

.....
.....
.....

(L.N. 369 of 1980; L.N. 85 of 1987; L.N. 63 of 1997)

FORM 15 [reg. 24B(a)]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

APPLICATION FOR REGISTRATION OF PREMISES UNDER SECTION 13

We ..... of .....
(*Name of business*)
.....
(*Address of business*)

wish to apply for the registration under section 13 of the Pharmacy and Poisons Ordinance of the premises as set out in paragraph 1 of this application to conduct the retail sale of poisons at such premises.

1. Address of premises .....
2. Name of business at the premises .....
3. Business Registration No. .....
4. Telephone No. of the premises .....
5. Name of registered pharmacist in whose presence or under whose supervision the retail sale of poisons is conducted under section 11(1) of the Ordinance .....
.....
.....

In support of this application, we submit a copy of the certificate of registration of the pharmacist named in paragraph 5.

Signature .....
Full name of signatory .....
Signed on behalf of .....
(*Name of business*)

Date .....

(L.N. 85 of 1987; L.N. 63 of 1997)

FORM 16 [reg. 24C]

PHARMACY AND POISONS ORDINANCE

(Chapter 138)

CERTIFICATE FOR REGISTRATION OF PREMISES UNDER SECTION 13

This is to certify that the premises known as .....
..... and situated at .....
(*Name of business*)
..... are, for the

(*Address of premises*)

period from the date of this certificate until ....., (*Date of expiry*)

registered under section 13 of the Pharmacy and Poisons Ordinance as being premises where the retail sale of poisons may be conducted, subject to the conditions endorsed hereon.

Dated this ..... day of..... 19.....

.....
for *Pharmacy and Poisons Board.*

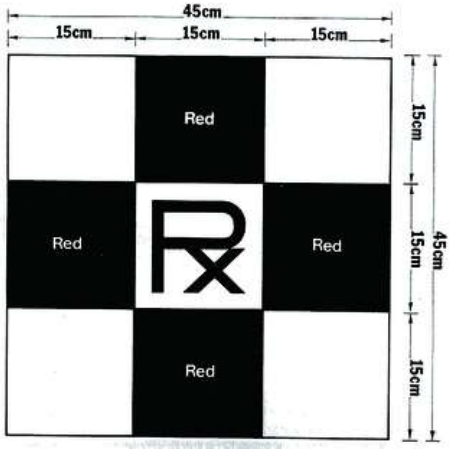
CONDITIONS

.....
.....
.....

(L.N. 85 of 1987; L.N. 63 of 1997)

FORM 17 [reg. 41(2A)]

Form of logo which may be displayed under section 13A



(L.N. 85 of 1987)

NINTH SCHEDULE

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

FEES

Item	Particular	Fee
		$
1.	Examination in each subject prescribed by the Board *(L.N. 60 of 2001)*	1110
2.	Issue of a certificate of registration as a pharmacist *(L.N. 60 of 2001)*	790
3.	Issue of a duplicate certificate of registration as a pharmacist	395
4.	Registration of premises of an authorized seller of poisons	1000
5.	Retention of premises on the register of premises, each year	1310
6.	Application for entry on the list of listed sellers of poisons	455
7.	Retention on the list of listed sellers of poisons, each year	430
8.	Any alteration to the register of premises or to the list of listed sellers	250
9.	An annual licence for wholesale dealers in poisons	625
10.	Annual licence for manufacturers	2680
11.	Application for registration of a product	1100
12.	Certificate of registration of a product	1370
13.	Renewal of a certificate of registration of a product	575
14.	Free Sale Certificate of Pharmaceutical Product	180
15.	Certificate of Pharmaceutical Product	140
16.	Certificate and Interim Certificate for Manufacturer	2020
17.	Annual practising certificate for a registered pharmacist *(34 of 1995 s. 43; L.N. 60 of 2001)*	520
18.	Application for a clinical trial or medicinal test	1420
19.	Certificate for clinical trial or medicinal test	1420
20.	Application for registration as an importer or exporter of pharmaceutical products	720
21.	Duplicate of any certificate	220
22.	Issue of a certificate of good standing *(L.N. 60 of 2001)*	415

(L.N. 597 of 1994; L.N. 214 of 1997; L.N. 126 of 2006)