File reference: FHB/H/23/1 Pt.9

LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance
(Chapter 138)

PHARMACY AND POISONS (AMENDMENT) BILL 2014

INTRODUCTION

At the meeting of the Executive Council on 11 March 2014, the Council ADVISED and the Chief Executive ORDERED that the proposed Pharmacy and Poisons (Amendment) Bill 2014 (the Bill), at
A Annex A, should be introduced into the Legislative Council (LegCo).

JUSTIFICATIONS

2. In the light of a number of incidents concerning pharmaceutical products in Hong Kong in early 2009, the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee)[1] was set up in March 2009 to conduct a comprehensive review on the existing regime for the regulation of pharmaceutical products. After examining in detail the existing regulatory regime, the Review Committee considers that while the framework and the rationale behind the existing regime is sound and should continue to be adopted, the coverage and depth of the regulatory measures should be enhanced. In December 2009, the Review Committee issued a report and made a total of 75 recommendations on
B improvement measures (as summarized in Annex B).

3. The recommendations of the Review Committee have been accepted by the Administration and are being implemented progressively. Among the 75 recommendations, 16 recommendations require amendments to be made to the existing PPO and its subsidiary
C legislation (see Annex C). To assess the impacts of the proposed

[1] The Review Committee is chaired by the Permanent Secretary for Food and Health (Health) of the Food and Health Bureau and comprises members from the pharmaceutical sectors, medical profession, academia, patient groups and consumer representatives.

legislative amendments to pharmaceutical dealers, the Administration commissioned a consultant to conduct a Regulatory Impact Assessment (RIA). Having considered the RIA result concluded in January 2013 and views expressed by the relevant stakeholders, the Administration has decided to propose legislative amendments to PPO and its subsidiary legislation to implement most of the recommendations in Annex C which are conducive to enhancing the regulatory regime without causing significant impact to the relevant parties. For the remaining recommendations in Annex C, the Administration would monitor the situation and formulate appropriate implementing measures in due course. Apart from implementing certain recommendations of the Review Committee, as certain provisions of the PPO and its subsidiary legislation have become outdated, the Administration has taken this opportunity to propose certain legislative amendments to bring these provisions into line with the prevailing regulatory framework for pharmaceutical products in Hong Kong. Details of the proposed legislative amendments are set out in the ensuing paragraphs.

Proposed legislative amendments

(A) General provisions

4. To align with the international practice, we propose to revise the definition of "pharmaceutical product" in the PPO in accordance with the definition adopted by the European Union in order to cover also a substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals.

5. As recommended by the Review Committee, we propose to empower the Pharmacy and Poisons Board (the Board) to promulgate corresponding codes of conduct and codes of practice in order to provide practical guidance and enhance monitoring for the conduct of the activities of registered pharmacists, different licensed traders and traders subject to registration requirement (including manufacturers, wholesalers and retailers). We have also taken this opportunity to update and clarify the provisions governing the issuance, suspension and revocation of various licences issued under or registrations maintained by the PPO and the Pharmacy and Poisons Regulations (Cap. 138A) (PPR) so as to ensure that the Board and its executive committees are empowered to impose licensing or registration conditions and vary such conditions, issue directions to revoke or suspend a licence or registration, suspend such directions, or issue warning letters to the relevant licence or registration holders on non-compliance with the codes of conduct or codes of practice or licensing or registration conditions or on conviction of the relevant offences.

6. In response to the Review Committee's recommendation to set up a dedicated team to oversee and uphold the regulatory regime for pharmaceutical products in Hong Kong, the Department of Health (DH) has set up a Drug Office headed by an Assistant Director (Drug) who is a registered pharmacist. Since the drug regulatory agency in Hong Kong has been headed by the Assistant Director (Drug) instead of the Chief Pharmacist of the DH, the membership of the Board as stipulated in the PPO[2] will be revised accordingly.

(B) Regulation of manufacturers

7. To avoid drug incidents caused by wrong labelling or wrong content of carton boxes arising in the secondary packaging[3] process, the Review Committee has recommended that secondary packaging should only be carried out by a licensed manufacturer. For avoidance of doubt on whether secondary packaging forms part of a manufacturing process, we propose to revise the definition of "manufacture"[4] in the PPO to explicitly include secondary packaging. In other words, packaging activities should only be carried out by a licensed manufacturer[5] who complies with the Good Manufacturing Practice[6] (GMP) requirements. To minimize the impact on the trade, certain secondary packaging activities which do not affect the safety, efficacy and quality of the products will be exempted from the licensing control for manufacturers.

8. To further tighten up the manufacturing of pharmaceutical products, we propose to introduce new provisions in the PPR to require

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[2] In order to ensure the continuity of the work of the Board and its committees, the Assistant Director (Drug) will serve as a member of the Board and its Examination Committee.

[3] "Primary packaging" refers to product packaging that is in direct contact with the product (e.g. blister packaging), and "secondary packaging" refers to packaging activities which do not expose the pharmaceutical product to air such as putting bottles of pharmaceutical products into carton boxes, putting strip-packed tablets into carton boxes, labelling of bottles or carton boxes, etc.

[4] Under the existing PPO "manufacture" means "the preparation of pharmaceutical products for sale or distribution but shall not include the individual dispensing on a prescription or otherwise of any pharmaceutical product".

[5] As stipulated in Regulation 29 of the PPR, all pharmaceutical manufacturers must first obtain the required licence from the Pharmacy and Poisons (Manufacturers Licensing) Committee of the Board. As of 31 December 2013, there were 24 licensed GMP pharmaceutical manufacturers.

[6] GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled according to quality standards appropriate to the products' intended use.

manufacturers to ensure that the registrable particulars of the finished products correspond exactly with the registered particulars of the products and to label the container of each pharmaceutical product with batch number and expiry date. Moreover, all the relevant manufacturing records should be completed at the time when the manufacturing process is being carried out.

9. According to the GMP requirements, the release of pharmaceutical products with intended quality should be the responsibility of the Authorized Person (AP) of a licensed manufacturer. To tighten up the regulation of AP and to implement the Review Committee's recommendation to enhance the quality of pharmaceutical products manufactured by licensed manufacturers, we propose to: require each licensed manufacturer to employ at least one AP who is to be responsible for the quality of pharmaceutical products; introduce new provisions into the PPR to set out the qualification requirements of AP; require the Board to maintain a register of AP; and require the Board to remove any AP from the register should the AP be found incompetent to perform the role of an AP.

(C) Regulation of importers, exporters and wholesalers

10. The Review Committee considers that pharmaceutical products classified as non-poisons, though less dangerous, could also endanger patient health if they are not stored and handled properly. It is therefore essential to monitor their quality and maintain a complete record to facilitate recall, if necessary. Moreover, as wholesalers of non-poisons usually handle pharmaceutical products in large quantity and are therefore an important link in the supply chain and an important player in quality maintenance of pharmaceutical products, we propose to impose licensing control on wholesalers of non-poisons. We have also taken this opportunity to streamline the licensing arrangements and by taking reference from the Chinese Medicine Ordinance (Cap. 549), we propose to merge the proposed licensing of wholesalers of non-poisons, the registration of importers or exporters of pharmaceutical products[7] with the licensing of wholesalers of poisons[8] and subject these traders to the same set of licensing control and inspection. Furthermore, to enhance traceability and facilitate recall of pharmaceutical products if necessary, we have adopted the Review

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[7] For companies involved in the import or export of pharmaceutical products not classified as poisons under the PPO, a Certificate of Registration as an Importer and Exporter (IE Certificate) is required. As of 31 December 2013, 94 IE Certificates were issued.

[8] For companies involved in the import, export or wholesale of substances or articles consisting of or containing any poison regulated by the PPO, a Wholesale Poisons Licence (WPL) is required. As of 31 December 2013, 714 WPLs were issued.

Committee's recommendation to introduce new provisions to require wholesalers to keep transaction records for all pharmaceutical products (including both poisons and non-poisons). The records should also include additional details such as registered pack size and batch number of products.

(D) Regulation of retailers

11. According to the recommendation of the Review Committee, we propose to amend the relevant provision to the effect that, apart from the poisons listed in the First Schedule to the PPR, all poisons listed in Part I of the Poisons List Regulations (Cap. 138B) (PLR) (which will be merged into the PPR under our proposal) will also be required to be stored in locked receptacles at the registered premises of the authorized sellers of poisons (ASP)[9] with the key kept by the registered pharmacist.

12. To adopt the Review Committee's recommendation to heighten control, we also propose to tighten up the regulation of the ASP by providing for the direction of Disciplinary Committee to, at the conclusion of a disciplinary inquiry of an ASP convicted of offence under the relevant provisions, disqualify the ASP and remove its premises from the register of premises to take effect immediately if it is in the public interest to do so. We have also taken the opportunity to revise the definition of ASP to reflect the usage in the legislation as an entity that carries on the retail sales of poisons.

(E) Pre-market control of drugs

13. At present, the PPR only authorizes local licensed manufacturers to register a pharmaceutical product with the Board if the pharmaceutical product is manufactured in Hong Kong. In other words, a licensed manufacturer (which is also a licensed wholesaler) who has already contracted out the manufacturing activities to other local licensed manufacturers would still have to retain its manufacturer's licence solely for the purpose of registering the pharmaceutical products so produced. To remove such unnecessary restriction and facilitate the trade, we propose to allow licensed wholesalers who have contracted out the manufacturing to other local licensed manufacturers to apply for registration of pharmaceutical products.

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[9] ASP, commonly known as pharmacy, is authorized under the PPO to sell pharmaceutical products including those classified as poisons listed either in Part I or Part II of the PLR. The Board will issue a certificate of registration of premises to an ASP if it is satisfied that the applicant is a fit and proper person, and that the premises are suitable to conduct the retail sale of poisons. As of 31 December 2013, there were 597 ASPs.

14. To follow up on the Review Committee's recommendation to expedite the registration process of pharmaceutical products, we propose –

(a) to repeal the PLR and migrate its contents to the PPR so as to consolidate the classification and control of the pharmaceutical products under the PPR, thereby streamlining the legislative procedures required for registration of pharmaceutical products; and

(b) that further amendments to the relevant Schedules to the PPR (i.e. the First, Second and Third Schedules) and the Poisons List to be migrated from PLR to the PPR under the proposal in (a) above, should be made by means of negative vetting, as opposed to positive vetting as required under the existing provisions, by the LegCo in order to expedite the imposition of suitable control on pharmaceutical products and poisons.

15. We propose to empower the Board to require holders of certificate of drug registration to submit updated information for renewal of drug registration. In considering an application for registration of an imported pharmaceutical product, if the applicant or importer is unable to provide evidence of compliance with the GMP standard adopted by the Board and hence requests the Board to conduct inspection of the manufacturing site of the overseas manufacturer, the Board will also be empowered to recover from the applicant or importer the cost incurred for the GMP inspection conducted at the overseas manufacturing site to ensure its GMP compliance.

16. To be in line with the international practice, we propose to exempt the possession or use of pharmaceutical products for the purpose of administration in clinical trial in accordance with the clinical trial certificate from the registration requirement for pharmaceutical products. Furthermore, to address the Review Committee's concern that the current two-year validity of the clinical trial certificate is often too short for the completion of a clinical trial, we propose to extend the validity of clinical trial certificate to not more than five years, so that the applicant does not need to apply for a certificate again if a trial lasts more than two years. In addition, it is proposed that any person who conducts a clinical trial without a clinical trial certificate will be subject to penalty upon conviction.

17. As regards the labelling of pharmaceutical products classified as Part I poisons by the PPO, we have accepted the recommendation of the Review Committee to replace the text "Poison 毒藥" by "Prescription drug 處方藥物" or "Drug under supervised sale 監督售賣藥物" depending on the sale restriction so as to avoid confusion that the pharmaceutical products might be harmful and unsuitable for use or consumption.

(F) Special provisions with respect to institutions

18. Taking into account the requests and practical operation of the Hospital Authority, we propose that pharmaceutical products supplied by institutions (as defined in the PPO) to out-patients will be labelled with instructions for use in either English or Chinese, instead of both languages. Besides, we propose that poisons on the First Schedule of the PPR will no longer be required to be stored in locked receptacle solely reserved for the storage of such poisons.

(G) Recovery of conviction-related expenses

19. To increase the deterrent effect, we propose to empower the Court to order recovery of all expenses incidental to the taking, examination and analyses of any sample of pharmaceutical products incurred by the Administration in respect of which the conviction is based from the defendant. In line with the concept on recovery of costs, the amount to be granted should be compensatory in nature.

OTHER OPTIONS

20. We must amend the PPO and its subsidiary legislation in order to bring the above proposals into effect. There are no other options.

THE BILL

21. The key provisions of the Bill are set out as follows –

General

(a) **Clause 4(3)** expands the definitions of "pharmaceutical product" and "medicine" to cover also a substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals.

(b) **Clause 6** adds a new section 4B to the PPO to empower the Board to issue codes of conduct or codes of practice for providing practical guidance in respect of the conduct of activities relating to poisons and pharmaceutical products.

Non-compliance with such codes may lead to disciplinary actions under the PPO or PPR.

(c) **Clauses 13, 14, 15, 20, 46 and 50** amend the relevant provisions of the PPO and PPR to update and clarify the provisions governing the registration maintained and the issuance, suspension and revocation of various licences issued under the PPO and the PPR respectively.

Regulation of manufacturers

(d) **Clause 4(2)** revises the definition of "manufacture" in section 2(1) of the PPO to expressly cover the packaging and repackaging of pharmaceutical products so that such activities must, subject to the exception provided for in regulation 29(1A) of the PPR (clause 50), be carried out by licensed manufacturers.

(e) **Clause 53** amends regulation 31 of the PPR to require licensed manufacturers to label the containers of pharmaceutical products with two additional particulars, namely the batch number and the expiry date of the products.

(f) **Clause 57** amends regulation 35 of the PPR to state more clearly the time by which licensed manufacturers must complete the records relating to the manufacture, testing and sale or supply, etc. of pharmaceutical products.

(g) **Clause 52** adds the new regulations 30A to 30F to the PPR. The new regulation 30A requires a licensed manufacturer to employ at least one AP to ensure and certify that pharmaceutical products are manufactured in accordance with the GMP Guide. The new regulation 30B requires a register of APs to be kept for the purposes of the PPR and specifies the particulars to be entered in the register. The new regulations 30C, 30D and 30E respectively provide for the application for registration as APs, the determination of such applications and the renewal of registration of APs. The qualifications required for registration as an AP are listed in new regulation 30C.

Regulation of importers, exporters and wholesalers

(h) **Clause 22** substitutes section 28A of the PPO to replace the existing registration system for importers and exporters of pharmaceutical products with a licensing system for wholesale dealers. A person who was registered under the existing registration system is, for the remainder of the term of the registration, to be regarded as a licensed wholesale

dealer.

(i) **Clauses 45 and 46** amend respectively regulations 25 and 26 of the PPR to expand the licensing control on sale or supply of poisons by way of wholesale dealing to cover pharmaceutical products. A new wholesale dealer licence (covering both poisons and pharmaceutical products) is to replace the existing wholesale poisons licence.

(j) **Clause 48** amends regulation 28 of the PPR to require records regarding transactions of not only Part I poisons but also pharmaceutical products to be kept by licensed wholesale dealers or licensed manufacturers. It also specifies the additional particulars (such as the batch number and pack size of pharmaceutical products) to be contained in such records.

Regulation of retailers

(k) **Clause 38** amends regulation 19 of the PPR to change the scope of control over the storage of poisons from substances included in the First Schedule to the PPR to all poisons included in Part I of the Poisons List.

Pre-market control of drugs

(l) **Clause 30** adds a new section 34A to the PPO to provide for the recovery from any person convicted of an offence under the PPO of the costs and expenses incurred by the Government in collecting, analyzing or examination any poison, pharmaceutical product or other substance for the purpose of the criminal proceedings.

(m) **Clause 33** adds a new regulation 2A to the PPR to introduce the new Schedule 10 containing the Poisons List which was originally set out in the Schedule to the PLR. **Clause 23(20)** creates a new section 29(1B) to the PPO such that further amendments to the relevant Schedules to the PPR should be made by means of negative vetting by the LegCo.

(n) The existing regulation 15 of the PPR requires "Poison 毒藥" or other prescribed text to be displayed on a separate label or in red lettering, etc. on the container of any poison. **Clause 37** amends that regulation to dispense with the requirements.

(o) **Clause 59** amends regulation 36B of the PPR to extend the maximum validity period of any clinical trial certificate from 2 years to 5 years.

LEGISLATIVE TIMETABLE

22. The legislative timetable will be as follows –

Publication in the Gazette	21 March 2014
First Reading and commencement of Second Reading Debate	26 March 2014
Resumption of Second Reading Debate, Committee Stage and Third Reading	To be notified

IMPLICATIONS OF THE PROPOSAL

23. The proposal is in conformity with the Basic Law, including the provisions concerning human rights. It has no productivity, environmental or family implications. The amendments proposed in the Bill will not affect the binding effect of the existing provisions of the PPO and its subsidiary legislation. The financial, civil service, economic and sustainability implications of the Bill are set out at Annex D. D

PUBLIC CONSULTATION

24. The Review Committee has a broad representation of members (please refer to footnote 1) and it has thoroughly considered and duly taken into account its members' views in the course of finalizing its recommendations. The recommendations of Review Committee's report were discussed at a plenary session in the Hong Kong Pharmacy Conference on 24 January 2010. During the RIA mentioned in paragraph 5 above, the consultant concerned conducted a series of stakeholder consultations. Also, a public opinion survey was conducted by the University of Hong Kong to gauge the sentiments of the general public towards the proposed changes. In general, the public and the relevant stakeholders support the proposals to enhance the regulatory regime on pharmaceutical products, although some dealers expressed concerns about the likely impact of the proposed changes on their operations.

25. We briefed LegCo Panel on Health Services (the Panel) on the above proposed legislative amendments to the PPO and its subsidiary legislation at its meeting held on 18 November 2013. The Panel also held two special meetings respectively on 10 December 2013 and 10 February 2014 to collect deputations' views towards and further discuss the proposed legislative amendments. Members of the Panel and the deputations attending the special meetings were generally

supportive of the proposed legislative amendments. Noting that some Members and deputations have grave concern about the proposal to require the registered premises of an ASP to be under the personal control of a registered pharmacist whenever the registered premises are open for business (which is longer than the current requirement of not less than two-thirds of the daily business hours of the ASP) and considering that the manpower supply of registered pharmacists in the coming few years will unlikely be sufficient to meet the manpower demand of the above proposal, we have removed the relevant proposed provision from the Bill. We would maintain the status quo that the registered premises of an ASP are still required to be under the personal control of a registered pharmacist for not less than two-thirds of the opening hours. As such, the ASP concerned will not be allowed to sell Part I poisons whenever the registered pharmacist is not present at the premises.

PUBLICITY

26. We shall issue a press release on 21 March 2014 (i.e. the same day when the Bill will be published in the Gazette). A spokesperson will be available to answer media and public enquiries.

BACKGROUND

27. Regulation of pharmaceutical products is essentially governed by the PPO and PPR and implemented through a multi-pronged approach with the dual targets of (a) control of the trade; and (b) control of the pharmaceutical products. The enforcement of the PPO and PPR is carried out by the Board, established under Section 3 of the PPO. Section 4A of the PPO further allows the Board to establish executive committees to register pharmaceutical products and license various pharmaceutical dealers.

ENQUIRY

28. Any enquiry on this brief can be addressed to Ms Ophelia Lui, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau
19 March 2014

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A BILL

To

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

Enacted by the Legislative Council.

Part 1

Preliminary

1. Short title and commencement

(1) This Ordinance may be cited as the Pharmacy and Poisons (Amendment) Ordinance 2014.

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

Part 2

Amendments to Pharmacy and Poisons Ordinance

2. Pharmacy and Poisons Ordinance amended

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

3. Long title amended

The long title, after "pharmacy"—

Add

", pharmaceutical products".

4. Section 2 amended (interpretation)

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

Repeal

"business authorized to sell"

Substitute

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

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

Repeal

everything after "means" and before "the individual"

Substitute

"—

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

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

but does not include".

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

Repeal

everything after "any substance or"

Substitute

"combination of substances—

(a) presented as having properties for treating or preventing disease in human beings or animals; or

(b) that may be used in, or administered to, human beings or animals, either with a view to—

(i) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(ii) making a medical diagnosis;".

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

Add

"made under section 29".

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

Repeal the full stop

Substitute a semicolon.

(6) Section 2(1)—

Add in alphabetical order

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

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

court (法庭) includes a magistrate;

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

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

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

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

(7) After section 2(1)—

Add

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

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

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

(1) Section 3(2)—

Repeal paragraph (d)

Substitute

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

(2) Section 3(2)(g)—

Repeal

"Executive;"

Substitute

"Executive; and".

(3) Section 3(2)(h)—

Repeal

"; and"

Substitute a full stop.

(4) Section 3(2)—

Repeal paragraph (i).

6. Section 4B added

After section 4A—

Add

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

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

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

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

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

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

(a) identify the code; and

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

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

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

(a) identify the code or part revised; and

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

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

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

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

7. Section 5 amended (the register of pharmacists)

Section 5(2)—

Repeal

"the headquarters of the Department of Health in".

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

Section 8(3)—

Repeal paragraph (c)

Substitute

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

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

Section 9(1)—

Repeal

"prescribed form"

Substitute

"specified form".

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

Section 10(1)—

Repeal

everything after "an offence"

Substitute a full stop.

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

After section 10A(2)—

Add

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

12. Section 11 amended (authorized sellers of poisons)

Section 11(1)—

Repeal

everything before "under this"

Substitute

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

13. Section 13 amended (registration of premises)

(1) Section 13(2)—

Repeal

"prescribed form"

Substitute

"specified form".

(2) After section 13(4)—

Add

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

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

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

(3) Section 13(5)(a)—

Repeal

"prescribed form"

Substitute

"specified form".

(4) Section 13(7)(b)—

Repeal

"subsection (3)."

Substitute

"subsection (3); and".

(5) After section 13(7)(b)—

Add

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

(6) After section 13(7)—

Add

"(7A) An authorized seller of poisons may apply to the Secretary for approval to alter the entry, contained in the register of premises, relating to any premises registered in respect of the authorized seller of poisons.

(7B) If the Secretary approves the alteration, the authorized seller of poisons must pay the prescribed fee for the alteration.".

14. Section 15 amended (appointment of Disciplinary Committee)

(1) Section 15—

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

(2) Before section 15(1A)—

Add

"(1) If—

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

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

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

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

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

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

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

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

(3) Section 15(1A)—

Repeal

everything before "of—"

Substitute

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

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

(1) Section 16(1)—

Repeal

"or body" (wherever appearing).

(2) Section 16(1), English text—

Repeal

"or which".

(3) Section 16(2)(a)—

Repeal

"either".

(4) Section 16(2)(a)(i)—

Repeal

"or".

(5) After section 16(2)(a)(i)—

Add

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

(6) Section 16(2)(a)(ii)—

Repeal

"subject to subsection (5),".

(7) Section 16(2)(b)—

Repeal

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

Substitute

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

(8) Section 16(2)(b)(i)—

Repeal

"body"

Substitute

"authorized seller of poisons".

(9) Section 16(2)(b)(ii)—

Repeal

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

Substitute

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

(10) Section 16(2)(b)(ii)—

Repeal

", from being registered therein; or"

Substitute a semicolon.

(11) After section 16(2)(b)(ii)—

Add

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

(12) Section 16(2)(b)(iii)—

Repeal

"body"

Substitute

"authorized seller of poisons".

(13) After section 16(2)—

Add

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

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

(b) in any other case—

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

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

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

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

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

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

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

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

(14) Section 16(3)(a)—

Repeal

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

Substitute

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

(15) Section 16(3)(b)—

Repeal

"direction"

Substitute

"direction or finding".

(16) Section 16(4)—

Repeal

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

Substitute

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

(17) Section 16—

Repeal subsection (5).

(18) Section 16(6)—

Repeal

"or body concerned,"

Substitute

"concerned".

(19) Section 16(6)(b), Chinese text—

Repeal

"某團體"

Substitute

"該人".

(20) Section 16(7)—

Repeal

"subsection (5)"

Substitute

"subsection (2A)".

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

(1) Section 16A(3)—

Repeal

"of $500"

Substitute

"at level 3".

(2) Section 16A(5)—

Repeal

"of $500"

Substitute

"at level 3".

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

Section 17(2)(d)—

Repeal

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

Substitute

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

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

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

Add

"**or findings**".

(2) Section 19(1)—

Repeal

"any direction"

Substitute

"any direction or finding".

(3) Section 19(1)—

Repeal

"the direction"

Substitute

"the direction or finding".

(4) Section 19—

Repeal subsection (2).

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

(1) Section 22(1)(a)—

Repeal

"in writing"

Substitute

"in the specified form and".

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

Add

"in the specified form".

(3) Section 22(4)—

Repeal

"of $5,000"

Substitute

"at level 2".

20. Section 25 amended (listed sellers of poisons)

(1) After section 25(2)—

Add

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

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

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

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

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

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

Add

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

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

Add

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

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

Add

"or suspend".

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

Add

"or suspension".

(6) After section 25(3)—

Add

"(3A) If a listed seller of poisons has contravened a code of practice applicable to, or a condition imposed under

subsection (2A) in respect of, the listed seller of poisons, the Board may—

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

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

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

(7) Section 25(5)—

Repeal

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

Substitute

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

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

Section 27—

Repeal paragraph (c)

Substitute

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

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

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

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

22. Section 28A substituted

Section 28A—

Repeal the section

Substitute

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

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

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

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

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

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

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

(3) If—

(a) a person was registered under this section, as in force before the commencement date of the

Pharmacy and Poisons (Amendment) Ordinance 2014 (of 2014) (***amending Ordinance***), to carry on business as an importer or exporter of pharmaceutical products; and

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

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

23. Section 29 amended (power to make regulations)

(1) Section 29(1)(aa)—

Repeal

everything after "prescribing"

Substitute

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

(2) Section 29(1)(b)—

Repeal

everything after "prescribing" and before "and for"

Substitute

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

(3) Section 29(1)(c)—

Repeal

everything after "of premises"

Substitute

"and providing for appeals;".

(4) Section 29(1)(ca)—

Repeal

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

Substitute

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

(5) Section 29(1)—

Repeal paragraph (f)

Substitute

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

(6) Section 29(1)—

Repeal paragraph (g).

(7) Section 29(1)(h)—

Repeal

everything after "of wholesale dealers in poisons"

Substitute

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

(8) Section 29(1)(ha)—

Repeal

"wholesale dealers in poison"

Substitute

"licensed wholesale dealers or licensed manufacturers".

(9) Section 29(1)(j)—

Repeal

everything after "of manufacturers"

Substitute

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

(10) Section 29(1)(ja)—

Repeal

"pharmaceutical products and poisons;"

Substitute

"poisons or pharmaceutical products including—

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

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

(11) After section 29(1)(ja)—

Add

"(jb) providing for the registration and renewal of registration of any person or class of persons referred to in paragraph (ja)(i), for the cancellation, suspension or variation of conditions of the registration, for the issue of warning letters to any such person, and for appeals against a refusal, cancellation, suspension or variation of conditions of the registration or issue of warning letters, and prescribing the fees payable on the issue of a certificate of registration or renewed certificate of registration;

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

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

Add

"or pharmaceutical products".

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

Add

"or pharmaceutical products".

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

Add

"and renewal of registration".

(15) Section 29(1)(q)—

Repeal

everything after "thereof"

Substitute

"(including the fees payable for carrying out inspections for determining an application for such registration and renewal

of registration), for the deregistration, suspension or variation of conditions of such registration, for the issue of warning letters to holders of registration certificates, and for appeals against a refusal, deregistration, suspension or variation of conditions of such registration or issue of warning letters;".

(16) Section 29(1)(qa)—

Repeal

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

(17) Section 29(1)—

Repeal paragraph (qb)

Substitute

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

(18) Section 29(1)(r)—

Repeal the full stop

Substitute a semicolon.

(19) After section 29(1)(r)—

Add

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

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

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

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

(20) After section 29(1A)—

Add

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

(a) the Poisons List; or

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

(i) to which a provision in this Ordinance, or in a regulation made under this section, applies; or

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

24. Section 29A added

After section 29—

Add

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

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

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

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

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

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

(1) Section 30(1)(aa)—

Repeal

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

Substitute

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

(2) After section 30(1)(aa)—

Add

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

26. Section 31 amended (Poisons Committee)

(1) Section 31(1), Chinese text—

Repeal

"分銷"

Substitute

"分發".

(2) Section 31(1)(a)—

Repeal

"and (i)".

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

Section 32(b)—

Repeal

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

Substitute

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

28. Section 33 amended (offences)

Section 33(1)—

Repeal

"or 28"

Substitute

", 28 or 28A".

29. Section 34 amended (penalty)

Section 34—

Repeal

"of $100,000"

Substitute

"at level 6".

30. Section 34A added

After section 34—

Add

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

(1) If a person is convicted of an offence under this Ordinance, the court may order the person to pay to the Government the sum the court considers appropriate for the costs and expenses reasonably incurred by the

Government in relation to the collection, analysis or examination of a poison, pharmaceutical product or any other substance for the purpose of the criminal proceedings.

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

Part 3

Amendments to Pharmacy and Poisons Regulations

31. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 32 to 70.

32. Regulation 2 amended (interpretation)

Regulation 2(1)—

Add in alphabetical order

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

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

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

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

33. Regulation 2A added

After regulation 2—

Add

"**2A. Poisons List**

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

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

Regulation 3—

Repeal

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

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

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

Add

"licensed".

(2) Regulation 5(5)—

Repeal

"of $10,000"

Substitute

"at level 3".

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

Regulation 8(2)—

Repeal

"Parts VII, VIII, VIIIA,"

Substitute

"Parts VI, VII, VIII,".

37. Regulation 15 substituted

Regulation 15—

Repeal the regulation

Substitute

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

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

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

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

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

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

38. Regulation 19 amended (storage of poisons)

(1) Regulation 19(2)—

Repeal

"substance included in the First Schedule"

Substitute

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

(2) Regulation 19(2)—

Repeal

"the substance"

Substitute

"the poison".

(3) Regulation 19(3)—

Repeal

"or substance".

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

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

Add

"and".

(2) Regulation 22(4)—

Repeal subparagraph (b).

(3) Regulation 22(5)—

Repeal

"English and in"

Substitute

"either English or".

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

Regulation 23(3)—

Repeal

everything after "labelled"

Substitute

"with words describing its contents.".

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

(1) Regulation 24(2)(b)—

Repeal

"solely".

(2) Regulation 24—

Repeal paragraph (3).

(3) Regulation 24—

Repeal paragraph (4).

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

Regulation 24A(4)—

Repeal

"person aggrieved by a decision of the Committee"

Substitute

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

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

Regulation 24B—

Repeal paragraph (a).

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

Regulation 24C—

Repeal the regulation.

45. Regulation 25 substituted

Regulation 25—

Repeal the regulation

Substitute

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

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

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

(b) is an authorized seller of poisons; or

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

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

(1) Regulation 26(3)—

Repeal

"issue a wholesale poisons"

Substitute

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

(2) Regulation 26(4)—

Repeal

"poisons"

Substitute

"dealer".

(3) Regulation 26(4)—

Repeal

everything after "be in"

Substitute

"the specified form.".

(4) Regulation 26—

Repeal paragraph (5)

Substitute

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

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

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

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

(5A) The circumstances are—

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

(i) a condition of the licence; or

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

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

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

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

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

(5) Regulation 26(6)—

Repeal

"person aggrieved by a decision of the Committee under this regulation"

Substitute

"applicant aggrieved by a decision made in respect of the applicant under paragraph (3), or any licensed wholesale dealer aggrieved by a decision made in respect of the licensed wholesale dealer under paragraph (5),".

(6) Regulation 26(8)—

Repeal

"poisons licence"

Substitute

"dealer licence".

(7) Regulation 26(8)(a)—

Repeal

"poisons"

Substitute

"the poisons or pharmaceutical products".

(8) Regulation 26(8)(b)—

Repeal

"a deputy"

Substitute

"one or more deputies".

(9) Regulation 26(9)—

Repeal

"of the Board".

(10) After regulation 26(9)—

Add

"(10) If—

(a) a person was issued with a wholesale poisons licence under this regulation, as in force before the commencement date of the Pharmacy and Poisons (Amendment) Ordinance 2014 (of 2014) (***amending Ordinance***); and

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

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

47. Regulation 27 amended (sales by wholesale dealers)

(1) Regulation 27, heading—

Repeal

"Sales by wholesale dealers"

Substitute

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

(2) Regulation 27—

Repeal everything before paragraph (a)

Substitute

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

(3) Regulation 27—

Repeal paragraph (a)

Substitute

"(a) a licensed wholesale dealer;

(ab) a licensed manufacturer;".

(4) Regulation 27—

Repeal paragraph (j)

Substitute

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

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

(1) Regulation 28, heading—

Repeal

"wholesale dealer"

Substitute

"licensed wholesale dealers or licensed manufacturers".

(2) Regulation 28(1)—

Repeal

everything before "acquired by"

Substitute

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

(3) Regulation 28(1)(c)—

Repeal

"and unit of quantity"

Substitute

"or pharmaceutical product".

(4) After regulation 28(1)(c)—

Add

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

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

Add

"or pharmaceutical product".

(6) Regulation 28(2)—

Repeal

everything before "disposition is"

Substitute

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

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

Add

"or pharmaceutical product".

(8) Regulation 28(2)(d)—

Repeal

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

Substitute

"total quantity of the poison or pharmaceutical product".

(9) Regulation 28(2)(f)—

Repeal

everything after "product"

Substitute a semicolon.

(10) After regulation 28(2)(f)—

Add

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

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

Add

"or pharmaceutical product".

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

Add

"or pharmaceutical product".

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

Add

"or pharmaceutical product".

(14) Regulation 28(4)—

Repeal

everything after "transactions"

Substitute

"must be in the specified form.".

(15) Regulation 28(7)—

Repeal

everything after "of an" and before "retain"

Substitute

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

(16) Regulation 28(8)—

Repeal

everything before "set up"

Substitute

"(8) A licensed wholesale dealer must".

49. Regulation 28A added

Part VII, before regulation 29—

Add

"28A. Good Manufacturing Practice Guide

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

(2) The GMP Guide—

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

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

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

(a) identify the Guide; and

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

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

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

(a) identify the Guide or part revised; and

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

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

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

50. Regulation 29 amended (licensing of manufacturers)

(1) Regulation 29(1)—

Repeal

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

Substitute

"A person must not".

(2) After regulation 29(1)—

Add

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

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

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

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

(iii) the name of the product; and

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

(i) particulars mentioned in subparagraph (a);

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

(3) Regulation 29—

Repeal paragraph (2).

(4) Regulation 29(3)—

Repeal

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

Substitute

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

(5) Regulation 29—

Repeal paragraph (4)

Substitute

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

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

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

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

(4A) The circumstances are—

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

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

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

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

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

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

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

(6) Regulation 29(5)—

Repeal

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

Substitute

"specified forms.".

(7) Regulation 29(6)—

Repeal

"manufacturer licensed under this regulation"

Substitute

"licensed manufacturer".

(8) Regulation 29(6)—

Repeal

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

Substitute

"specified forms.".

(9) Regulation 29(7)—

Repeal

"person"

Substitute

"applicant or licensed manufacturer".

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

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

Add

"or".

(2) Regulation 30(1)—

Repeal subparagraph (b).

52. Regulations 30A to 30F added

After regulation 30—

Add

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

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

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

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

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

(3) In this regulation—

registered particulars (註冊詳情) has the meaning given by regulation 35A;

registrable particulars (須註冊詳情) has the meaning given by regulation 35A.

30B. Register of authorized persons

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

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

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

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

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

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

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

30C. Application for registration as authorized person

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

(2) The requirements are that—

(a) the person—

(i) is a registered pharmacist; or

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

(b) the person—

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

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

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

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

30D. Registration as authorized person

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

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

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

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

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

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

30E. Renewal of registration of authorized person

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

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

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

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

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

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

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

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

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

(a) cancel the registration;

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

(c) issue a warning letter to the person;

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

(2) The circumstances are—

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

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

(i) a condition of the registration; or

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

(c) that the person has been convicted of—

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

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

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

(4) The Committee must cause the Secretary to—

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

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

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

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

53. Regulation 31 amended (labelling by manufacturers)

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

Add

"**licensed**".

(2) Regulation 31(1)—

Repeal

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

Substitute

"licensed manufacturer".

(3) Regulation 31(1)(c)—

Repeal

"manufacturer; and"

Substitute

"manufacturer;".

(4) Regulation 31(1)(d)—

Repeal

"Board."

Substitute

"Board;".

(5) After regulation 31(1)(d)—

Add

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

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

(6) Regulation 31(2)(b)(ii)—

Repeal

"article."

Substitute

"article;".

(7) After regulation 31(2)(b)—

Add

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

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

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

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

(8) Regulation 31(3), Chinese text—

Repeal

"分銷"

Substitute

"分發".

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

(1) Regulation 32—

Repeal

"manufacturer shall"

Substitute

"licensed manufacturer must".

(2) Regulation 32—

Repeal

"or packing".

55. Regulation 33 amended (duties of manufacturers)

(1) Regulation 33, heading—

Repeal

"manufacturers"

Substitute

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

(2) Regulation 33(1)—

Repeal

"a manufacturer shall"

Substitute

"a licensed manufacturer must".

(3) Regulation 33(1A)—

Repeal

"a manufacturer"

Substitute

"a licensed manufacturer".

(4) Regulation 33—

Repeal paragraph (2)

Substitute

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

(5) Regulation 33(4)—

Repeal

"A manufacturer shall"

Substitute

"A licensed manufacturer must".

(6) Regulation 33(4)—

Repeal

everything after "less than"

Substitute

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

(7) Regulation 33(5)—

Repeal

"A manufacturer shall"

Substitute

"A licensed manufacturer must".

(8) After regulation 33(5)—

Add

"(6) In this regulation—

expiry date (使用期限) has the meaning given by regulation 31(2)(d);

registered particulars (註冊詳情) has the meaning given by regulation 35A;

registrable particulars (須註冊詳情) has the meaning given by regulation 35A.".

56. Regulation 34 amended (manufacturer's premises)

(1) Regulation 34, heading—

Repeal

"Manufacturer's"

Substitute

"Licensed manufacturer's".

(2) Regulation 34(1)—

Repeal

"and packaging".

(3) Regulation 34(1)(b)—

Repeal

"and packing".

(4) Regulation 34(2)—

Repeal

", packing".

(5) Regulation 34(5)—

Repeal

"and packing".

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

(1) Regulation 35, heading—

Repeal

"manufacturers"

Substitute

"licensed manufacturers".

(2) Regulation 35(1)—

Repeal

"A manufacturer shall"

Substitute

"A licensed manufacturer must".

(3) Regulation 35—

Repeal paragraph (2)

Substitute

"(2) A record showing the matters mentioned in paragraph (1)(a), (b), (d), (e) or (g) must be completed when the

manufacturing process or test concerned is being carried out.

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

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

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

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

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

(1) Regulation 36(1), Chinese text—

Repeal

"分銷，或為銷售、分銷"

Substitute

"分發，或為銷售、分發".

(2) Regulation 36(1)(a)—

Repeal

"manufacturer,"

Substitute

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

(3) Regulation 36(1)(b)—

Repeal

"the importer"

Substitute

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

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

Repeal

"分銷"

Substitute

"分發".

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

Add

"or".

(6) Regulation 36(1A)(a)(ii)—

Repeal

"pharmaceutical manufacturer"

Substitute

"licensed manufacturer".

(7) Regulation 36(1A)(a)—

Repeal sub-subparagraph (iii).

(8) After regulation 36(1A)(a)—

Add

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

(9) Regulation 36(1A)(b)—

Repeal

"Kong."

Substitute

"Kong;".

(10) After regulation 36(1A)(b)—

Add

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

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

(11) Regulation 36(2)—

Repeal

"form prescribed in the Eighth Schedule"

Substitute

"specified form".

(12) Regulation 36(2)—

Repeal

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

(13) Regulation 36(5)—

Repeal

everything after "may" and before "valid"

Substitute

", subject to any conditions it thinks fit to impose, register a pharmaceutical product or substance by issuing to the

applicant a registration certificate in the specified form and the certificate is".

(14) Regulation 36(5)—

Repeal

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

(15) Regulation 36(7)—

Repeal

everything after "renewable on"

Substitute

"—

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

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

(16) After regulation 36(7)—

Add

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

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

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

Add

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

(18) Regulation 36(9)—

Repeal

"person"

Substitute

"applicant or holder of a registration certificate".

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

(1) Regulation 36B—

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

(2) Before regulation 36B(1C)—

Add

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

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

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

(3) Regulation 36B(2)—

Repeal

"sample of the product or substance and a".

(4) Regulation 36B(3)—

Repeal

everything after "may" and before "years"

Substitute

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

(5) Regulation 36B(3)—

Repeal

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

(6) After regulation 36B(3)—

Add

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

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

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

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

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

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

(7) Regulation 36B(4)—

Repeal

"person"

Substitute

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

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

(1) Regulation 37(3)—

Repeal

"by an importer"

Substitute

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

(2) Regulation 37(3)—

Repeal

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

Substitute

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

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

Add

"produce".

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

Add

"produce".

(5) Regulation 37(3)(b)—

Repeal

"with."

Substitute

"with;".

(6) After regulation 37(3)(b)—

Add

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

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

Part VIIIA—

Repeal the Part.

62. Regulation 38B added

Part X, before regulation 39—

Add

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

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

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

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

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

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

(1) Regulation 39(d)—

Repeal

"holders of wholesale poisons licences"

Substitute

"licensed wholesale dealers or licensed manufacturers".

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

Add

"licensed".

(3) Regulation 39—

Repeal

"holder of wholesale poison licence or manufacturer"

Substitute

"licensed wholesale dealer or licensed manufacturer".

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

(1) Regulation 41, Chinese text, heading—

Repeal

"**表格**"

Substitute

"**式樣**".

(2) Regulation 41(1)—

Repeal

everything after "be in the"

Substitute

"specified form.".

(3) Regulation 41—

Repeal paragraph (2).

(4) Regulation 41(2A), Chinese text—

Repeal

"*表格*"

Substitute

"*式樣*".

(5) Regulation 41—

Repeal paragraph (3).

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

(1) First Schedule, heading—

Repeal

"15, 19, 22, 23"

Substitute

"22".

(2) First Schedule—

Repeal

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

Substitute

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

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

Repeal

"Colchicum, alkaloids of"

Substitute

"Colchicum, alkaloids of; their salts".

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

Repeal

"Bacillus Calmette-Guerin"

Substitute

"Bacillus Calmette-Guérin".

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

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

(b) **Add in alphabetical order**

"Japanese encephalitis".

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

Repeal

"Besylate"

Substitute

"besylate".

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

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

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

Add

"Benzquinamide".

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

Repeal

"Sulphur Hexafluoride"

Substitute

"Sulphur hexafluoride".

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

Repeal

"Dihydrallazine"

Substitute

"Dihydralazine".

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

Repeal

"Trisodium Hexahydrate"

Substitute

"trisodium hexahydrate".

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

Repeal

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

Substitute

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

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

Repeal

"N-(3-parafluorobenzoyl-propyl)"

Substitute

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

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

Repeal

"Hydiazines"

Substitute

"Hydrazines".

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

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

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

Add

"Hydralazine; its salts".

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

Repeal

"Ketanserine"

Substitute

"Ketanserin".

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

Repeal

"Ketoconazole"

Substitute

"Ketoconazole,".

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

Repeal

"Sulphate"

Substitute

"sulphate".

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

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

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

Add

"Moclobemide; its salts".

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

Repeal

"Acid"

Substitute

"acid".

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

Add

"; its salts".

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

Repeal

"1-diphenylpropanecarboxylic"

Substitute

"1-diphenylpropane carboxylic".

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

Repeal

"Minoxidil except"

Substitute

"Minoxidil, except".

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

Repeal

"Acid"

Substitute

"acid".

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

Repeal

"Piroxicam"

Substitute

"Piroxicam,".

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

Repeal

"salts"

Substitute

"salts,".

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

Repeal

"; their salts".

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

Repeal

"Tetracosatrin"

Substitute

"Tetracosactide".

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

Repeal

"Acid"

Substitute

"acid".

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

Repeal

"acid"

Substitute

"acid,".

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

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

(b) After item "Vasopressins"—

Add

"Vecuronium; its salts".

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

Repeal

"Warfarin"

Substitute

"Warfarin; its".

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

(a) **Repeal item "乙丙氨酯";**

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

Add

"己丙氨酯".

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

Repeal

"苯胺類"

Substitute

"酰苯胺類".

(34) First Schedule, Chinese text, Division A, item "六甲嗪胺"—

Repeal

"嗪"

Substitute

"蜜".

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

Repeal

"賓"

Substitute

"濱".

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

Repeal

"偉"

Substitute

"韋".

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

(a) **Repeal item "甲納曲酮；其鹽類";**

(b) Before item "甲氯芬那酸；其鹽類"—

Add

"甲納曲酮；其鹽類".

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

Repeal

"呱"

Substitute

"哌".

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

Repeal

"泮"

Substitute

"平".

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

(a) **Repeal item "代昔洛韋；其鹽類";**

(b) After item "伐地昔布；其鹽類"—

Add

"伐昔洛韋；其鹽類".

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

Repeal

"具有雙氫-1，4-苯二氮䓬的化學結構在任何程度上被取代"

Substitute

"含有雙氫-1，4-苯二氮䓬的化學結構(在任何程度上被取代者)".

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

Repeal

"米貝"

Substitute

"米貝拉".

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

Repeal

"物"

Substitute

"特".

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

Repeal

"奈"

Substitute

"胺".

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

Repeal

"乙型流感嗜血杆菌"

Substitute

"乙型流感嗜血桿菌".

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

Repeal

"安他唑林"

Substitute

"安他唑啉".

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

Repeal

"已"

Substitute

"己".

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

Repeal

"秦"

Substitute

"嗪".

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

(a) **Repeal item "阿伐他汀；其鹽類";**

(b) Before item "阿托伐醌"—

Add

"阿托伐他汀；其鹽類".

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

Add

"上述".

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

(a) **Repeal item "阿紮胞苷；其鹽類";**

(b) After item "阿扎那韋；其鹽類"—

Add

"阿扎胞苷；其鹽類".

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

Repeal

"其四級化合物，"

Substitute

"其四級化合物；".

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

Repeal

"甙"

Substitute

"苷".

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

Repeal

"脂"

Substitute

"酯".

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

Repeal

"書"

Substitute

"韋".

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

Repeal

"溴".

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

Repeal the colon.

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

(a) **Repeal item "苯甲酸利扎曲普坦；其鹽類";**

(b) Before item "利匹韋林；其鹽類"—

Add

"利扎曲坦；其鹽類".

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

Repeal

"噁"

Substitute

"諾".

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

Repeal

"千"

Substitute

"4".

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

Repeal

"地諾前列素(前列腺素 F_2a)"

Substitute

"地諾前列素(前列腺素 $F_{2\alpha}$)".

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

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

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

"貝美前列素".

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

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

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

"曲伏前列素".

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

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

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

"烏諾前列酮".

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

Repeal

"份"

Substitute

"分".

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

Repeal

"特"

Substitute

"德".

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

Repeal

"稀"

Substitute

"烯".

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

Repeal

"坦"

Substitute

"坦".

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

Repeal

"磷"

Substitute

"膦".

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

Repeal

"a"

Substitute

"α".

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

(a) **Repeal item "6-烟鹼可待因；其鹽類";**

(b) After item relating to "煙酸及其鹽類"—

Add

"6-煙鹼可待因；其鹽類".

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

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

(b) After item "培氟沙星；其鹽類；其酯類"—

Add

"培哚普利拉；其鹽類；其酯類；它們的鹽類".

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

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

(b) After item "索拉非尼；其鹽類"—

Add

"班布特羅及其鹽類，載於噴霧器時".

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

Repeal

"甙"

Substitute

"苷".

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

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

(b) After item "普蘆卡必利；其鹽類"—

Add

"普蘆沙星；其鹽類；其酯類；它們的鹽類".

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

(a) **Repeal item "富馬酸喹硫平；其鹽類";**

(b) After item "喹高利特；其鹽類"—

Add

"喹硫平；其鹽類".

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

Repeal

"左"

Substitute

"佐".

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

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

(b) After item "噻托；其鹽類"—

Add

"噻奈普汀；其鹽類；其酯類；它們的鹽類".

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

(a) **Repeal item "Anagrelide；其鹽類";**

(b) After item "阿那曲唑；其鹽類"—

Add

"阿那格雷；其鹽類".

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

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

(b) After item "布托啡諾；其鹽類"—

Add

"布林佐胺；其鹽類".

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

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

(b) Before item "吩那多松；其鹽類"—

Add

"坎地沙坦；其鹽類；其酯類；它們的鹽類".

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

(a) **Repeal item "Celecoxib；其鹽類";**

(b) After item "塞利洛爾；其鹽類"—

Add

"塞來考昔；其鹽類".

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

(a) **Repeal item "Cidofovir；其鹽類";**

(b) After item "西曲瑞克；其鹽類；其酯類；它們的鹽類"—

Add

"西多福韋；其鹽類".

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

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

(b) After item "達非那新；其鹽類"—

Add

"達促紅素 α".

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

(a) **Repeal item "Eletriptan；其鹽類";**

(b) After item "依泊丁"—

Add

"依來曲坦；其鹽類".

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

(a) **Repeal item "Eprosartan；其鹽類";**

(b) After item "依普利酮"—

Add

"依普羅沙坦；其鹽類".

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

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

(b) Before item "依替福林；其鹽類"—

Add

"依替巴肽；其鹽類".

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

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

(b) Before item "依那普利；其鹽類"—

Add

"依那西普".

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

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

(b) After item "縮宮素類(催產素類)"—

Add

"磺達肝素(癸)；其鹽類".

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

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

(b) Before item "伊普吲哚；其鹽類"—

Add

"伊班膦酸；其鹽類".

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

(a) **Repeal item "Imatinib；其鹽類";**

(b) After item "伊索昔康；其鹽類"—

Add

"伊馬替尼；其鹽類".

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

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

(b) After item "伊立替康；其鹽類"—

Add

"伊米苷酶".

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

(a) **Repeal item "Indinavir；其鹽類";**

(b) Before item "茚達特羅；其鹽類；其酯類；它們的鹽類"—

Add

"茚地那韋；其鹽類".

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

(a) **Repeal item "Lepirudin；其鹽類";**

(b) Before item "來曲唑"—

Add

"來匹蘆定；其鹽類".

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

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

(b) After item "左乙拉西坦；其鹽類"—

Add

"左西孟旦；其鹽類".

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

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

(b) After item "諾氟沙星；其鹽類；其酯類"—

Add

"錳福地吡；其鹽類".

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

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

(b) After item "琥珀膽鹼；其鹽類"—

Add

"氰氟蟲腙；其鹽類".

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

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

(b) After item "帕利哌酮；其鹽類"—

Add

"帕利珠單抗".

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

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

(b) After item "吡洛芬；其鹽類"—

Add

"吡美莫司".

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

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

(b) Before item "拉米夫定；其鹽類"—

Add

"拉布立酶；其鹽類".

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

(a) **Repeal item "Ritonavir；其鹽類";**

(b) After item "利托君；其鹽類"—

Add

"利托那韋；其鹽類".

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

(a) **Repeal item "Sevelamer；其鹽類";**

(b) After item "司替氨酯"—

Add

"司維拉姆；其鹽類".

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

(a) **Repeal item "Stavudine；其鹽類";**

(b) After item "司巴丁(金雀花鹼)；其鹽類"—

Add

"司他夫定；其鹽類".

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

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

(b) After item "他莫昔芬；其鹽類"—

Add

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

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

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

(b) After item "替拉曲考；其鹽類"—

Add

"替奈普酶；其鹽類".

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

(a) **Repeal item "Topotecan；其鹽類";**

(b) After item "托芬那酸；其鹽類"—

Add

"托泊替康；其鹽類".

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

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

(b) Before item "烏拉地爾；其鹽類"—

Add

"烏司奴單抗".

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

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

(b) After item "纈沙坦；其鹽類"—

Add

"纈更昔洛韋；其鹽類".

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

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

(b) After item "維莫非尼；其鹽類"—

Add

"維替泊芬；其鹽類".

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

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

(b) After item "曲普瑞林；其鹽類"—

Add

"伏立康唑；其鹽類".

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

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

(b) After item "齊多夫定"—

Add

"齊拉西酮；其鹽類".

(112) First Schedule, Chinese text, Division B, item "銀鹽類，硫酸銀除外"—

Repeal

"銀鹽類"

Substitute

"銀的鹽類".

66. Third Schedule amended

(1) Third Schedule—

Repeal

"[reg. 9(1)]"

Substitute

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

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

Add in alphabetical order

"Colchicum, alkaloids of; their salts

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

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

Vinca, alkaloids of".

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

Repeal

"Bacillus Calmette-Guerin"

Substitute

"Bacillus Calmette-Guérin".

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

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

(b) **Add in alphabetical order**

"Japanese encephalitis".

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

Repeal

"Besylate"

Substitute

"besylate".

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

Repeal

"Sulphur Hexafluoride"

Substitute

"Sulphur hexafluoride".

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

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

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

Add

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

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

Repeal

"Dihydrallazine"

Substitute

"Dihydralazine".

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

Repeal

"Trisodium Hexahydrate"

Substitute

"trisodium hexahydrate".

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

Repeal

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

Substitute

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

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

Repeal

"Hydrallazine"

Substitute

"Hydralazine".

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

Repeal

"Ketanserine"

Substitute

"Ketanserin".

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

Repeal

"Ketoconazole"

Substitute

"Ketoconazole,".

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

Repeal

"Sulphate"

Substitute

"sulphate".

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

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

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

Add

"Moclobemide; its salts".

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

Repeal

"Minoxidil except"

Substitute

"Minoxidil, except".

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

Repeal

"Piroxicam"

Substitute

"Piroxicam,".

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

Repeal

"salts"

Substitute

"salts,".

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

Repeal

"; their salts".

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

Repeal

"Tetracosatrin"

Substitute

"Tetracosactide".

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

Repeal

"acid"

Substitute

"acid,".

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

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

(b) After item "Vasopressins"—

Add

"Vecuronium; its salts".

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

Repeal

"Warfarin"

Substitute

"Warfarin; its".

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

(a) **Repeal item "乙丙氨酯";**

(b) Before item "干擾素"—

Add

"己丙氨酯".

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

Repeal

"胺，"

Substitute

"胺；".

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

Repeal

"醇，"

Substitute

"醇；".

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

Repeal

"嘧"

Substitute

"蜜".

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

Repeal

"賓"

Substitute

"濱".

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

Repeal

"偉"

Substitute

"韋".

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

(a) **Repeal item "甲納曲酮；其鹽類";**

(b) After item "甲麥角林"—

Add

"甲鈉曲酮；其鹽類".

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

Repeal

"呱"

Substitute

"哌".

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

Repeal

"泮"

Substitute

"平".

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

(a) **Repeal item "代昔洛韋；其鹽類";**

(b) After item "伐地昔布；其鹽類"—

Add

"伐昔洛韋；其鹽類".

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

Repeal

"具有雙氫-1，4-苯二氮䓬的化學結構在任何程度上被取代"

Substitute

"含有雙氫-1，4-苯二氮䓬的化學結構(在任何程度上被取代者)".

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

Repeal

"米貝"

Substitute

"米貝拉".

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

Repeal

"物"

Substitute

"特".

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

Repeal

"奈"

Substitute

"胺".

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

Repeal

"乙型流感嗜血杆菌"

Substitute

"乙型流感嗜血桿菌".

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

Repeal

"安他唑林"

Substitute

"安他唑啉".

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

Repeal

"已"

Substitute

"己".

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

Repeal

"秦"

Substitute

"嗪".

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

(a) **Repeal item "阿伐他汀；其鹽類";**

(b) Before item "阿托伐醌"—

Add

"阿托伐他汀；其鹽類".

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

(a) **Repeal item "阿紮胞苷；其鹽類";**

(b) After item "阿扎那韋；其鹽類"—

Add

"阿扎胞苷；其鹽類".

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

Repeal

"脂"

Substitute

"酯".

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

Repeal

"甙"

Substitute

"苷".

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

Repeal

"脂"

Substitute

"酯".

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

Repeal

"書"

Substitute

"韋".

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

Repeal

"溴".

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

Repeal

"它們的鹽類；它們的其酰基衍生物；它們的鹽類"

Substitute

"它們的鹽類；它們的酰基衍生物；它們的鹽類".

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

Repeal

"與"

Substitute

"及".

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

(a) **Repeal item "苯甲酸利扎曲普坦；其鹽類";**

(b) Before item "利匹韋林；其鹽類"—

Add

"利扎曲坦；其鹽類".

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

Repeal

"噁"

Substitute

"諾".

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

Repeal

"地諾前列素(前列腺素 F_{2a})"

Substitute

"地諾前列素(前列腺素 $F_{2\alpha}$)".

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

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

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

"貝美前列素".

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

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

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

"曲伏前列素".

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

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

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

"烏諾前列酮".

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

Repeal

"特"

Substitute

"德".

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

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

(b) After item "氧烯洛爾；其鹽類"—

Add

"茴香酰化纖溶酶原溶栓酶活化劑複合物".

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

Repeal

"稀"

Substitute

"烯".

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

Repeal

"呾"

Substitute

"坦".

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

Repeal

"磷"

Substitute

"膦".

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

Repeal

"a"

Substitute

"α".

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

(a) **Repeal item "6-烟鹼可待因；其鹽類";**

(b) After item relating to "煙酸及其鹽類"—

Add

"6-煙鹼可待因；其鹽類".

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

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

(b) After item "培氟沙星；其鹽類；其酯類"—

Add

"培哚普利拉；其鹽類；其酯類；它們的鹽類".

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

Repeal

"甙"

Substitute

"苷".

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

Repeal

"物，"

Substitute

"物；".

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

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

(b) After item "普蘆卡必利；其鹽類"—

Add

"普蘆沙星；其鹽類；其酯類；它們的鹽類".

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

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

(b) After item "索拉非尼；其鹽類"—

Add

"班布特羅及其鹽類，載於噴霧器時".

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

(a) **Repeal item "富馬酸喹硫平；其鹽類";**

(b) After item "喹高利特；其鹽類"—

Add

"喹硫平；其鹽類".

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

Repeal

"具有雄激素或孕激素作用的類固醇化合物；它們的酯類茴"

Substitute

"具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類".

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

Repeal

"左"

Substitute

"佐".

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

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

(b) After item "噻托；其鹽類"—

Add

"噻奈普汀；其鹽類；其酯類；它們的鹽類".

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

(a) **Repeal item "Anagrelide；其鹽類";**

(b) After item "阿那曲唑；其鹽類"—

Add

"阿那格雷；其鹽類".

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

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

(b) After item "布托啡諾；其鹽類"—

Add

"布林佐胺；其鹽類".

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

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

(b) Before item "克拉屈濱"—

Add

"坎地沙坦；其鹽類；其酯類；它們的鹽類".

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

(a) **Repeal item "Celecoxib；其鹽類";**

(b) After item "塞利洛爾；其鹽類"—

Add

"塞來考昔；其鹽類".

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

(a) **Repeal item "Cidofovir；其鹽類";**

(b) After item "西曲瑞克；其鹽類；其酯類；它們的鹽類"—

Add

"西多福韋；其鹽類".

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

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

(b) After item "達非那新；其鹽類"—

Add

"達促紅素 α".

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

(a) **Repeal item "Eletriptan；其鹽類";**

(b) After item "依泊丁"—

Add

"依來曲坦；其鹽類".

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

(a) **Repeal item "Eprosartan；其鹽類";**

(b) After item "依普利酮"—

Add

"依普羅沙坦；其鹽類".

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

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

(b) Before item "依替福林；其鹽類"—

Add

"依替巴肽；其鹽類".

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

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

(b) Before item "依那普利；其鹽類"—

Add

"依那西普".

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

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

(b) After item "縮宮素類(催產素類)"—

Add

"磺達肝素(癸)；其鹽類".

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

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

(b) Before item "伊普唄唻；其鹽類"—

Add

"伊班膦酸；其鹽類".

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

(a) **Repeal item "Imatinib；其鹽類";**

(b) After item "伊索昔康；其鹽類"—

Add

"伊馬替尼；其鹽類".

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

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

(b) After item "伊立替康；其鹽類"—

Add

"伊米苷酶".

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

(a) **Repeal item "Indinavir；其鹽類";**

(b) Before item "茚達特羅；其鹽類；其酯類；它們的鹽類"—

Add

"茚地那韋；其鹽類".

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

(a) **Repeal item "Lepirudin；其鹽類";**

(b) Before item "來曲唑"—

Add

"來匹蘆定；其鹽類".

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

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

(b) After item "左乙拉西坦；其鹽類"—

Add

"左西孟旦；其鹽類".

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

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

(b) After item "諾氟沙星；其鹽類；其酯類"—

Add

"錳福地吡；其鹽類".

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

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

(b) After item "琥珀膽鹼；其鹽類"—

Add

"氰氟蟲腙；其鹽類".

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

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

(b) After item "帕利哌酮；其鹽類"—

Add

"帕利珠單抗".

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

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

(b) After item "吡洛芬；其鹽類"—

Add

"吡美莫司".

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

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

(b) Before item "拉米夫定；其鹽類"—

Add

"拉布立酶；其鹽類".

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

(a) **Repeal item "Ritonavir；其鹽類";**

(b) After item "利托君；其鹽類"—

Add

"利托那韋；其鹽類".

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

(a) **Repeal item "Sevelamer；其鹽類";**

(b) After item "司替氨酯"—

Add

"司維拉姆；其鹽類".

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

(a) **Repeal item "Stavudine；其鹽類";**

(b) After item "司巴丁(金雀花鹼)；其鹽類"—

Add

"司他夫定；其鹽類".

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

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

(b) After item "他莫昔芬；其鹽類"—

Add

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

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

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

(b) After item "替拉曲考；其鹽類"—

Add

"替奈普酶；其鹽類".

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

(a) **Repeal item "Topotecan；其鹽類";**

(b) After item "托芬那酸；其鹽類"—

Add

"托泊替康；其鹽類".

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

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

(b) Before item "烏拉地爾；其鹽類"—

Add

"烏司奴單抗".

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

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

(b) After item "纈沙坦；其鹽類"—

Add

"纈更昔洛韋；其鹽類".

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

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

(b) After item "維莫非尼；其鹽類"—

Add

"維替泊芬；其鹽類".

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

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

(b) After item "曲普瑞林；其鹽類"—

Add

"伏立康唑；其鹽類".

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

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

(b) After item "齊多夫定"—

Add

"齊拉西酮；其鹽類".

(106) Third Schedule, Division A—

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

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

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

(d) item "Vinca, alkaloids of"—

Repeal the items.

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

(1) Fifth Schedule, heading—

Repeal

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

Substitute

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

(2) Fifth Schedule—

Repeal

"[reg. 15(2)]"

Substitute

"[reg. 15]".

(3) Fifth Schedule, English text—

(a) Paragraph 1;

(b) Paragraph 2;

(c) Paragraph 3;

(d) Paragraph 4;

(e) Paragraph 5;

(f) Paragraph 6;

(g) Paragraph 7;

(h) Paragraph 8;

(i) Paragraph 9;

(j) Paragraph 10—

Repeal

"words" (wherever appearing)

Substitute

"text".

(4) Fifth Schedule—

Add

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

Medicine containing a poison included in the Third Schedule

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

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

68. Eighth Schedule amended

(1) Eighth Schedule—

(a) Form 1;

(b) Form 2;

(c) Form 3;

(d) Form 4;

(e) Form 5;

(f) Form 5A;

(g) Form 6;

(h) Form 7;

(i) Form 8;

(j) Form 9;

(k) Form 10;

(l) Form 12;

(m) Form 13;

(n) Form 14;

(o) Form 15;

(p) Form 16—

Repeal the Forms.

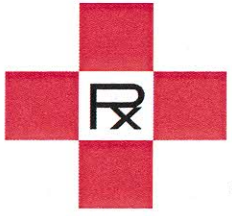
(2) Eighth Schedule—

Repeal Form 17

Substitute

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

Form of Logo Prescribed for Section 13A



".

69. Ninth Schedule amended (fees)

(1) Ninth Schedule—

Repeal

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

Substitute

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

(2) Ninth Schedule, item 5—

Repeal

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

Substitute

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

(3) Ninth Schedule, item 9—

Repeal

"licence for wholesale dealers in poisons"

Substitute

"wholesale dealer licence".

(4) Ninth Schedule, after item 10—

Add

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

(5) Ninth Schedule—

Repeal item 20.

70. Schedule 10 added

After the Ninth Schedule—

Add

"Schedule 10 [reg. 2A]

Poisons List

1. Interpretation

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

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

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

(2) In the Poisons List—

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

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

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

(ii) similar pharmaceutical activity;

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

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

(3) In the Poisons List—

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

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

2. Poisons List

The Poisons List is set out in the Table.

Table

Part I

Division A

Abacavir; its salts

Abatacept

Abciximab

Abiraterone; its salts

Acamprosate; its salts

Acarbose; its salts

Acebutolol; its salts

Acemetacin; its salts

Acetanilide; alkyl acetanilides

Acetazolamide; its salts

Acetohexamide

Acetorphine; its salts; its esters and ethers; their salts

Acetylcarbromal

Acetyldihydrocodeine; its salts

Aciclovir; its salts

Acipimox; its salts

Acitretin; its salts; its esters

Adalimumab

Adapalene; its salts; its esters

Adefovir; its salts; its esters; their salts

Aflibercept

Agalsidase beta

Agomelatine; its salts

Alclofenac; its complexes

Alcuronium; its salts

Aldesleukin

Alefacept

Alemtuzumab

Alendronic acid; its salts

Alfuzosin; its salts

Alglucosidase alfa

Aliskiren; its salts; its esters; their salts

Alizapride; its salts

Alkaloids, the following; their quaternary compounds; any

salt, simple or complex, of any substance falling within the following—

Aconite, alkaloids of

Atropine

Belladonna, alkaloids of

Brucine

Calabar bean, alkaloids of

Coca, alkaloids of

Cocaine

Codeine; its esters and ethers

Colchicum, alkaloids of; their salts

Coniine

Cotarnine

Curare, alkaloids of; curare bases

Ecgonine; its esters and ethers

Emetine

Ephedra, alkaloids of

Ergot, alkaloids of

Galantamine

Gelsemium, alkaloids of

Homatropine

Hyoscine

Hyoscyamine

Lobelia, alkaloids of

Morphine; its esters and ethers

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

Nux Vomica, alkaloids of

Papaverine

Pilocarpus, alkaloids of

Pomegranate, alkaloids of

Quebracho, alkaloids of

Rauwolfia, alkaloids of; their derivatives

Sabadilla, alkaloids of

Stavesacre, alkaloids of

Strychnine

Thebaine

Veratrum, alkaloids of

Vinca, alkaloids of

Yohimba, alkaloids of

Allergen extract of Dermatophagoides pteronyssinus

Allopurinol

Allylisopropylacetylurea

Allylprodine; its salts

Almitrine; its salts

Alphadolone; its esters

Alphaxalone

Alprenolol; its salts

Alteplase

Alufibrate

Amantadine; its salts

Amidopyrine; its salts

Amifostine; its salts

Amiloride; its salts

Amineptine; its salts

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

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

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

Aminoglutethimide

Aminophylline; its salts

Aminopterin; its derivatives

Aminorex; its salts

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

Amiodarone; its salts

Amisulpride; its salts

Amitriptyline; its salts

Amlodipine; its salts

Amrinone

Amsacrine; its salts

Amyl nitrite

Amylene hydrate

Anagrelide; its salts

Anastrozole; its salts

Androgenic, oestrogenic and progestational substances, the following—

Benzoestrol

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

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

Anidulafungin; its salts; its esters; their salts

Anileridine; its salts

Anistreplase

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

Acrivastine

Antazoline

Astemizole

Azelastine

Bromodiphenhydramine

Buclizine

Chlorcyclizine

Cyclizine

Desloratadine

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

Dimethothiazine

Diphenhydramine

Doxylamine

Ebastine

Fexofenadine

Isothipendyl

Ketotifen

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

Mebhydrolin

Meclozine

Methdilazine

Phenindamine

Promethazine

Terfenadine

Thenalidine

Trimeprazine

Tripelennamine

Substances being tetra-substituted N derivatives of

ethylene-diamine or propylenediamine

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

Antilymphocyte Immunoglobulins

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

Antisera, antitoxins, immunoglobulins and vaccines—

(a) the following—

Bacillus Calmette-Guérin (BCG)

Meningococcal vaccines

Normal immunoglobulins

Pneumococcal vaccines

Rotavirus vaccines

Snake venom antisera

Staphylococcal vaccines

Streptococcal vaccines;

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

Bordetella species

Botulism

Canine infectious disease

Cholera

Diphtheria

Feline calicivirus

Feline Chlamydia psittaci

Feline immunodeficiency virus

Feline leukemia virus

Feline panleukopenia virus

Feline rhinotracheitis virus

Haemophilus influenzae type b

Hepatitis A

Hepatitis B

Herpes simplex

Herpes zoster

Human papillomavirus

Influenza

Japanese encephalitis

Measles

Mumps

Pertussis

Plague

Poliomyelitis

Rabies

Rubella

Tetanus

Typhoid

Varicella

Yellow fever

Antithymocyte Immunoglobulin

Apixaban; its salts

Apomorphine; its salts; its quaternary compounds

Apraclonidine; its salts

Aprepitant; its salts

Aprindine; its salts

Aripiprazole

Arsenic trioxide when contained in pharmaceutical products

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

Artemether; its salts

Articaine; its salts

Asenapine; its salts; its isomers

Atazanavir; its salts

Atenolol; its salts

Atomoxetine; its salts

Atorvastatin; its salts

Atosiban; its salts

Atovaquone

Atracurium besylate

Auranofin

Axitinib; its salts

Azacitidine; its salts

Azacyclonol; its salts

Azapropazone

Azauridine; its derivatives

Azilsartan; its salts; its esters; their salts

Aziridine; its derivatives

Baclofen

Bambuterol; its salts

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

Basiliximab; its salts

Becaplermin; its salts

Befunolol; its salts

Belimumab

Bemiparin; its salts

Benactyzine; its salts

Benazepril; its salts

Benoxaprofen; its salts

Benserazide; its salts

Benzbromarone

Benzethidine; its salts

Benzhexol; its salts

Benzoylmorphine; its salts

Benzquinamide

Benztropine and its homologues; their salts

Benzydamine; its salts

Benzylmorphine; its salts

Besifloxacin; its salts; its esters; their salts

Betaxolol; its salts

Bethanidine; its salts

Bevacizumab

Bezafibrate

Bezitramide; its salts

Bicalutamide; its salts

Bifonazole; its salts

Biperiden; its salts

Biphenylacetic acid; its salts; its esters

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

Bisoprolol; its salts

Bitolterol; its salts

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

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

Boceprevir; its salts

Bortezomib

Bosentan; its salts

Botulinum toxin complexes

Bretylium tosylate

Brimonidine; its salts

Brinzolamide; its salts

Bromocriptine; its salts

Bromvaletone

Broncho-Vaxom

Brotizolam

Bucolome

Bufexamac

Buformin; its salts

Bumadizone; its salts

Bumetanide; its salts; its derivatives; their salts

Bupivacaine; its salts

Bupranolol; its salts

Buprenorphine; its salts

Bupropion; its salts

Buserelin; its salts

Buspirone; its salts

Busulphan; its salts

Butorphanol; its salts

Butylchloral hydrate

Cabazitaxel; its salts; its esters; their salts

Cabergoline; its salts

Calcipotriol; its salts

Canakinumab

Candesartan; its salts; its esters; their salts

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

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

Cantharidin; cantharidates

Capecitabine; its salts

Captodiamine; its salts

Captopril

Caramiphen; its salts

Carbachol

Carbamazepine

Carbidopa; its salts

Carbimazole; its salts

Carboplatin

Carbromal

Carbutamide

Carisoprodol

Carmustine

Carperidine; its salts

Carprofen; its salts

Carteolol; its salts

Carvedilol; its salts

Caspofungin; its salts

Celecoxib; its salts

Celiprolol; its salts

Cerivastatin; its salts

Certolizumab pegol

Cetrorelix; its salts; its esters; their salts

Cetuximab

Chlofenamic acid; its salts

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

Chlordiazepoxide; its salts

Chlormethiazole; its salts

Chlormezanone

Chloroform

Chloroquine; its salts; its derivatives; their salts

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

Chlorphenoxamine; its salts

Chlorphentermine; its salts

Chlorpropamide; its salts

Chlorprothixene and other derivatives of 9-methylenethiaxanthen; their salts

Chlorthalidone and other derivatives of ortho-chlorobenzenesulphonamide

Chlorzoxazone

Chorionic Gonadotrophin

Chymopapain

Cicletanine; its salts

Cidofovir; its salts

Cilazapril; its salts

Cilostazol; its salts

Cinacalcet; its salts

Cinepazide; its salts

Ciprofibrate; its salts

Ciprofloxacin; its salts; its esters

Cisapride

Cisatracurium besylate

Cisplatin

Citalopram; its salts

Cladribine

Clioquinol

Clobazam

Clodronic acid; its salts; its esters

Clofarabine; its salts; its esters; their salts

Clofazimine; its salts

Clofibrate

Clomiphene; its salts

Clomipramine; its salts; its derivatives; their salts

Clonidine; its salts

Clonitazene; its salts

Clopidogrel; its salts

Clorexolone

Cloridarol

Clorprenaline; its salts

Clothiapine

Clotrimazole; its salts

Clozapine; its salts

Colaspase

Colfosceril; its salts

Collagen, purified

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

Acetrizoic acid

Diatrizoic acid

Ferucarbotran

Gadobenic acid

Gadobutrol

Gadodiamide

Gadopentetic acid

Gadoteric acid

Iobitridol

Iocarmic acid

Iocetamic acid

Iodamide

Iodipamide

Iodised oil

Iodixanol

Iodoxamic acid

Ioglicic acid

Ioglycamic acid

Iohexol

Iomeprol

Iopamidol

Iopanoic acid

Iophendylate

Iopromide

Iothalamic acid

Iotrolan

Iotroxic acid

Ioversol

Ioxaglic acid

Ioxitalamic acid

Ipodic acid

Metrizamide

Propyliodone

Sulphur hexafluoride

Tyropanoic acid

Corifollitropin alfa

Corticorelin; its salts

Corticotrophins

Corynebacterium parvum

Creosote obtained from wood

Crizotinib; its salts

Croton, oil of

4-Cyano-2-dimethylamino-4,4-diphenylbutane; its salts

4-Cyano-1-methyl-4-phenylpiperidine; its salts

Cyclarbamate

Cyclobenzaprine; its salts

Cyclofenil

1-Cyclohexyl-3-para-toluenesulphonylurea (tolcyclamide)

Cyclosporin A

Cycrimine; its salts

Cytarabine; its salts

Dabigatran etexilate; its salts

Dacarbazine

Daclizumab

Dalteparin; its salts

Dapoxetine; its salts

Dapsone

Darbepoetin alfa

Darifenacin; its salts

Darunavir; its salts

Dasatinib; its salts

Deanol acetamidobenzoate

Debrisoquine; its salts

Deferasirox; its salts; its esters; their salts

Deferiprone; its salts

Degarelix; its salts

Dehydroemetine; its salts

Demecarium bromide

Denosumab

Desferrioxamine; its salts

Desipramine; its salts

Desomorphine; its salts; its esters and ethers; their salts

Desvenlafaxine; its salts

Dexketoprofen; its salts

Dexlansoprazole; its salts

Dexmedetomidine; its salts

Dexrazoxane; its salts

Diacerein; its salts; its esters

Diacetylnalorphine; its salts

Diampromide; its salts

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

Diazoxide

Diclofenac; its salts

Didanosine; its salts

Diethylaminoethylephedrine; its salts

Diethyl para-nitrophenyl phosphate

Difenoxin; its salts

Diflunisal

Digitalis, glycosides of; other active principles of digitalis

Dihydralazine; its salts

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

Dihydrocodeinone; its salts

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

Dihydrocodeinone enol acetate; its salts

Dihydroergotamine; its salts, simple or complex

Dihydroetorphine; its salts

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

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

Diltiazem; its salts

Dimefline; its salts

Dimenoxadole; its salts

Dimepheptanol; its salts; its esters and ethers; their salts

Dioxaphetyl butyrate; its salts

Diperodon; its salts

Diphenoxylate; its salts

Dipipanone; its salts

Diprenorphine; its salts

Dipyridamole

Disopyramide; its salts

Distigmine; its salts

Disulfiram

Dithienylallylamines; dithienylalkylallylamines; their salts

Dobutamine; its salts

Docetaxel; its salts

Domperidone; its salts

Donepezil; its salts

Dopamine; its salts

Dornase alfa

Dorzolamide; its salts

Dothiepin; its salts

Doxapram; its salts

Doxazosin; its salts

Doxepin; its salts; its derivatives; their salts

Dronedarone; its salts

Droperidol

Drotrecogin alfa

Duloxetine; its salts

Dutasteride

Dyflos

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

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

Etomidate; its salts

Etonitazene; its salts

Etoposide; its esters

Etoricoxib; its salts

Etorphine; its salts; its esters and ethers; their salts

Etoxeridine; its salts

Etravirine

Etretinate

Etryptamine; its salts

Everolimus; its salts; its esters; their salts

Exemestane; its salts

Exenatide

Ezetimibe

Famciclovir; its salts

Fampridine; its salts

Febuxostat; its salts; its esters; their salts

Felodipine

Fenbufen

Fencamfamin; its salts

Fenclofenac; its salts

Fendiline; its salts

Fenfluramine; its salts

Fenofibrate

Fenoprofen; its salts

Fenoterol; its salts

Fenoxazoline; its salts

Fentanyl; its salts

Fentiazac; its salts

Fenticonazole; its salts

Feprazone

Fesoterodine; its salts; its esters; their salts

Filgrastim

Finasteride

Fingolimod; its salts; its esters; their salts

Flavoxate; its salts

Flecainide; its salts

Fleroxacin; its salts; its esters

Fluanisone

Fluconazole; its salts

Flucytosine

Fludarabine; its salts

Flufenamic acid; its salts; its esters; their salts

Flumazenil

Flumethrin; its salts

Fluorouracil; its derivatives

Fluoxetine; its salts

Flupenthixol; its salts

Flurbiprofen

Fluspirilene
Flutamide
Fluvastatin
Fluvoxamine; its salts
Folinic acid; its salts
Fondaparinux; its salts
Formestane
Formoterol; its salts
Fosaprepitant; its salts
Foscarnet trisodium hexahydrate
Fosinopril; its salts
Fosphenytoin; its salts
Fotemustine; its salts
Frusemide
Fulvestrant
Furethidine; its salts
Gabapentin; its salts
Gadoxetic acid; its salts
Gallamine; its salts; its quaternary compounds
Gallopamil; its salts
Galsulfase
Ganciclovir; its salts
Ganirelix; its salts
Gatifloxacin; its salts; its esters

Gefitinib; its salts
Gemcitabine; its salts
Gemfibrozil
Gimeracil; its salts
Glibenclamide
Glibornuride
Gliclazide
Glimepiride; its salts
Glipizide
Gliquidone
Glucagon; its salts
Glutethimide; its salts
Glyceryl trinitrate
Glycopyrronium; its salts
Glymidine
Golimumab
Gonadorelin; its salts
Goserelin; its salts
Granisetron; its salts
Grepafloxacin; its salts; its esters
Guanabenz; its salts
Guanethidine; its salts
Guanfacine; its salts
Guanidines, the following—
Polymethylene diguanidines; di-para-anisyl-para-

phenethylguanidine; their salts

Halofantrine; its salts

Halofuginone; its salts

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

Hexamethylmelamine

Hexapropymate

Hexobendine; its salts

Hydralazine; its salts

Hydrazines, the following and their alpha-methyl derivatives—

Benzyl hydrazine

Phenethyl hydrazine

Phenoxyethyl hydrazine

their salts; their acyl derivatives; their salts

Hydrocyanic acid; cyanides, other than ferrocyanides and ferricyanides

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

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

Hydroxycinchoninic acids; derivatives of; their salts; their esters

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

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

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

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

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

Hydroxyphenamate

Hydroxyurea

Hydroxyzine; its salts

Ibandronic acid; its salts

Ibritumomab tiuxetan

Ibuprofen; its salts

Idursulfase

Ifosfamide

Iloprost; its salts

Imatinib; its salts

Imidapril; its salts

Imiglucerase

Imipramine; its salts

Imiquimod; its salts

Indacaterol; its salts; its esters; their salts

Indinavir; its salts

Indomethacin; its salts

Indoprofen; its salts

Indoramin; its salts

Infliximab

Inosine

Inosine pranobex

Insulin

Interferons

Iprindole; its salts

Irbesartan; its salts

Irinotecan; its salts

Isoaminile; its salts

Isoconazole; its salts

Isoetharine; its salts

Isomethadone; its salts

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

Isoprenaline; its salts

Isopyrin; its salts

Isosorbide; its nitrates

Isotretinoin

Isoxicam; its salts

Isradipine

Itraconazole; its salts

Ivabradine; its salts

Ketamine; its salts

Ketanserin; its salts

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

Ketoconazole

Ketophenylbutazone

Ketoprofen; its salts

Ketorolac; its salts; its esters

Labetalol; its salts

Lacidipine; its salts

Lacosamide; its salts

Lamivudine; its salts

Lamotrigine; its salts

Lanreotide; its salts

Lansoprazole

Lanthanum carbonate

Lapatinib; its salts

Laronidase

Laropiprant; its salts

Laudexium; its salts

Lead acetates; compounds of lead with acids from fixed oils

Leflunomide; its salts

Lenalidomide; its salts

Lepirudin; its salts

Lercanidipine; its salts

Letrozole

Leuprorelin; its salts

Levallorphan; its salts

Levetiracetam; its salts

Levodropropizine; its salts

Levosimendan; its salts

Lidoflazine

Lignocaine; its salts

Linagliptin; its salts

Linezolid; its salts

Liraglutide

Lisinopril; its salts

Lithium carbonate

Lithium sulphate

Lodoxamide tromethamine

Lomefloxacin; its salts; its esters

Lomustine

Lonazolac; its salts

Lopinavir; its salts

Loracarbef; its salts

Lorcainide; its salts

Losartan; its salts

Lovastatin

Loxapine; its salts

Lumefantrine; its salts

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

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

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

Lysuride; its salts

Mangafodipir; its salts

Mannityl hexanitrate

Mannomustine; its salts

Maprotiline; its salts

Maraviroc; its salts

Marbofloxacin; its salts

Mazindol

Mebezonium iodide

Mebutamate

Mecamylamine; its salts

Meclofenamic acid; its salts

Meclofenoxate; its salts

Medigoxin

Mefenamic acid; its salts; its esters; their salts

Mefloquine; its salts

Mefruside

Melagatran; its salts; its derivatives; their salts

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

Melitracen; its salts

Meloxicam; its salts

Memantine; its salts

Mephenesin; its esters; their salts

Mephenoxalone

Mepirizole; its salts

Mepivacaine; its salts

Meprobamate

alpha-Meprodine; its salts

beta-Meprodine; its salts

Mercaptopurine; its salts; its derivatives; their salts

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

Meropenem; its salts

Mertiatide; its salts; its esters; their salts

Mesalazine; its salts

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

Mesocarb; its salts

Metaflumizone; its salts

Metaraminol; its salts

Metaxalone

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

Metergoline

Metformin; its salts

Methadone; its salts

Methadyl acetate; its salts

Methaqualone; its salts

Methimazole; its salts

Methixene; its salts

Methocarbamol

Methorphan; its salts; its optical isomers; their salts

Methoxsalen

Methoxyphenamine; its salts

Methylaminoheptane; its salts

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

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

Methyldopa; its esters; their salts

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

Methylnaltrexone; its salts

Methylpentynol; its derivatives

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

Methylphenidate; its salts

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

Methyprylone

Metipranolol; its salts

Metoclopramide; its salts

Metolazone

Metopon; its salts; its esters and ethers; their salts

Metoprolol; its salts

Metronidazole; its salts

Metyrapone; its salts

Mexiletine; its salts

Mianserin; its salts

Mibefradil; its salts

Micafungin; its salts; its esters

Miconazole; its salts

Midodrine; its salts

Miglitol; its salts

Milnacipran; its salts

Milrinone; its salts

Minoxidil

Mirabegron; its salts; its esters; their salts

Mirtazapine; its salts

Mitobronitol

Mitopodozide; its salts

Mitotane

Mitoxantrone; its salts

Mivacurium; its salts

Mizolastine; its salts

Moclobemide; its salts

Moexipril; its salts

Mofebutazone; its salts

Molgramostim

Molindone; its salts

Montelukast; its salts

Moracizine; its salts

Moramide; its salts; its optical isomers; their salts

Moroxydine; its salts

Morpheridine; its salts

Moxifloxacin; its salts

Moxonidine; its salts

Muromonab-CD3

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

Muzolimine

Mycophenolic acid; its salts; its esters

Myrophine; its salts

Myrtecaine; its salts

Nabumetone

Nadolol; its salts

Nadroparin; its salts

Nafarelin; its salts

Naftidrofuryl; its salts

Nalbuphine; its salts

Nalidixic acid

Nalorphine; its salts

Naloxone; its salts

Naltrexone; its salts

alpha-Naphthylacetic acid; its salts

Naproxen; its salts

Naratriptan; its salts

Natalizumab

Nateglinide; its salts; its esters

Nebivolol; its salts

Nedocromil; its salts

Nefazodone; its salts

Nefopam; its salts

Nelfinavir; its salts

Neostigmine; its salts

Nepafenac; its salts

Nesiritide

Nevirapine; its salts

Nicergoline

Niclofolan

Nicocodine; its salts

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

Nifedipine

Nifenazone

Niflumic acid; its salts

Nilotinib; its salts

Nilvadipine

Nimesulide; its salts

Nimodipine

Nisoldipine

Nitrendipine

Nitromethaqualone; its salts

Nomifensine; its salts

Noracymethadol; its salts

Noramidopyrine methanesulphonate; its salts

Norcodeine; its salts; its esters and ethers; their salts

Norfloxacin; its salts; its esters

Normethadone; its salts

Normorphine; its salts; its esters and ethers; their salts

Norpipanone; its salts

Nortriptyline; its salts

Octreotide; its salts

Ofloxacin; its salts; its esters

Olanzapine; its salts

Olmesartan; its salts; its esters; their salts

Olsalazine; its salts

Omalizumab
Omeprazole; its salts
Omoconazole; its salts
Ondansetron; its salts
Opipramol; its salts; its derivatives; their salts
Opium
Orciprenaline; its salts
Orgotein
Orlistat; its salts
Orphenadrine; its salts
Orthocaine; its salts
Oseltamivir; its salts
Oteracil; its salts
Ouabain
Oxalic acid; its salts other than quadroxalates
Oxaliplatin; its salts
Oxanamide
Oxcarbazepine; its salts
Oxethazaine; its salts
Oxiconazole; its salts
Oxolamine; its salts
Oxprenolol; its salts
Oxycinchoninic acid; its derivatives; their salts; their esters
Oxycodone; its salts; its esters and ethers; their salts

Oxyfedrine; its salts
Oxymorphone; its salts; its esters and ethers; their salts
Oxypertine
Oxyphenbutazone
Oxytocins
Paclitaxel
Paliperidone; its salts
Palivizumab
Palonosetron; its salts
Pamidronate; its salts
Pancuronium; its salts
Panitumumab
Pantethine; its salts
Pantoprazole; its salts
Paraldehyde
Paramethadione
Parecoxib; its salts
Pargyline; its salts
Paricalcitol; its salts; its esters; their salts
Paroxetine; its salts
Pasireotide; its salts
Pazopanib; its salts
Pefloxacin; its salts; its esters
Pegaptanib; its salts

Pegfilgrastim

Pegvisomant; its salts

Pemetrexed; its salts; its esters; their salts

Pemirolast; its salts

Pemoline; its salts

Pempidine; its salts

Penbutolol; its salts

Penciclovir; its salts

Penicillamine; its salts

Pentaerythritol tetranitrate

Pentamidine; its salts

Pentazocine; its salts

Pentolinium; its salts

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

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

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

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

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

Phenoxybenzamine; its salts

Phenprenazone

Phenprobamate

Phentolamine; its salts

Phenylbutazone; its salts

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

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

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

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

Picric acid

Picrotoxin

Pimecrolimus

Piminodine; its salts

Pioglitazone; its salts

Pipecuronium; its salts

Pipemidic acid

Pipobroman

Piritramide; its salts

Piromidic acid; its salts

Piroxicam

Pirprofen; its salts

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

Pizotifen; its salts

Plerixafor; its salts

Podophyllum resin

Polymethylenebistrimethylammonium salts

Poractant alfa

Posaconazole; its salts; its esters; their salts

Pralidoxime; its salts

Pramipexole; its salts

Pramoxine; its salts

Prasugrel; its salts

Pravastatin; its salts; its esters

Prazosin; its salts

Pregabalin; its salts

Pridinol; its salts

Primaquine; its salts

Primidone

Prindolol; its salts

Probucol

Procainamide; its salts

Procarbazine; its salts

Procaterol; its salts

Procyclidine; its salts

alpha-Prodine; its salts

beta-Prodine; its salts

Proglumetacin; its salts

Proguanil; its salts

Proheptazine; its salts

Promoxolane

Propafenone; its salts

Propanidid

Propiverine; its salts

Propofol

Propoxur; its salts

Propoxyphene; its salts; its optical isomers; their salts

Propranolol; its salts; its derivatives; their salts

Propylhexedrine; its salts

Propylthiouracil; its salts

Proquazone

Prostaglandins, the following and their derivatives—

Alprostadil

Bimatoprost

Dinoprost

Dinoprostone

Latanoprost

Misoprostol

Travoprost

Unoprostone

their salts; their esters

Prothionamide

Prothipendyl; its salts

Protirelin; its salts

Protriptyline; its salts; its derivatives; their salts

Prucalopride; its salts

Prulifloxacin; its salts; its esters; their salts

Pseudoephedrine; its salts

Pyrazinamide

Pyricarbate (Pyridinolcarbamate)

Pyridostigmine; its salts

Pyrimethamine

Pyrithyldione

Quetiapine; its salts

Quinagolide; its salts

Quinapril; its salts

Quinethazone

Quinidine; its salts

Quinine; its salts; its derivatives; their salts

Rabeprazole; its salts

Racecadotril; its salts

Ractopamine; its salts

Raloxifene; its salts

Raltegravir; its salts

Raltitrexed; its salts

Ramipril; its salts

Ranibizumab

Rasagiline; its salts

Rasburicase; its salts

Reboxetine; its salts

Recombinant human erythropoietin

Remifentanil; its salts

Remoxipride; its salts

Repaglinide; its salts; its esters

Reproterol; its salts

Rescinnamine

Reteplase

Retigabine; its salts

Reviparin; its salts

Ribavirin; its salts

Rilmenidine; its salts

Rilpivirine; its salts

Riluzole; its salts

Rimiterol; its salts

Rimonabant; its salts

Risedronic acid; its salts

Risperidone

Ritodrine; its salts

Ritonavir; its salts

Rituximab

Rivaroxaban; its salts

Rivastigmine; its salts

Rizatriptan; its salts

Rocuronium; its salts

Rofecoxib; its salts

Roflumilast; its salts

Romiplostim

Ropinirole; its salts

Ropivacaine; its salts

Rosiglitazone; its salts

Rosoxacin; its salts

Rosuvastatin; its salts

Rotigotine; its salts

Ruxolitinib; its salts

Salbutamol; its salts

Salmeterol; its salts

Saquinavir; its salts

Savin, oil of

Saxagliptin; its salts

Sermorelin; its salts

Sertaconazole; its salts

Sertindole; its salts

Sertraline; its salts

Sevelamer; its salts

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

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

Simvastatin

Sirolimus; its salts

Sitagliptin; its salts

Sodium aurothiomalate

Sodium cromoglycate

Sodium nitroprusside

Solifenacin; its salts; its esters; their salts

Somatostatin

Sorafenib; its salts

Sotalol; its salts

Sparfloxacin; its salts; its esters

Sparteine; its salts

Spinosad

Spironolactone

Stavudine; its salts

Streptokinase

Strontium ranelate

Strophanthus, glycosides of

Styramate

Sulconazole; its salts

Sulindac

Sulphinpyrazone

Sulphonal; alkyl sulphonals

Sulpiride

Sultopride

Sumatriptan; its salts

Sunitinib; its salts

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

Sutoprofen; its salts

Suxamethonium; its salts

Syrosingopine

Tacrine; its salts

Tacrolimus

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

Tafluprost

Tamoxifen; its salts

Tazarotene; its salts

Tegaserod; its salts

Telbivudine; its salts

Telmisartan; its salts

Temozolomide; its salts

Temsirolimus; its salts; its esters

Tenecteplase; its salts

Teniposide

Tenofovir; its salts; its esters; their salts

Tenoxicam

Terazosin; its salts

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

Terbutaline; its salts

Terconazole; its salts

Teriparatide; its salts

Terodiline; its salts

Tertatolol; its salts

Tetrabenazine; its salts

Tetracosactide; its salts

Thalidomide; its salts

Thallium, salts of

Theofibrate

Theophylline; its salts

Thiacetazone

Thiocarlide; its salts

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

Thiotepa

Thymosin alpha 1

Thyroid gland, the active principles of; their salts

Thyrotropin alfa

Tiagabine; its salts; its esters; their salts

Tianeptine; its salts; its esters; their salts

Tiapride; its salts

Ticagrelor; its salts; its esters; their salts

Ticlopidine; its salts

Tiletamine; its salts

Tilidate; its salts

Tiludronic acid; its salts

Timolol; its salts

Tinidazole; its salts

Tinoridine; its salts

Tinzaparin; its salts

Tioconazole; its salts

Tiotropium; its salts

Tiratricol; its salts

Tirofiban; its salts

Tizanidine; its salts

Tocainide; its salts

Tocilizumab

Todralazine; its salts

Tofenacin; its salts

Tolazamide

Tolbutamide

Tolcapone; its salts

Tolfenamic acid; its salts

Tolmetin; its salts

Tolperisone; its salts

Tolterodine; its salts

Tolvaptan

para-Tolylmethylcarbinol nicotinic acid ester

Topiramate; its salts

Topotecan; its salts

Torasemide

Trabectedin; its salts; its esters

Tramadol; its salts

Trandolapril; its salts

Tranexamic acid

Tranylcypromine; its salts

Trastuzumab

Trazodone; its salts

Tretamine; its salts

Tretinoin

Tretoquinol; its salts

Triamterene; its salts

Triaziquone

Tribromoethyl alcohol

2,2,2-Trichloroethyl alcohol, esters of; their salts

Trifluridine; its salts

Trilostane

Trimeperidine; its salts

Trimetaphan; its salts

Trimetazidine; its salts

Trimethadione

Trimethoprim

Trimetozine

Trimetrexate; its salts

Trimipramine; its salts

Trioxsalen

Triptorelin; its salts

Tromantadine; its salts

Tropisetron; its salts

Trovafloxacin; its salts; its derivatives; their salts

Tulobuterol; its salts

Tybamate

Urapidil; its salts

Urethane

Urokinase

Ustekinumab

Valaciclovir; its salts

Valdecoxib; its salts

Valganciclovir; its salts

Valnoctamide

Valproic acid; its salts; its esters

Valsartan; its salts

Vandetanib; its salts

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

Varenicline; its salts

Vasopressins

Vecuronium; its salts

Vemurafenib; its salts

Venlafaxine; its salts

Veralipride; its salts

Verapamil; its salts

Vernakalant; its salts

Verteporfin; its salts

Vidarabine; its salts

Vigabatrin

Vildagliptin; its salts

Viloxazine; its salts

Vindesine; its salts

Vinorelbine; its salts

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

Voriconazole; its salts

Warfarin; its salts

Xamoterol; its salts

Xylazine; its salts

Zafirlukast

Zalcitabine; its salts

Zaleplon; its salts

Zanamivir; its salts

Zidovudine

Zimelidine; its salts

Zipeprol; its salts

Ziprasidone; its salts

Zolazepam; its salts

Zoledronic acid; its salts

Zolmitriptan; its salts

Zolpidem; its salts

Zomepirac; its salts

Zopiclone

Zoxazolamine; its salts

Division B

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

Barium, salts of, except barium sulphate

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

Dinitronaphthols; dinitrophenols; dinitrothymols

Hexachlorophane, the following—

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

(b) preparations for animal use—

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

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

(iii) other medicinal products (except those for oral administration to sheep or cattle for liver fluke disease) containing more than 0.75%

hexachlorophane

meta-Nitrophenol; ortho-nitrophenol; para-nitrophenol

Phosmet

Phosphorus, yellow

Sulphuric acid, except substances containing not more than 70%, weight in weight, of sulphuric acid

Part II

Division A

Antihistamine substances not included in Part I of this List; their salts; their compounds with any other substance

Benzocaine when contained in condoms

alpha-Chloralose

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

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

Pharmaceutical products retailed in the form as supplied by the manufacturer, containing a poison included in Division A of Part I of this List, where the proportion of the poison does not exceed the equivalent of—

(a) 0.01% by weight of arsenic trioxide, cantharidin, cocaine, coniine, ecgonine, hydrocyanic acid, strychnine, alkaloids of aconite, alkaloids of coca or alkaloids of gelsemium;

(b) 2%, weight in volume, of mercurochrome when

contained in solutions for external use only; and

(c) 0.1% by weight in the case of other poisons,

except pharmaceutical products containing any poison—

(d) included in the Third Schedule; or

(e) in the following list—

Acetyldihydrocodeine; its salts

Alkaloids of belladonna; their salts

Alkaloids of ephedra; their salts

Atropine; its salts

Bambuterol; its salts

Benzydamine; its salts

Butropium; its salts

Codeine; its salts

Dextromethorphan; its salts

Diclofenac; its salts

Dihydrocodeine; its salts

Ethylmorphine; its salts

Fenoterol; its salts

Formoterol; its salts

Homatropine; its salts

Hyoscine; its salts

Hyoscyamine; its salts

Ipratropium; its salts

Methylaminoheptane; its salts

Morphine; its salts

Nicocodine; its salts

Norcodeine; its salts

Orciprenaline; its salts

Papaverine; its salts

Phenylpropanolamine; its salts

Pholcodine; its salts

Procaterol; its salts

Salmeterol; its salts

Terbutaline; its salts

Tretoquinol; its salts

Phenols as defined in Part I of this List in substances containing less than 60%, weight in weight, of phenols; compounds of phenol with a metal in substances containing less than the equivalent of 60%, weight in weight, of phenols

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

Division B

Ammonia

gamma-Benzene hexachloride (1,2,3,4,5,6-hexachlorocyclohexane)

Diamines, the following; their salts—

Phenylene diamines; toluene diamines; other alkylated-benzene diamines

Formaldehyde

Formic acid

Hydrochloric acid

Hydrofluoric acid; alkali fluorides; alkali metal bifluorides; ammonium bifluorides; sodium silicofluoride

Metallic oxalates

Nitric acid

Nitrobenzene

Phosphoric acid

Potassium hydroxide

Products retailed in the form as supplied by the manufacturer, containing a poison included in Division B of Part I of this List, where the proportion of such poison does not exceed the equivalent of 0.1%

Sodium hydroxide

Sodium nitrite".

Part 4

Repeal of Poisons List Regulations

71. Poisons List Regulations repealed

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

Part 5

Amendments Relating to Headings of Provisions

72. Amendments relating to headings of provisions

(1) The amendments relating to headings of provisions as specified in the Schedule have effect.

(2) The enactments specified in the Schedule are amended as set out in the Schedule.

Schedule

[s. 72]

Amendments Relating to Headings of Provisions

Part 1

Pharmacy and Poisons Ordinance (Cap. 138)

1. Part 1 heading added

Before section 1—

Add

"Part 1

Preliminary".

2. Part 2 heading added

Before section 3—

Add

"Part 2

Pharmacy and Poisons Board".

3. Part 3 heading added

Before section 5—

Add

"Part 3

Pharmacists: Requirements for Registration and Practising Certificate".

4. Part 4 heading added

Before section 11—

Add

"Part 4

Retail Sale of Poisons".

5. Part 5 heading added

Before section 15—

Add

"Part 5

Registered Pharmacists and Authorized Sellers of Poisons: Disciplinary Proceedings and Restriction on Use of Titles".

6. Part 6 heading added

Before section 21—

Add

"Part 6

Sale and Possession of Poisons".

7. Part 7 heading added

Before section 28A—

Add

"Part 7

Import and Export of Pharmaceutical Products".

8. Part 8 heading added

Before section 29—

Add

"Part 8

Miscellaneous".

Part 2

Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A)

9. Part III heading amended (supplementary provisions with respect to labelling and containers)

Part III, heading, after "CONTAINERS"—

Add

"OF POISONS".

10. Regulation 18 heading amended (form of containers)

Regulation 18, heading, after "**containers**"—

Add

"**of poisons**".

11. Part IV heading amended (storage and transport)

Part IV, heading, after "TRANSPORT"—

Add

"OF POISONS".

12. Part VB heading amended (registration of premises)

Part VB, heading, after "PREMISES"—

Add

"OF AUTHORIZED SELLERS OF POISONS".

13. Part VI heading amended (wholesale dealers)

Part VI, heading—

Repeal

"DEALERS"

Substitute

"DEALING IN POISONS AND PHARMACEUTICAL PRODUCTS".

14. Part VII heading amended (manufacturers)

Part VII, heading—

Repeal

"MANUFACTURERS"

Substitute

"MANUFACTURE OF PHARMACEUTICAL PRODUCTS".

Explanatory Memorandum

The main purpose of this Bill is to implement certain recommendations in the Report of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong published by the Food and Health Bureau in December 2009. The Bill also makes related, consequential and miscellaneous amendments to the Pharmacy and Poisons Ordinance (Cap. 138) (***Ordinance***), the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***Regulations***) and the Poisons List Regulations (Cap. 138 sub. leg. B).

2. The major amendments are explained below.

Control over manufacture of pharmaceutical products

3. Clause 4(2) revises the definition of ***manufacture*** in section 2(1) of the Ordinance to expressly cover the packaging and repackaging of pharmaceutical products so that those activities must, subject to the exception provided for in new regulation 29(1A) of the Regulations (clause 50(2)), be carried out by licensed manufacturers.

4. Clause 50(3) repeals regulation 29(2) of the Regulations so that an authorized seller of poisons (***ASP***) is no longer exempt from the requirement for a licence to manufacture pharmaceutical products.

5. Clause 53 amends regulation 31 of the Regulations to require licensed manufacturers to label the containers of pharmaceutical products with 2 additional particulars, namely the batch number and the expiry date of the products.

6. Clause 55 amends regulation 33 of the Regulations to require licensed manufacturers to ensure that the registrable particulars of each batch of pharmaceutical products in a finished form correspond exactly with the registered particulars of the products. It

also revises the period for which the control sample of finished pharmaceutical products is to be kept.

7. Clause 57 amends regulation 35 of the Regulations to state more clearly the time by which licensed manufacturers must complete the records relating to the manufacture, testing and sale or supply, etc. of pharmaceutical products.

8. Clause 63 provides that books or other documents required to be kept by licensed manufacturers under regulation 28 or 35 of the Regulations must be kept in accordance with regulation 39 of the Regulations.

Good Manufacturing Practice Guide

9. Because of the amended section 29(1)(ja) of the Ordinance (clause 23(10)) and the new regulation 28A of the Regulations (clause 49), the Pharmacy and Poisons Board (***Board***) is empowered to issue a Good Manufacturing Practice Guide (***GMP Guide***) providing for the principles and guidelines of good manufacturing practice in respect of pharmaceutical products. Non-compliance with the GMP Guide may lead to disciplinary actions under the Regulations.

Authorized person to ensure and certify compliance with GMP Guide

10. Clause 23(10) and (11) expands section 29 of the Ordinance to empower the making of regulations on persons to be employed or engaged for the manufacture of poisons or pharmaceutical products and on their registration.

11. Clause 52 adds new regulations 30A to 30F to the Regulations. The new regulation 30A requires a licensed manufacturer to employ at least one authorized person to ensure and certify that pharmaceutical products are manufactured and checked in accordance with the GMP Guide. The new regulation 30B requires a register of authorized persons to be kept for the purposes of the Regulations and specifies the particulars to be entered in the register.

12. The new regulations 30C, 30D and 30E respectively provide for the application for registration as authorized persons, the determination of the applications and the renewal of registration of authorized persons. The qualifications required for registration as an authorized person are listed in the new regulation 30C.

13. The new regulation 30F provides the Pharmacy and Poisons (Wholesale Licences) Committee with the disciplinary powers (such as the power to cancel or suspend a registration) in relation to authorized persons.

Control over labelling and storage of medicines and poisons

14. Clause 21 amends section 27 of the Ordinance in the requirement for texts to be displayed on the container of any poison included in Part I or Part II of the Poisons List. It differentiates medicines from other substances that are not medicines and requires different texts to be labelled on their respective containers.

15. Clause 67 amends the Fifth Schedule to the Regulations to prescribe the texts to be labelled on the containers of poisons.

16. The existing regulation 15 of the Regulations requires "Poison 毒藥" and other prescribed texts to be displayed on a separate label and in red lettering, etc. on the container of any poison. Clause 37 amends that regulation to dispense with the requirements.

17. Clause 38 amends regulation 19 of the Regulations to change the scope of control over the storage of poisons from substances included in the First Schedule to the Regulations to all poisons included in Part I of the Poisons List (***Part I poisons***). As a result, all Part I poisons kept at retail shops are required to be stored in locked receptacles placed in an area not accessible to customers.

18. Clauses 39, 40 and 41 amend regulations 22, 23 and 24 of the Regulations respectively. They seek to relax certain requirements about the labelling and storage of medicines and poisons currently

applicable in relation to certain institutions such as hospitals and clinics.

Control of clinical trials and medicinal tests

19. Clause 59 amends regulation 36B of the Regulations to prohibit the conduct of any clinical trial on human beings or medicinal test on animals without a clinical trial certificate or medicinal test certificate respectively. Contravention of the prohibition is an offence. The clause also extends the maximum validity period of any such certificate from 2 years to 5 years. A clinical trial certificate or medicinal test certificate may be cancelled or suspended for a contravention of any condition of the certificate or on the ground of public interest.

20. Also, the clause expressly empowers conditions to be imposed on issuing a clinical trial certificate or medicinal test certificate.

Import and export of pharmaceutical products

21. Clause 22 replaces section 28A of the Ordinance to replace the existing registration system for importers and exporters of pharmaceutical products with a licensing system. A person may import or export pharmaceutical products only if the person is either a licensed wholesale dealer or licensed manufacturer. A person who was registered under the existing registration system is, for the remainder of the term of the registration, to be regarded as a licensed wholesale dealer. Following this change, Part VIIIA of the Regulations which provides for the existing registration requirement is repealed (clause 61).

22. Clause 28 amends section 33(1) of the Ordinance to make any contravention of section 28A of the Ordinance an offence.

Sale and supply of poisons or pharmaceutical products by wholesale dealing

23. The existing regulation 25 of the Regulations controls the sale or supply of poisons by wholesale dealing. Clause 45 amends that regulation to expand the control to cover pharmaceutical products. The licensing and disciplinary powers of the Pharmacy and Poisons (Wholesale Licences) Committee specified in regulation 26 of the Regulations are expanded accordingly (clause 46).

24. Under the amended regulation 26 of the Regulations, a new wholesale dealer licence (covering both poisons and pharmaceutical products) is to replace the existing wholesale poisons licence. A holder of a wholesale poisons licence is, for the remainder of the term of the licence, to be regarded as the holder of a wholesale dealer licence for the purposes of the Ordinance and the Regulations (clause 46).

25. Regulation 27 of the Regulations lists the categories of persons to whom poisons may be sold or supplied by licensed wholesale dealers or licensed manufacturers. Clause 47 amends the regulation to make clear the circumstances in which and the persons to whom the regulation applies.

26. Clause 48 amends regulation 28 of the Regulations to require licensed wholesale dealers or licensed manufacturers to keep records regarding transactions of not only Part I poisons but also pharmaceutical products. It also specifies the additional particulars (such as the batch number and pack size of pharmaceutical products) to be contained in such records.

Registration of pharmaceutical products or substances

27. Clause 58 amends regulation 36 of the Regulations to add to the categories of persons who may register pharmaceutical products or substances with the Board. A new category is any licensed wholesale dealer who has entered into a manufacturing contract with the licensed manufacturer of the pharmaceutical products or substances concerned.

28. Clause 58(8) and (10) exempts from the registration requirement under regulation 36(1) of the Regulations any pharmaceutical products or substances that are possessed or to be used for treatment by certain medical professionals or to be administered for any clinical trial on human beings or medicinal test on animals.

29. Clause 58(15) amends regulation 36(7) of the Regulations to require the production of specified up-to-date information regarding the pharmaceutical product or substance concerned on renewing the registration of the product or substance.

Codes of conduct and codes of practice

30. Clause 6 adds a new section 4B to the Ordinance to empower the Board to issue codes of conduct and codes of practice for providing practical guidance in respect of the Ordinance. Non-compliance with such codes may lead to disciplinary actions under the Ordinance or the Regulations as explained in paragraphs 31 to 40.

Disciplinary powers over registered pharmacists, authorized and listed sellers of poisons, licensed wholesale dealers and licensed manufacturers, etc.

Registered pharmacists and authorized sellers of poisons

31. Clause 14 amends section 15 of the Ordinance mainly to expand the circumstances in which a Disciplinary Committee (***Disciplinary Committee***) may be appointed by the Board to inquire into the conduct of certain persons including registered pharmacists and ASPs. The additional circumstances include contraventions of codes of conduct, codes of practice or certain provisions of the Public Health and Municipal Services Ordinance (Cap. 132) or the Trade Descriptions Ordinance (Cap. 362).

32. Clause 15 amends section 16 of the Ordinance to give the Disciplinary Committee additional powers including the powers to

give a direction to issue warning letters to registered pharmacists, cancel the registration of any premises of an ASP, vary conditions relating to the registration of those premises, and provide when a direction made by it in a disciplinary inquiry is to take effect. The clause also empowers the Disciplinary Committee to suspend some of its directions (such as a direction to cancel the registration of a pharmacist or to disqualify a person from being an ASP).

33. If a direction to disqualify an ASP is made under section 16 of the Ordinance, the ASP is not a fit and proper person to conduct the retail sale of poisons for the purposes of section 13(4)(a) of the Ordinance. Therefore, the premises of the ASP would not be allowed to be registered under section 13 of the Ordinance (clause 13).

Listed sellers of poisons

34. Clause 20 amends section 25 of the Ordinance mainly to expand the disciplinary powers of the Board in relation to listed sellers of poisons (***LSP***). It empowers the Board to give a direction to issue warning letters to any LSP, or vary conditions imposed in respect of any LSP, if the LSP has contravened codes of practice or any such conditions. It also expands the circumstances in which the Board may remove a person from the list of LSP (including contraventions of codes of practice or conditions of being an LSP). Under the amended section 25 of the Ordinance, the Board may suspend its direction to remove a person's status as an LSP.

35. The clause also expressly empowers the Board to impose conditions subject to which a person may enjoy the status as an LSP.

Licensed wholesale dealers

36. Clause 46 amends regulation 26 of the Regulations to provide for the disciplinary powers of the Pharmacy and Poisons (Wholesale Licences) Committee in relation to licensed wholesale dealers. It

empowers the Committee to suspend or revoke a wholesale dealer licence, issue warning letters to a licensed wholesale dealer or vary conditions of a licence in circumstances such as a contravention of codes of practice or conviction of offences under specified Ordinances. The clause also empowers the Committee to suspend its decision to suspend or revoke a wholesale dealer licence.

37. Further, the clause expressly empowers the Committee to impose conditions on issuing a wholesale dealer licence.

Licensed manufacturers

38. Clause 50 amends regulation 29 of the Regulations to expand the circumstances in which a licence to manufacture pharmaceutical products may be suspended or revoked. The circumstances include a contravention of codes of practice or the GMP Guide or a conviction of offences under specified Ordinances. The amendment also provides for the issue of warning letters to licensed manufacturers and the suspension of a decision to suspend or revoke a licence.

39. The clause also expressly empowers the Pharmacy and Poisons (Wholesale Licences) Committee to impose conditions on issuing a licence to manufacture pharmaceutical products.

Deregistration of pharmaceutical products or substances, etc.

40. Clause 58 amends regulation 36 of the Regulations to provide for the deregistration and suspension of the registration of any pharmaceutical product or substance if it is in the public interest to do so or if any condition of the registration is contravened. It also expressly empowers the imposition of conditions on the registration of pharmaceutical products or substances.

Membership of Board and committees, etc.

41. Clause 5 amends section 3(2) of the Ordinance to change the composition of the Board by including the Assistant Director of

Health in the Drug Office of the Department of Health, and removing the Chief Pharmacist of the Department of Health and a registered medical practitioner nominated by the British Medical Association.

42. Clause 8 amends section 8(3)(c) of the Ordinance to change the composition of any committee of examiners established for section 8 of the Ordinance by replacing the reference to the Chief Pharmacist of the Department of Health with the reference to the Assistant Director of Health in the Drug Office of the Department of Health.

Forms

43. Clauses 9, 11, 13, 19 and 23 amend sections 9, 10A, 13, 22 and 29 of the Ordinance respectively as the form of the following documents is no longer prescribed by the Regulations: certificate of registration as a pharmacist, registered pharmacist's practising certificate, application form for registration of premises under section 13 of the Ordinance, certificate of registration issued to an ASP, certificate referred to in section 22(1)(a) of the Ordinance and poisons book.

44. Instead, the form of the documents mentioned in paragraph 43 is to be specified under a new section 29A of the Ordinance (added by clause 24) which empowers the Board to specify the form of certain documents for the purposes of the Ordinance or its subsidiary legislation.

45. Amendments are also made to regulations 24B, 24C, 26(4), 28(4), 29(3), (5) and (6), 36(2) and (5), 36B(3) and 41(1), (2) and (3) of, and the Eighth Schedule to, the Regulations as the form of the documents mentioned in paragraph 46 is no longer prescribed by the Regulations (clauses 43, 44, 46(3), 48(14), 50(4), (6) and (8), 58(11) to (14), 59(4) and (5), 64(2), (3) and (5) and 68).

46. Those documents are: application form for registration of premises under section 13 of the Ordinance, certificate of registration issued to an ASP, wholesale dealer licence, records of transactions of Part I poisons or pharmaceutical products, licence to manufacture pharmaceutical products, certificate for manufacture, interim-certificate for manufacture, free sale certificate of pharmaceutical product, certificate of pharmaceutical product, application form for the initial registration of a pharmaceutical product or substance, certificate of registration of pharmaceutical product or substance, clinical trial certificate, medicinal test certificate, certificate referred to in section 22(1)(a) of the Ordinance, certificate of registration as a pharmacist and poisons book.

47. Clause 62 adds a new regulation 38B to the Regulations to provide for the specification, by an executive committee established under section 4A of the Ordinance, of the form of certain documents for the purposes of the Regulations.

Amendments relating to penalty levels and recovery of enforcement costs and expenses

48. Clause 10 amends section 10(1) of the Ordinance to repeal the penalty level originally specified in the section for the offence of misusing a certificate of registration as a pharmacist. It follows that the general penalty level set out in section 34 of the Ordinance applies to the offence.

49. Clause 16 amends section 16A(3) and (5) of the Ordinance to increase the fine for an offence relating to a Disciplinary Committee's inquiry under section 16 of the Ordinance from $500 to a level 3 fine (currently $10,000).

50. Clause 19(3) amends section 22(4) of the Ordinance to change the reference to the fine for an offence relating to the sale of Part I poisons by an ASP from $5,000 to a level 2 fine (currently $5,000).

51. Clause 29 amends section 34 of the Ordinance to change the reference to the fine for an offence under the Ordinance (other than an offence for which the penalty is expressly specified) from $100,000 to a level 6 fine (currently $100,000).

52. Clause 30 adds a new section 34A to the Ordinance to provide for the recovery from any person convicted of an offence under the Ordinance of the costs and expenses incurred by the Government in collecting, analysing or examining any poison, pharmaceutical product or other substance for the criminal proceedings.

53. Clause 35(2) amends regulation 5(5) of the Regulations to change the reference to the fine for an offence relating to the purchase of Part I poisons by wholesale dealing from $10,000 to a level 3 fine (currently $10,000).

Fees

54. Clause 13(5) and (6) amends section 13 of the Ordinance to expressly require the payment of a fee for renewing a certificate of registration of premises at which the retail sale of poisons is conducted by an ASP, as well as the payment of a fee for altering the register of such premises.

55. Clause 20(1) amends section 25 of the Ordinance to expressly require an LSP to pay an annual fee for continuing to be an LSP and a fee for altering the list of LSP.

56. Clause 60 amends regulation 37(3) of the Regulations to require the payment of a fee representing the expenditure incurred, or likely to be incurred, in carrying out an inspection for determining an application for registration of any pharmaceutical products or substances manufactured outside Hong Kong.

57. Clause 69 amends the Ninth Schedule to the Regulations mainly to prescribe the fees for a certificate of registration of an authorized

person and a renewed certificate of registration of an authorized person.

Miscellaneous

Amendments relating to headings

58. Clause 72 and the Schedule contain textual amendments to the Part headings and regulation headings in the Ordinance and the Regulations. The purpose is to give the reader a better overview of the legislative text that follows each heading.

*Amendment to definition of **pharmaceutical product** and **medicine***

59. To align with international practice, the definition of ***pharmaceutical product*** and ***medicine*** in section 2(1) of the Ordinance is revised by reference to the definition of ***medicinal product*** adopted by the European Commission (Article 1 of Directive 2001/83/EC) (clause 4(3)).

Poisons List relocated

60. Clause 33 adds a new regulation 2A to the Regulations to introduce a new Schedule 10 containing the Poisons List which was originally set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B). As a result of the relocation of the Poisons List, the Poisons List Regulations are repealed (clause 71).

Amendments to Poisons List etc.

61. Clause 23 adds a new section 29(1B) to the Ordinance to empower the Board to amend the Poisons List or any list (which is contained in regulations made under section 29(1) of the Ordinance) of substances or articles to which any provision of the Ordinance or those regulations apply or do not apply.

Other miscellaneous amendments

62. Clause 17 amends section 17 of the Ordinance which provides for the liability of an ASP for the acts of employees. This amendment is consequential to the amendments to section 15 of the Ordinance which extend the scope of offences in respect of which the Disciplinary Committee may be appointed to hold an inquiry.

63. Clause 25 amends section 30(1) of the Ordinance to empower the Pharmacy and Poisons Appeal Tribunal to hear and determine appeals against any decision of the Board under any regulations made under section 29 of the Ordinance.

64. Clauses 65 and 66 make textual amendments to the First Schedule and Third Schedule to the Regulations respectively.

Summary of the 75 Recommendations put forth by the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee)

The Review Committee has made a total of 75 recommendations as follows. Recommendations which can be implemented with existing resources are marked with an "*" while recommendations which will be implemented when new resources are available are marked with an "#".

Regulation of Drug Manufacturers

Recommendation 1[#] – to upgrade Hong Kong's current Good Manufacturing Practice (GMP) licensing standards by a phased approach to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards over a period of four years.

Recommendation 2[#] – to require imported drugs to comply with the same standards once local drugs attained the PIC/S standards.

Recommendation 3[#] – to strengthen the control of the use of Active Pharmaceutical Ingredients (APIs) and contract laboratories by local manufacturers.

Recommendation 4* – to strengthen the experience requirement for existing APs from at least <u>one</u> year of relevant working experience to at least <u>three</u> years; and for the heads of production and quality control from at least <u>one</u> year to at least <u>two</u> years for pharmacy degree holders and from at least <u>two</u> years to at least <u>three</u> years for holders of higher diploma in pharmacy-related subjects.

Recommendation 5[#] – to draw up a set of qualification requirements of Authorized Persons (APs), to establish a licensing or listing scheme and to liaise with the universities for offering a structured training programme for APs.

Recommendation 6[#] – to empower the Pharmacy and Poisons Board to maintain an AP register and remove any AP from the register should he be found incompetent to perform the AP role.

Recommendation 7* – to increase the number of inspections to local manufacturers. While most of the inspections to manufacturing premises should remain announced, some unannounced inspections should be introduced. Further, one of the two inspectors in the inspection team should be retained for subsequent inspections to facilitate effective follow-up on irregularities identified.

Recommendation 8[#] – to set up a multi-disciplinary GMP inspection team with professionals of other related disciplines like biochemists, chemists, engineers, microbiologists, etc. for effective auditing of manufacturers with diversified production environment.

Recommendation 9[#] – to develop structured, practical and continuous training programmes for all levels of players in the GMP system including DH inspectors, APs, production and quality control heads, and other workers.

Recommendation 10* – to state in the licensing conditions that local manufacturers should either (a) appoint the AP as a board member; or (b) invite the AP to attend board meetings and allow the AP to speak and have his remarks put on record where safety, efficacy and quality issues of products are concerned. This recommendation should be put on trial for two years and then reviewed.

Recommendation 11[#] – to introduce a code of practice to govern the conducts of the manufacturers and the APs.

Recommendation 12* – to require all local manufacturers to adopt the enhanced microbiological monitoring model covering raw materials, granules, finished products and stability studies.

Pre-market Control of Drugs

Recommendation 13[#] – to require Bioavailability and Bioequivalence (BABE) studies as registration requirement for pharmaceutical products to enhance quality of generic drugs. The implementation should be by phases starting in April 2010. It will begin with antiepileptic drugs, which have a narrow therapeutic index where a comparatively small difference in the absorption of the drug by the human body may lead to undesirable consequences.

Recommendation 14* – to replace the term "Poison毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption.

Recommendation 15* – to delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products.

Recommendation 16* – to extend the validity of clinical trial certificate from not more than two years to not more than five years.

Recommendation 17[#] – to shorten the time-frame for processing applications for registration of pharmaceutical products, change of particulars of registered products and clinical trials by 40% - 50%.

Regulation of Importers/Exporters and Wholesalers

Recommendation 18[#] – to require all wholesalers of non-poisons to be subject to inspection and licensing control.

Recommendation 19[#] – to require all wholesalers to keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons, and to require wholesalers to keep samples of each batch of drugs handled to facilitate investigation when needed.

Recommendation 20* – to require both primary and secondary packaging be carried out by a licensed manufacturer.

Recommendation 21* – to introduce a code of practice for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc.

Recommendation 22# – to strengthen the monitoring of importers/exporters and wholesalers by means of more frequent and more detailed inspections, especially after the introduction of a code of practice.

Recommendation 23# – to set up a dedicated team of pharmacist inspectors to advise the Customs and Excise Department (C&ED) staff on pharmaceutical imports at various ports of entry.

Recommendation 24# – to set up a record and tracking system by requiring export licence (EL) applicants to produce the import licences (ILs) of the imported drugs to be re-exported.

Recommendation 25# – to prescribe in the licensing conditions for ILs for the products for re-export that the importer should not sell unregistered imported drugs in Hong Kong and must re-export the products within a specified period of time, say one year.

Recommendation 26# – to conduct a joint review with C&ED to determine a new weekly quota for post-shipment consignment checks of licences which should be a statistically significant sample size of the ILs and ELs population.

Recommendation 27# – to require exporters who chose to export products by mail to clear their products at designated post offices. DH should include the requirement in the ELs and discuss with C&ED for the introduction of a daily quota on outgoing mail parcels of drugs for verification of content and endorsement by C&ED.

Recommendation 28# – to develop an electronic record system

among DH, C&ED and the Trade and Industry Department to facilitate the tracking of imported and exported drugs.

Regulation of Retailers

Recommendation 29[#] – to require all retailers of non-poisons to be subject to licensing and inspection control.

Recommendation 30[#] – in the longer term after taking into account the market operating conditions and the availability of sufficient pharmacists, to require the presence of a registered pharmacist whenever an Authorized Seller of Poisons (ASP) is open for business. Heightened enforcement actions should be taken against those non-pharmacists who violate and interrupt the pharmacists' performance of their duties at ASPs.

Recommendation 31* – to require all Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should hold the key to the locked receptacle.

Recommendation 32* – to add a provision in the Pharmacy and Poisons Ordinance for the issuance and revision of the code of practice for ASPs in order to give a legal status to the code to enhance monitoring on the operation of ASPs; and to introduce a code of practice for Listed Sellers of Poisons (LSPs) which should enjoy the same legal status as the code for ASPs.

Recommendation 33* – to give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence.

Recommendation 34* – to tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. DH should evaluate what type of drug offences should be included based on their public health impact.

Recommendation 35[#] – to strengthen the monitoring of ASPs and LSPs by means of more frequent and more detailed inspections.

Recommendation 36* – to require ASPs and LSPs to purchase drugs from licensed traders only.

Recommendation 37* – to require that all orders for drugs to have written records.

Recommendation 38* – to require ASPs to sell pharmaceutical products in their original packing, save in the case of a doctor prescription drug which is required by law to be dispensed in exact quantity in accordance with the prescription and in the case of pharmacist dispensing drugs to patients according to their need with proper labelling.

Recommendation 39* – to require ASPs and LSPs to keep all the supporting documents including drug orders and sales invoices related to every purchase of all pharmaceutical products, and the documents should be kept as long as the expiry date of the pharmaceutical product concerned for DH's inspection if necessary.

Regulation of Drug Procurement

Recommendation 40# – both DH and Hospital Authority (HA) to conduct post-delivery surveillance including microbiological and chemical testing to ensure drug quality.

Recommendation 41* – both DH and HA to require the suppliers to provide additional information, such as pack size and registration number, etc. in the delivery documents to enable more effective physical checking and verification if drugs received are legally conforming.

Recommendation 42# – both DH and HA to provide additional training to staff and monitor the workflow in the repacking activities in drug dispensing to minimize errors.

Recommendation 43* – to impose a new requirement on suppliers to keep samples of each batch of drugs that are still within the expiration period to facilitate investigation when needed.

Recommendation 44[#] – to upgrade DH's central inventory monitoring computer system to enhance the traceability of drugs.

Recommendation 45[#] – DH to enrich the database of registered pharmaceutical products so as to provide more detailed information to the public on registration details of products, e.g. pack-size, labelling, legal classification, etc.

Recommendation 46* – HA to require suppliers to provide evidence that their products are either registered or are exempted from registration under the law.

Recommendation 47* – HA to require suppliers to provide microbiological test results for high risk drug items and batch release certificates on all drugs supplied to HA to ensure safety and quality.

Recommendation 48* – HA to use multiple sources for supply of high risk products with high usage volume.

Recommendation 49[#] – HA to establish a Drug Quality Assurance Office to enhance quality monitoring of products, performance management of manufacturers and suppliers and quality incident management as well as to monitor the implementation of all improvement initiatives.

Recommendation 50[#] – HA to enhance the current electronic system, such as exploring the use of radio-frequency identification (RFID), bar coding, wireless data transmission, etc. to enable product traceability and effective stores management.

Recommendation 51* – HA to require suppliers to provide drugs in suitable pack sizes as far as possible to reduce the need for repacking.

Recommendation 52* – DH to issue a set of guiding principles on drug procurement for the private medical sector and encourage private hospitals, managed care organisations and private medical practitioners in solo or joint practices to follow this set of guiding principles as far as practicable.

Recommendation 53* – DH to encourage private hospitals to develop an automated inventory management system and bar-coding system for pharmaceutical products.

Pharmacovigilance

Recommendation 54* – to establish a pharmacovigilance advisory body to review DH assessments of the adverse drug reaction (ADR) reports received, advise DH on action on specific cases, serve as an editorial advisory board of the pharmacovigilance bulletin and assist DH in the promotion of pharmacovigilance activities.

Recommendation 55[#] – DH to set up a dedicated team to promote pharmacovigilance work among professionals, education institutions and the industry; handle ADR reports received; disseminate information; and support the pharmacovigilance advisory body.

Recommendation 56* – DH to publish a regular pharmacovigilance bulletin for distribution to all doctors, dentists and pharmacists, and a user-friendly version of the bulletin for reference of the general public.

Recommendation 57[#] – DH to include an ADR report form in mails to doctors and pharmacists, enhance DH website such that doctors and pharmacists could subscribe and receive emails from DH on ADR as soon as they become known, encourage the use of electronic reporting of ADRs, and develop additional electronic interface for dentists and pharmacists to facilitate ADR reporting.

Recommendation 58[#] – DH to publish guidelines for the drug industry on their responsibilities to report ADRs, to educate and encourage them to report ADRs and to develop a culture of awareness of pharmacovigilance.

Recommendation 59* – to require the drug industry to report any actions taken by overseas drug regulatory authorities on any drugs as a consequence of safety issues and require manufacturers to inform DH if they have committed to the request of European

Union (EU) or United States (US) to develop an EU Risk Management Plans or US Risk Evaluation and Mitigation Strategies as a condition for approving a new drug.

Recommendation 60* – DH to review ADR reports within three working days.

Recommendation 61* – DH to establish liaison with overseas health authorities for exchange of ADR information as well as providing training on pharmacovigilance to staff.

Recommendation 62[#] – DH to review the progress and effectiveness of the development and implementation of the improved pharmacovigilance measures in two years' time.

Recommendation 63[#] – DH to continue the heightened surveillance against high risk products sold in the market and set up a dedicated team of pharmacists to handle increased sampling of high risk products.

Recommendation 64* – to adopt a risk-based approach in drug recall and public communication. Specifically DH should revise the recall guidelines to include the different stages of recall procedures, the classification of the recall, the level of the recall, the strategy of the recall including the dissemination of information to the public, the responsibilities of the trade including refund, and the monitoring of all follow up actions, including the effectiveness of the recall.

Recommendation 65* – DH to inform the Consumer Council on every drug recall incident at consumer level to widen the dissemination network of the drug recall message.

Recommendation 66* – DH to add a refund mechanism in the recall guidelines requiring manufacturers and wholesalers to provide refund details to consumers at retail level in the event of drug recall.

Risk Communication

Recommendation 67[#] – to set up a dedicated, multi-disciplinary team to oversee education and training. The team should collaborate with and coordinate efforts of the academia, Consumer Council and relevant professional bodies in the provision of education and training programmes on drug safety.

Recommendation 68[#] – to continue organizing seminars with additional focus on quality control for the management at different levels of the drug supply chain as well as front-line staff.

Recommendation 69[#] – to enhance the content of "Compendium of Pharmaceutical Products" on DH website to provide more information about each registered drug.

Recommendation 70[#] – to set up a designated website on drug safety to provide a better platform for information dissemination and exchange.

Recommendation 71* – to establish a working group to work out the prototype of the enhanced website and its contents.

Recommendation 72[#] – to require that more information on drugs and patient-oriented advice be provided along with drugs dispensed to patients at hospitals or clinics.

Penalty System

Recommendation 73* – to include more aggravating factors in the facts of the case submitted to the Court to reflect the seriousness of the offence concerned for the Court to impose an appropriate sentence.

Recommendation 74* – to amend the Pharmacy and Poisons Ordinance to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect.

Manpower Requirements

Recommendation 75[#] – to expand DH's Pharmaceutical Service into a dedicated office on drugs to strengthen DH's regulatory role in enhancing drug safety. In the long run, consideration will be given to expanding the office to be a "Centre for Drug Safety".

Annex C

Summary on the Recommendations of the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong (Review Committee) which Require Amendments to the Pharmacy and Poisons Ordinance (PPO) and its subsidiary legislation

No.[1]	Details of recommendation	The Administration's response to the recommendation
6	Empower the Pharmacy and Poisons Board to maintain an Authorized Person (AP) register and remove any AP from the register should the AP be found incompetent to perform the role of an AP.	The Administration will implement the recommendation through legislative amendments.
11	Introduce a code of practice (COP) to govern the conducts of the manufacturers and the APs.	The Administration will implement the recommendation through legislative amendments.
14	Replace the term "Poison 毒藥", as required to be labelled on pharmaceutical products classified as poisons, with other terms to alleviate the unnecessary concern of consumers that the products might be harmful and unsuitable for use or consumption.	The Administration will implement the recommendation through legislative amendments.
15	Delete the phrase "to be marketed for use within Hong Kong" on the certificate of registration of pharmaceutical products.	The Administration will implement the recommendation through legislative amendments.
16	Extend the validity of clinical trial certificate from "not more than two years" to "not more than five years".	The Administration will implement the recommendation through legislative amendments.
18 & 29	All wholesalers and retailers of non-poisons shall be subject to inspection and licensing control.	Due to (i) the significant impact to the large number of direct sellers of non-poisons; and (ii) the significant cost

[1] Denotes the number of the recommendations put forward by the Review Committee as appeared in its report issued in December 2009.

No.[1]	Details of recommendation	The Administration's response to the recommendation
		to trade due to the wide range of products and huge volume involved, the Administration considers it not appropriate to impose licensing control on retailers of non-poisons.
19	All wholesalers are required to (i) keep transactions records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons; and (ii) keep samples of each batch of drugs handled to facilitate investigation when needed.	The Administration proposes to implement (i). For (ii), as additional space is required for sample retention and keeping samples of expensive drugs is costly, the Administration does not consider it necessary to implement (ii) if traders can provide samples within specified period upon request. Moreover, manufacturers of registered drugs must reach Good Manufacturing Practice (GMP) standards and must keep drug samples under GMP requirements.
20	Require secondary packaging be carried out by a licensed manufacturer.	The Administration will implement the recommendation through legislative amendments.
21	Introduce a COP for importers/exporters and wholesalers detailing their roles and responsibilities, including the requirement of batch release certificate, the reporting of adverse drug reactions, proper storage and transportation of drugs, etc.	The Administration will implement the recommendation through legislative amendments.
30	Registered pharmacist should be present at authorized seller of poisons (ASP) whenever an ASP is open for business.	Having regard to the insufficient manpower supply of registered pharmacists currently and in the near future, the Administration does not consider it an appropriate timing to implement this recommendation at this stage.
31	All Part I Poisons be stored in locked receptacle in the premises of an ASP and that only the pharmacist should	The Administration will implement the recommendation through legislative amendments.

No.[1]	Details of recommendation	The Administration's response to the recommendation
	hold the key to the locked receptacle.	
32	Add a provision in the PPO for the issuance and revision of the COP for ASPs in order to give a legal status to the COP to enhance monitoring on the operation of ASPs; and to introduce a COP for listed sellers of poisons (LSP) which should enjoy the same legal status as the COP for ASPs.	The Administration will implement the recommendation through legislative amendments.
33	Give the Pharmacy and Poisons Board the authority to revoke the licence of an ASP at any time after the ASP has been convicted of serious drug offence.	The Administration will implement the recommendation through legislative amendments.
34	Tighten the licensing conditions for the refusal or renewal of ASP or LSP applications. Department of Health should evaluate which types of drug offences should be included based on their public health impact.	The Administration will implement the recommendation through legislative amendments.
74	Amend the PPO to include provision for the Court to order the convicted person to pay the analytical costs incurred by the Government to increase the deterrent effect.	To increase the deterrent effect, the Administration will propose legislative amendment to empower the Court to order recovery of all expenses incidental to the taking, examination and analyses of any sample of drugs in respect of which the conviction is based from the defendant.

Annex D

Implications of the Proposal

Financial and civil service implications

The proposal will lead to (i) the creation of two new fee items relating to the proposed registration of AP which would generate an annual revenue of about $284,000, and (ii) the merging of the registration of importers/exporters of pharmaceutical products with the licensing of wholesale dealers which would result in decrease of annual revenue of about $9,000.

2. The concerned bureaux/departments will endeavor to absorb additional workload, if any, within their existing resources. Where necessary, they will justify and seek additional resources in accordance with the established mechanism. As for the additional workload for the Judiciary, if any, in line with the existing funding arrangements, the Administration will provide the Judiciary with the necessary manpower and financial resources should such need arise in future.

Economic and sustainability implications

3. As regards the economic and sustainability implications, the proposal would strengthen the regulatory regime for the pharmaceutical products, thus safeguarding the health of the public. Although the tightened control measures may impose additional compliance requirements on traders of pharmaceutical products and thereby increase their operational cost, the enhanced regulatory regime will strengthen public confidence towards pharmaceutical products and traders in Hong Kong which shall facilitate the development of the pharmaceutical sectors. The proposal to streamline the registration of new pharmaceutical products would enhance the efficiency of the drug registration processes and hence expedite the sale and supply of new pharmaceutical products in Hong Kong. As most of the new pharmaceutical products are used for treating relatively serious diseases, allowing an early sale and control of such products to fill an unmet medical need will eventually benefit the patients in Hong Kong. We expect the benefits brought to the community as a whole by our legislative proposal will outweigh the increased administrative and operational costs of traders of pharmaceutical products.