LN160-E

# Chinese Medicines Regulation

(Made by the Chinese Medicine Council of Hong Kong under section 161(5) of the Chinese Medicine Ordinance (Cap. 549) with the approval of the Secretary for Health, Welfare and Food)

## PART 1

## Preliminary

1. Commencement

This Regulation shall come into operation on a day to be appointed by the Secretary for Health, Welfare and Food by notice published in the Gazette.

2. Interpretation

In this Regulation, unless the context otherwise requires---

"batch number" (批次編號) means a series of numbers, letters or other symbols, or a series consisting of a combination of numbers, letters and other symbols, used---

(a) in the case of a Chinese herbal medicine supplied to a wholesale dealer in Chinese herbal medicines, for the purpose of identifying when and by whom the medicine is supplied to the dealer; or

(b) in the case of a proprietary Chinese medicine, for the purpose of identifying when and by whom the medicine is produced;

"excipient" (賦形劑), in relation to a proprietary Chinese medicine, means a substance or compound that is used or intended to be used in the preparation or production of the medicine but which is not an active ingredient of the medicine;

"expiry date" (失效日期), in relation to a proprietary Chinese medicine, means the expiry date of the medicine as determined by the manufacturer who produces the medicine, being the date after which the medicine should not be administered;

"ingredient" (成分), in relation to a proprietary Chinese medicine, means---

(a) its active ingredient; or

(b) its excipient;

"intermediate product" (中間產品) means a substance or compound generated in the course of manufacture of a proprietary Chinese medicine and which is to be used in further preparation or production process of the medicine;

"manufacturing process" (製造程序), in relation to a proprietary Chinese medicine, means the preparation, production, packing or repacking process of the medicine;

"packing material" (包裝物料), in relation to a proprietary Chinese medicine, means a material used for packing or repacking the medicine;

"responsible person" (負責人)---

(a) in relation to the dispensing of Chinese herbal medicines, means a person

responsible for the supervision of the dispensing or his deputies---

(i) as nominated in an application for a retailer licence under section 114(2)(b) of the Ordinance; or

(ii) as notified to the Medicines Board under section 145(2) of the Ordinance;

(b) in relation to the manufacture of proprietary Chinese medicines, means a person responsible for the supervision of the manufacture or his deputies---

(i) as nominated in an application for a manufacturer licence under section 132(1)(b) of the Ordinance; or

(ii) as notified to the Medicines Board under section 145(2) of the Ordinance;

"Schedule 1 medicine" (附表1藥材) means a Chinese herbal medicine specified in Schedule 1 of the Ordinance;

"Schedule 2 medicine" (附表2藥材) means a Chinese herbal medicine specified in Schedule 2 of the Ordinance;

"Vocational Training Council" (職業訓練局) means the Vocational Training Council established under section 4 of the Vocational Training Council Ordinance (Cap. 1130).

Part 2

Licensing Requirements in Respect of Applications for Retailer, Wholesaler and Manufacturer Licences

3. Licensing requirements in respect of applications made under section 114 of the Ordinance

For the purposes of section 114(3) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a retailer licence---

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material;

(d) where Chinese herbal medicines are to be dispensed in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for dispensing the medicines are provided in the premises;

(e) the premises are in all other respects suitable for carrying on a business in the retail of Chinese herbal medicines; and

(f) each responsible person nominated in the application complies with the minimum requirements regarding knowledge and experience as set out in section 1 of Schedule 1.

4. Licensing requirements in respect of applications made under section 115 of the Ordinance

For the purposes of section 115(3) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a wholesaler licence in Chinese herbal medicines---

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material; and

(d) the premises are in all other respects suitable for carrying on a business in the wholesale of Chinese herbal medicines.

5. Licensing requirements in respect of applications made under section 132 of the Ordinance

For the purposes of section 132(2) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a manufacturer licence---

(a) the premises to which the application relates are in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are to be stored in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) where any Schedule 1 medicine is to be stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, arrangements are made so that the Schedule 1 medicine can be stored effectively separated from the Schedule 2 medicine or material;

(d) fittings and equipment suitable for use in the manufacturing process specified in the application are provided in the premises;

(e) where intermediate products generated or proprietary Chinese medicines

manufactured in the course of manufacture, or both, are to be stored in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the products or medicines, or both, as the case may be, are provided in the premises;

(f) the humidity, lighting, temperature and ventilation of the part of the premises provided for---

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines,

are suitable for their respective purposes;

(g) the premises are in all other respects suitable for carrying on a business in the manufacture of proprietary Chinese medicines; and

(h) each responsible person nominated in the application complies with the minimum requirements regarding knowledge and experience as set out in section 2 of Schedule 1.

6. Licensing requirements in respect of applications made under section 135 of the Ordinance

For the purposes of section 135(2) of the Ordinance, the following are the prescribed licensing requirements in respect of an application for a wholesaler licence in proprietary Chinese medicines---

(a) the premises to which the application relates are in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing proprietary Chinese medicines are provided in the premises; and

(c) the premises are in all other respects suitable for carrying on a business in the wholesale of proprietary Chinese medicines.

Part 3

Duties of Holders of Retailer Licences

7. General duties of holders of retailer licences

A holder of a retailer licence shall ensure that---

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) the facilities for storing Chinese herbal medicines are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule

2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) where Chinese herbal medicines are dispensed in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for dispensing the medicines are provided in the premises;

(f) the facilities (if any) for dispensing Chinese herbal medicines are maintained in good condition;

(g) each type of Chinese herbal medicine stored in the premises is stored in a separate container;

(h) each container referred to in paragraph (g)---

(i) has the name of the medicine stored in it being printed or affixed in a conspicuous position;

(ii) has the name of the medicine stored in it being clearly and distinctly set out and not in any way obscured or obliterated; and

(iii) is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicine stored in it;

(i) no Chinese herbal medicine in his possession is dispensed to any person otherwise than under the supervision of a responsible person;

(j) he does not---

(i) sell by retail;

(ii) dispense to another person; or

(iii) possess for the purpose of retail,

any Chinese herbal medicine other than those acquired or received by him from a holder of a wholesaler licence in Chinese herbal medicines; and

(k) where a prescription given by a registered or listed Chinese medicine practitioner is presented for dispensing any Chinese herbal medicine, the prescription is, as soon as is reasonably practicable after the dispensation is completed, returned to the person by whom it is presented with the following particulars added on it---

(i) the date of the dispensation; and

(ii) the name, address and telephone number of the licence holder.

8. Other duties of holders of retailer licences---

keeping of records

(1) A holder of a retailer licence shall ensure that every transaction whereby a Chinese herbal medicine is acquired or received by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction---
(a) the date of the transaction;
(b) the name and quantity of the medicine acquired or received;
(c) the name, address and telephone number of the person who sells or distributes the medicine to him; and
(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

9. Additional duties of holders of retailer licences in respect of Schedule 1 medicines

(1) A holder of a retailer licence in respect of Schedule 1 medicines shall ensure that the following particulars in respect of each dispensation of a Schedule 1 medicine conducted in accordance with a prescription given by a registered Chinese medicine practitioner under section 109(1) of the Ordinance are recorded---
(a) the name and quantity of the medicine dispensed;
(b) the name and address of the registered Chinese medicine practitioner who gives the prescription;
(c) the name and, if known by the responsible person who supervises the dispensation, the address and telephone number of the person to whom the prescription is given;
(d) the date of the dispensation; and
(e) the name of the responsible person referred to in paragraph (c).

(2) The licence holder shall also ensure that---
(a) the particulars mentioned in subsection (1) are recorded as soon as is reasonably practicable after the dispensation;
(b) the responsible person referred to in subsection (1)(c) has affixed his signature in the record prepared pursuant to subsection (1); and
(c) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the dispensation.

10. Additional duties of holders of retailer licences in respect of Schedule 2 medicines

A holder of a retailer licence in respect of Schedule 2 medicines shall ensure that where a prescription given by a registered or listed Chinese medicine practitioner is presented for dispensing any Schedule 2 medicine, the medicine is dispensed in accordance with the prescription.

Part 4

Duties of Holders of Wholesaler Licences in
Chinese Herbal Medicines

11. General duties of holders of wholesaler licences in Chinese herbal medicines

A holder of a wholesaler licence in Chinese herbal medicines shall ensure that---

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing Chinese herbal medicines are provided in the premises;

(c) the facilities for storing Chinese herbal medicines are maintained in good condition;

(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;

(e) each type of Chinese herbal medicine stored in the premises is stored in a separate container;

(f) each container referred to in paragraph (e) is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the Chinese herbal medicine stored in it;

(g) where any Chinese herbal medicine or mixture of Chinese herbal medicines is processed in the premises---

(i) equipment and facilities suitable for processing are provided in the premises;

(ii) the equipment and facilities for processing are maintained in good condition;

(iii) the processed medicine or mixture is examined by the licence holder to ensure its quality before it is offered for sale or supplied to or used by any other person;

(iv) the following particulars in relation to each processing are recorded---

(A) the name and quantity of each type of material (including the Chinese herbal medicine or mixture of Chinese herbal medicines to be processed) used in the processing;

(B) the name and quantity of the processed medicine or mixture;

(C) the name or a description of the processing method;

(D) the date of the completion of the processing;

(E) the result of the examination referred to in subparagraph (iii); and

(F) the name of the person who supervises the processing;

(v) the particulars mentioned in subparagraph (iv) are recorded within 72 hours after the completion of the processing; and

(vi) the record prepared pursuant to subparagraph (iv) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the completion of the processing;

(h) no Chinese herbal medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(i) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any Chinese herbal medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

12. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 1 medicines---selling restrictions

A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines may sell or distribute a Schedule 1 medicine only to the following categories of persons or entities---

(a) a holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines;

(b) a holder of a retailer licence in respect of Schedule 1 medicines;

(c) a holder of a manufacturer licence;

(d) a registered Chinese medicine practitioner;

(e) a person or an institution exempted under section 158(1) of the Ordinance requiring the medicine for the purpose of education or scientific research;

(f) a Government department or public officer requiring the medicine for the purpose of public service;

(g) a purchaser outside Hong Kong;

(h) a hospital or clinic managed or controlled by the Hospital Authority established under section 3(1) of the Hospital Authority Ordinance (Cap. 113); or

(i) a hospital within the meaning of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165).

13. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 1 medicines---keeping of records

(1) A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 1 medicines shall ensure that the following particulars in respect of every transaction whereby a Schedule 1 medicine is acquired, received, sold or distributed by him are recorded---

(a) the date of the transaction;
(b) the nature of the transaction;
(c) the name and quantity of the medicine acquired, received, sold or distributed, as the case may be;
(d) the name, address and telephone number of---
(i) the person who sells or distributes the medicine to him; or
(ii) the person to whom he sells or distributes the medicine,
as the case may be;
(e) the reference number of the invoice or other document evidencing the transaction; and
(f) the balance of the medicine remaining in his possession after the completion of the transaction.
(2) The licence holder shall ensure that---
(a) the particulars mentioned in subsection (1) are recorded within 72 hours after the completion of the transaction; and
(b) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.
(3) The licence holder shall also ensure that---
(a) every transaction mentioned in subsection (1) is evidenced by an invoice or other document which contains the particulars mentioned in subsection (1)(a) to (e); and
(b) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.
14. Additional duties of holders of wholesaler licences in Chinese herbal medicines in respect of Schedule 2 medicines---keeping of records
(1) A holder of a wholesaler licence in Chinese herbal medicines in respect of Schedule 2 medicines shall ensure that every transaction whereby a Schedule 2 medicine is acquired, received, sold or distributed by him is evidenced by an invoice or other document.
(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction---
(a) the date of the transaction;
(b) the name and quantity of the medicine acquired, received, sold or distributed, as the case may be;
(c) the name, address and telephone number of---

(i) the person who sells or distributes the medicine to him; or

(ii) the person to whom he sells or distributes the medicine,

as the case may be; and

(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

Part 5

Registration of Proprietary Chinese Medicines

15. Particulars to be registered for proprietary Chinese medicines

For the purposes of section 121(1)(b) of the Ordinance, the following particulars are required to be registered for a proprietary Chinese medicine---

(a) its Chinese and English name;

(b) its dose form;

(c) the name and quantity of each of its active ingredient;

(d) the name and quantity of each of its excipient (if any);

(e) its specification;

(f) its indication (if any);

(g) its dosage and method of usage;

(h) each of its labels to be attached or printed on its package;

(i) the package insert to be supplied for its sales inside Hong Kong;

(j) each of the package inserts to be supplied for its sales outside Hong Kong (if any);

(k) the name and address of each of its manufacturer; and

(l) its function or pharmacological action.

Part 6

Duties of Holders of Manufacturer Licences

16. General duties of holders of manufacturer licences

A holder of a manufacturer licence shall ensure that---

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) where ingredients or packing materials, or both, used for manufacturing proprietary Chinese medicines are stored in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the ingredients or packing materials, or both, as the case may be, are provided in the premises;

(c) the facilities (if any) for storing ingredients or packing materials, or both, as the case may be, are maintained in good condition;
(d) where any Schedule 1 medicine is stored in the same premises with any Schedule 2 medicine or material of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Schedule 1 medicine is stored effectively separated from the Schedule 2 medicine or material;
(e) fittings and equipment suitable for use in the manufacturing process specified in the licence are provided in the premises;
(f) the fittings and equipment used in the manufacturing process are maintained in good condition;

(g) where intermediate products generated or proprietary Chinese medicines manufactured in the course of manufacture, or both, are stored in the premises---

(i) adequate space; and

(ii) adequate and suitable facilities,

for storing the products or medicines, or both, as the case may be, are provided in the premises;
(h) the facilities (if any) for storing intermediate products or proprietary Chinese medicines, or both, are maintained in good condition;
(i) the humidity, lighting, temperature and ventilation of the part of the premises provided for---

(i) storing ingredients or packing materials;

(ii) manufacturing proprietary Chinese medicines; or

(iii) storing intermediate products or proprietary Chinese medicines,

are suitable for their respective purposes;
(j) where any ingredient is used in the manufacturing process, the ingredient is examined by a responsible person before it is used to ensure its identity and quality;
(k) no manufacturing process is carried out in the premises otherwise than under the supervision of a responsible person;
(l) adequate steps have been taken to prevent contamination of any ingredient or packing material used, any intermediate product generated or any proprietary Chinese medicine manufactured in the course of manufacture;
(m) each batch of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture, or both, is examined by a responsible person before it is sold or distributed by the holder of the licence to ensure its quality;
(n) no proprietary Chinese medicine that he manufactures is sold or distributed by

him after its expiry date;
(o) each container or package of intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the products or medicines, as the case may be;
(p) no intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the product or medicine, as the case may be;
(q) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any intermediate product generated or proprietary Chinese medicine manufactured in the course of manufacture which has been sold or distributed in the event of the product or medicine, as the case may be, being found to be dangerous, injurious to health or unfit for human consumption;
(r) a control sample of each batch of intermediate product (if any) generated in the course of manufacture which has been sold is retained, under suitable conditions of storage, in the premises from the date on which the batch of product is generated until the expiry of 2 years from the date of the last transaction in the batch of product; and
(s) a control sample of each batch of proprietary Chinese medicine (if any) manufactured in the course of manufacture is retained, under suitable conditions of storage, in the premises from the date of the manufacture until the expiry of 2 years from the expiry date of the batch of medicine.
17. Other duties of holders of manufacturer licences---keeping of documents relating to acquisition of ingredients

(1) A holder of a manufacturer licence shall ensure that every transaction whereby a batch of ingredient is acquired or received by him is evidenced by an invoice or other document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction---
(a) the date of the transaction;
(b) the name and quantity of the batch of ingredient acquired or received by him;
(c) the name, address and telephone number of the person who sells or distributes the batch of ingredient to him; and
(d) the reference number of the invoice or other document.

(3) Subject to subsections (4) and (5), the licence holder shall also ensure that

the invoice or other document evidencing the transaction is retained in the premises to which the licence relates from the date of the transaction until the expiry of 2 years---

(a) in the case where a batch of intermediate product is generated from the batch of ingredient, from the date of generation of the batch of product; or

(b) in the case where a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, from the expiry date of the batch of medicine.

(4) Where 2 or more batches of intermediate product or proprietary Chinese medicine are generated or manufactured, as the case may be, from the batch of ingredient and they have different dates of generation or expiry dates, as the case may be, the invoice or other document shall be retained until the expiry of 2 years from the latest of such dates of generation or expiry dates, as the case may be.

(5) Where a batch of intermediate product is generated and a batch of proprietary Chinese medicine is manufactured from the batch of ingredient, the invoice or other document shall be retained until the expiry of 2 years from the latter of the dates referred to in subsection (3)(a) or (b).

18. Other duties of holders of manufacturer licences---keeping of manufacturing records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of each manufacturing process of a proprietary Chinese medicine carried out by him are recorded---

(a) the name of the intermediate product generated or proprietary Chinese medicine manufactured from the manufacturing process, or both, as the case may be;

(b) the quantity of the batch of product or medicine, or both, as the case may be;

(c) the expiry date and batch number of the batch of medicine (applicable only where a proprietary Chinese medicine is manufactured from the manufacturing process);

(d) the name and quantity of each ingredient or packing material used in the manufacturing process;

(e) a description of each manufacturing method used; and

(f) the date on which the manufacturing process---

(i) begins; and

(ii) is completed.

(2) The licence holder shall also ensure that---

(a) the particulars mentioned in subsection (1) (other than those referred to in subsection (1)(b) and (f)(ii)) are recorded within 72 hours after the manufacturing process begins;

(b) the particulars mentioned in subsection(1)(b) and (f)(ii) are recorded within 72 hours after the manufacturing process is completed; and

(c) subject to subsection (3), the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years---

(i) in the case where the record relates to a batch of intermediate product, from the date of the last transaction in the batch of product or the date when the batch of product is used up by the licence holder, whichever is later; or

(ii) in the case where the record relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) Where the record prepared pursuant to subsection (1) relates to a batch of intermediate product and proprietary Chinese medicine, the record shall be retained until the expiry of 2 years from the latter of the dates referred to in subsection (2)(c)(i) or (ii).

19. Other duties of holders of manufacturer licences---keeping of transaction records

(1) A holder of a manufacturer licence shall ensure that the following particulars in respect of every transaction whereby a batch of intermediate product generated or a batch of proprietary Chinese medicine manufactured in the course of manufacture is sold or distributed by him are recorded---

(a) the date of the transaction;

(b) the name and quantity of the batch of product or medicine sold or distributed, as the case may be;

(c) the name, address and telephone number of the person to whom he sells or distributes the batch of product or medicine, as the case may be;

(d) the batch number of the batch of medicine (applicable only where the transaction relates to a proprietary Chinese medicine); and

(e) the reference number of the invoice or other document evidencing the transaction.

(2) The licence holder shall ensure that---

(a) the particulars mentioned in subsection (1) are recorded within 72 hours after the completion of the transaction; and

(b) the record prepared pursuant to subsection (1) is retained in the premises to which the licence relates from the date of preparation of the record until the expiry of 2 years---

(i) in the case where the transaction relates to a batch of intermediate product, from the date of the transaction; or

(ii) in the case where the transaction relates to a batch of proprietary Chinese medicine, from the expiry date of the batch of medicine.

(3) The licence holder shall also ensure that---

(a) every transaction mentioned in subsection (1) is evidenced by an invoice or other document which contains the particulars mentioned in that subsection; and

(b) the invoice or other document evidencing the transaction is retained in the premises to which the licence relates from the date of the transaction until the expiry of 2 years from the dates referred to in subsection (2)(b)(i) or (ii), as the case may be.

Part 7

Duties of Holders of Wholesaler Licences in Proprietary Chinese Medicines

20. General duties of holders of wholesaler licences in proprietary Chinese medicines

A holder of a wholesaler licence in proprietary Chinese medicines shall ensure that---

(a) the premises to which the licence relates are maintained in sanitary condition;

(b) (i) adequate space; and

(ii) adequate and suitable facilities,

for storing proprietary Chinese medicines are provided in the premises;

(c) the facilities for storing proprietary Chinese medicines are maintained in good condition;

(d) no proprietary Chinese medicine in his possession is sold or distributed after its expiry date;

(e) all proprietary Chinese medicines sold or distributed by him are packed using materials that are sufficiently stout to prevent leakage and contamination arising from the ordinary risks involved in handling the medicine;

(f) no proprietary Chinese medicine in his possession is consigned for transport unless suitable arrangements have been made to prevent leakage and contamination arising from the ordinary risks involved in the delivery and transport of the medicine; and

(g) a system of control is set up and maintained, which will enable the rapid and, so far as practicable, complete recall of any proprietary Chinese medicine sold or distributed by him in the event of the medicine being found to be dangerous, injurious to health or unfit for human consumption.

21. Other duties of wholesalers in proprietary Chinese medicines---keeping of transaction records

(1) A holder of a wholesaler licence in proprietary Chinese medicines shall ensure that every transaction whereby a proprietary Chinese medicine is acquired, received, exported, sold or distributed by him is evidenced by an invoice or other

document.

(2) The licence holder shall ensure that the invoice or other document evidencing the transaction contains the following particulars in respect of the transaction---

(a) the date of the transaction;

(b) the name and quantity of the medicine acquired, received, exported, sold or distributed, as the case may be;

(c) the name, address and telephone number of---

(i) the person who imports, sells or distributes the medicine to him; or

(ii) the person to whom he exports, sells or distributes the medicine, as the case may be; and

(d) the reference number of the invoice or other document.

(3) The licence holder shall also ensure that the invoice or other document evidencing the transaction is retained in the premises to which the licence relates for a period of not less than 2 years from the date of the transaction.

Part 8

Requirements Regarding Labelling of Containers and Packages

22. Chinese herbal medicines to be labelled

For the purposes of section 142 of the Ordinance, a wholesale dealer in Chinese herbal medicines shall attach to or print on each container of Chinese herbal medicine a label in a conspicuous position, or cause a label to be so attached or printed.

23. Labelling of containers of Schedule 1 medicines by wholesale dealers

(1) A wholesale dealer in Schedule 1 medicines shall ensure that a label attached to or printed on a container in which a Schedule 1 medicine is stored---

(a) includes the particulars set out in subsection (2); and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) A label referred to in subsection (1) shall include the following particulars in respect of the medicine stored in the container---

(a) the name, at least in Chinese, of the medicine;

(b) the name of the wholesale dealer as specified in its wholesaler licence;

(c) the batch number of the medicine;

(d) a warning containing the Chinese text: "毒性中藥" or "毒性中藥"; and

(e) (if the warning referred to in paragraph (d) is to be available in English also) a warning containing the English text: "Toxic Chinese Medicine".

24. Labelling of containers of Schedule 2 medicines by wholesale dealers

A wholesale dealer in Schedule 2 medicines shall ensure that a label attached to or printed on a container in which a Schedule 2 medicine is stored---

(a) includes the name, at least in Chinese, of the medicine; and

(b) has the name of the medicine being clearly and distinctly set out and not in any way obscured or obliterated.

25. Proprietary Chinese medicines to be labelled

For the purposes of section 143 of the Ordinance, no person shall sell or have in his possession for the purpose of selling any proprietary Chinese medicine unless the package of the medicine is labelled in a conspicuous position.

26. Labelling of proprietary Chinese medicines to be sold in Hong Kong

(1) A person who sells in Hong Kong or has in his possession for the purpose of selling in Hong Kong a proprietary Chinese medicine shall ensure that a label on a package of the medicine---

(a) includes the particulars set out in subsection (2), (3) or (4), as the case may be; and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) Except as otherwise provided in subsections (3) and (4), a label on a package of a proprietary Chinese medicine to be sold in Hong Kong, whether being the outermost package to be sold or distributed to an ultimate user of the medicine or otherwise, shall include the following particulars, at least in Chinese---

(a) the name of the medicine;

(b) if---

(i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient; or

(ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients;

(c) the name of the country or territory in which the medicine is produced;

(d) the registration number of the medicine as specified in its certificate of registration;

(e) if the package---

(i) is the outermost package, the name of the holder of the certificate of registration of the medicine as specified in the certificate; or

(ii) is not the outermost package, either the particulars set out in paragraph (e)(i) or the name of the manufacturer who produces the medicine;

(f) its packing specification;

(g) its dosage and method of usage;

(h) its expiry date; and
(i) its batch number.

(3) Except as otherwise provided in subsection (4), a label on a package of a proprietary Chinese medicine to be sold in Hong Kong, not being the outermost package to be sold or distributed to an ultimate user of the medicine, which---

(a) is in the form of a strip pack, blister pack or similar article, shall include, at least in Chinese, the name of the medicine, the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine, and the expiry date, packing specification and batch number of the medicine;
(b) is in the form of an ampoule, vial or similar receptacle, with not more than 10 ml capacity or equivalent, shall include, at least in Chinese, the name of the medicine; or
(c) contains a single dose in the form of a pill, shall include, at least in Chinese, the name of the medicine.

(4) A label on a package of a proprietary Chinese medicine which is---
(a) manufactured in the premises in respect of which a manufacturer licence is in force;
(b) manufactured by or under the supervision of a responsible person in accordance with a prescription given by a registered or listed Chinese medicine practitioner; and
(c) to be sold or distributed to the Chinese medicine practitioner,
shall include the following particulars, at least in Chinese---
(d) if the prescription is given to a patient under the direct care of the Chinese medicine practitioner, and the prescription indicates that the medicine is for internal application or both internal and external application---

(i) the name and address of the Chinese medicine practitioner;
(ii) the name and address of the manufacturer who produces the medicine;
(iii) its batch number;
(iv) the date on which it is produced;
(v) its dose form;
(vi) its packing specification;
(vii) its expiry date;
(viii) the name and quantity of each ingredient listed in the prescription;
(ix) a statement containing the following Chinese text---

(A) "須按照中醫指示使用"; or
(B) "須按照中醫指示使用";

(x) (if the statement referred to in subparagraph (ix) is to be available in English also) a statement containing the English text: "To be used only in accordance with the instructions of a Chinese medicine practitioner";

(xi) a statement containing the following Chinese text---

(A) "只供中醫施用於或供應予獲開給本成藥的處方，並且是由他直接治理的病人"; or

(B) "只供中醫施用於或供應予獲開給本成藥的處方，並且是由他直接治理的病人"; and

(xii) (if the statement referred to in subparagraph (xi) is to be available in English also) a statement containing the English text: "To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to the patient to whom the prescription of this medicine is given and who is under his direct care";

(e) if the medicine is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner, and the prescription indicates that the medicine is for external application only---

(i) the name and address of the Chinese medicine practitioner;

(ii) the name and address of the manufacturer who produces the medicine;

(iii) its batch number;

(iv) the date on which it is produced;

(v) its dose form;

(vi) its packing specification;

(vii) its expiry date;

(viii) the name and quantity of each ingredient listed in the prescription;

(ix) a statement containing the following Chinese text---

(A) "須按照中醫指示使用"; or

(B) "須按照中醫指示使用";

(x) (if the statement referred to in subparagraph (ix) is to be available in English also) a statement containing the English text: "To be used only in accordance with the instructions of a Chinese medicine practitioner";

(xi) a statement containing the following Chinese text---

(A) "只供中醫施用於或供應予由他直接治理的病人"; or

(B) "只供中醫施用於或供應予由他直接治理的病人";

(xii) (if the statement referred to in subparagraph (xi) is to be available in English also) a statement containing the English text: "To be supplied to a Chinese medicine practitioner solely for the purpose of administering or supplying to a patient or patients under his direct care";

(xiii) a statement containing the Chinese text: "只供外用"; and

(xiv) (if the statement referred to in subparagraph (xiii) is to be available in English also) a statement containing the English text: "For external application

only".

27. Labelling of proprietary Chinese medicines to be exported

A person who exports or has in his possession for the purpose of exporting a proprietary Chinese medicine manufactured in Hong Kong shall ensure that a label on the outermost package of the medicine likely to be sold or distributed to an ultimate user of the medicine---

(a) includes the following particulars---

(i) the name of the medicine;

(ii) the name of the holder of the certificate of registration of the medicine as specified in the certificate; and

(iii) the registration number of the medicine as specified in its certificate of registration; and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

Part 9

Requirements for Package Inserts

28. Requirements for package inserts

(1) For the purposes of section 144 of the Ordinance, no person shall sell in Hong Kong or have in his possession for the purpose of selling in Hong Kong any proprietary Chinese medicine without a package insert which---

(a) includes the particulars set out in subsection (2); and

(b) has the particulars being clearly and distinctly set out and not in any way obscured or obliterated.

(2) A package insert of a proprietary Chinese medicine to be sold in Hong Kong shall include, at least in Chinese, the following particulars in respect of the medicine---

(a) the name of the medicine;

(b) if---

(i) the medicine is composed of less than 3 kinds of active ingredients, the name of each kind of active ingredient and its quantity; or

(ii) the medicine is composed of 3 or more kinds of active ingredients, the names of more than half of the total number of kinds of active ingredients and their respective quantities;

(c) either the name of the holder of the certificate of registration of the medicine as specified in the certificate or the name of the manufacturer who produces the medicine;

(d) its dosage and method of usage;
(e) its functions or pharmacological action;
(f) its indications (if any);
(g) its contra-indications (if any);
(h) its side-effects (if any);
(i) its toxic effects (if any);
(j) the precautions to be taken regarding its use (if any);
(k) its storage instructions; and
(l) its packing specification.

Part 10

Duration of Licences and Certificates

29. Duration of licences

(1) A licence issued under section 114(3), 115(3), 132(2) or 135(2) of the Ordinance shall be for a period of 2 years.

(2) A licence renewed under section 116(3) or 136(3) of the Ordinance shall be for a period of 2 years or for such shorter period as considered appropriate by the Medicines Board.

30. Duration of certificates

(1) A certificate issued under section 121(2) of the Ordinance shall be for a period of 5 years.

(2) A certificate renewed under section 123(3) of the Ordinance shall be for a period of 5 years or for such shorter period as considered appropriate by the Medicines Board.

(3) A certificate issued under section 133 of the Ordinance shall be for a period of 2 years or for such shorter period as considered appropriate by the Medicines Board.

Part 11

Offences and Penalties

31. Offences and penalties

A person who contravenes a provision of this Regulation set out in column 1 of Schedule 2 commits an offence and is liable on conviction to the penalty set out opposite that provision in columns 2 and 3 of that Schedule.

Part 12

Exemptions

32. Exemptions for applications for retailer licences

Section 114(2)(b) of the Ordinance shall not apply in respect of an application for a retailer licence if the application states that no Chinese herbal medicine is to be dispensed in the premises to which the application relates.

33. Exemptions for persons or institutions concerned

with education or scientific research

The Medicines Board may exempt, with or without conditions or restrictions, a person or institution concerned with education or scientific research from the application of sections 143 and 144 of the Ordinance if the proprietary Chinese medicine in question is required for the purpose of education or scientific research.

34. Exemptions for proprietary Chinese medicines imported for re-export and conducting clinical
trials or medicinal tests

Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is---

(a) imported by a wholesaler in proprietary Chinese medicines for the purpose of re-exporting by the same wholesaler; or

(b) imported by a holder of a valid certificate for clinical trial and medicinal test issued under section 129 of the Ordinance and to be used for the purpose of the clinical trial or medicinal test to which the certificate relates.

35. Exemptions for proprietary Chinese medicines manufactured in Hong Kong and to be
exported

Section 144 of the Ordinance shall not apply in the case where a person is in possession of a proprietary Chinese medicine manufactured in Hong Kong for the purpose of exporting the medicine.

36. Exemptions for proprietary Chinese medicines compounded by Chinese medicine practitioners
or in accordance with prescriptions given by
Chinese medicine practitioners

Sections 143 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine which is---

(a) compounded by or under the supervision of a registered or listed Chinese medicine practitioner at the premises where he practises if, and only if, such proprietary Chinese medicine is being used for the purpose of administering or supplying to a patient under his direct care; or

(b) individually prepared or compounded---

(i) by a responsible person; or

(ii) under the supervision of such person,

at the premises in respect of which a retailer licence is in force and in accordance with a prescription given by a registered or listed Chinese medicine practitioner.

37. Exemptions for proprietary Chinese medicine manufactured in accordance with

prescriptions
given by Chinese medicine practitioners and to
be administered or supplied to their patients

(1) Sections 119 and 144 of the Ordinance shall not apply in respect of a proprietary Chinese medicine if---

(a) the medicine is manufactured---

(i) in the premises in respect of which a manufacturer licence is in force; and

(ii) by or under the supervision of a responsible person in accordance with a prescription given by a registered or listed Chinese medicine practitioner;

(b) the medicine is---

(i) for internal application or both internal and external application, and the medicine is to be administered or supplied to the patient to whom the prescription is given and who is under the direct care of the Chinese medicine practitioner; or

(ii) for external application only, and the medicine is to be administered or supplied to a patient or patients under the direct care of the Chinese medicine practitioner; and

(c) the Medicines Board has received from the manufacturer, at least 1 working day before the day on which the manufacturing process of the medicine begins, a written notification including the particulars set out in subsection (2) and being accompanied by an undertaking referred to in subsection (3).

(2) A notification referred to in subsection (1)(c) shall include---

(a) the quantity of the medicine to be manufactured;

(b) the names and quantities of each ingredient listed in the prescription;

(c) its dose form;

(d) the name and address of the registered or listed Chinese medicines practitioner; and

(e) the date on which the Chinese medicine practitioner entrusts the manufacturer to manufacture the proprietary Chinese medicine.

(3) A notification referred to in subsection (1)(c) shall be accompanied by a written undertaking given by the registered or listed Chinese medicine practitioner to the manufacturer, stating that the medicine will only be administered or supplied to---

(a) (in the case where the medicine is for internal application or both internal and external application) the patient to whom the prescription is given and who is under his direct care; or

(b) (in the case where the medicine is for external application only) a patient or patients under his direct care.

Part 13
Forms
38. Certificate of sale of proprietary Chinese medicine

A certificate issued under section 130(1) of the Ordinance shall be in the form prescribed in Schedule 3.

39. Manufacturer licence

A licence issued under section 132(2) of the Ordinance shall be in the form prescribed in Schedule 4.

40. Certificate for manufacturer

A certificate issued under section 133 of the Ordinance shall be in the form prescribed in Schedule 5.

SCHEDULE 1 [ss. 3 & 5]

Minimum Requirements Regarding Knowledge and Experience of Responsible Persons

1. A responsible person nominated under section 114(2)(b) of the Ordinance shall---

(a) (i) hold a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 6 months' practical experience in dispensing Chinese herbal medicines in Hong Kong;

(b) (i) hold a diploma in Chinese medicines awarded by a university in Hong Kong;

(ii) hold a diploma in Chinese medicines awarded by the Vocational Training Council; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 1 year's practical experience in dispensing Chinese herbal medicines in Hong Kong;

(c) in the case where he is a registered or listed Chinese medicine practitioner, have 6 months' practical experience in dispensing Chinese herbal medicines in Hong Kong;

(d) in the case where he is a pharmacist registered under the Pharmacy and Poisons Ordinance (Cap. 138)---

(i) hold a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or

(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),

and have 1 year's practical experience in dispensing Chinese herbal medicines in Hong Kong;
(e) (i) hold a certificate in Chinese medicines awarded by a university in Hong Kong on completion of a 120 hour course;
(ii) hold a certificate in Chinese medicines awarded by the Vocational Training Council on completion of a 120 hour course; or
(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),
and have 3 years' practical experience in dispensing Chinese herbal medicines in Hong Kong; or
(f) have 5 years' practical experience in dispensing Chinese herbal medicines in Hong Kong.
2. A responsible person nominated under section 132(1)(b) of the Ordinance shall---
(a) (i) hold a bachelor's degree in Chinese medicine awarded by a university in Hong Kong; or
(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),
and have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;
(b) (i) hold a diploma in Chinese medicines awarded by a university in Hong Kong;
(ii) hold a diploma in Chinese medicines awarded by the Vocational Training Council; or
(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),
and have 1 year's practical experience in manufacturing proprietary Chinese medicines in Hong Kong;
(c) in the case where he is a registered or listed Chinese medicine practitioner, have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;
(d) in the case where he is a pharmacist registered under the Pharmacy and Poisons Ordinance (Cap. 138)---
(i) hold a postgraduate certificate in Chinese medicines awarded by a university in Hong Kong; or
(ii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i),
and have 6 months' practical experience in manufacturing proprietary Chinese medicines in Hong Kong;
(e) (i) hold a certificate in Chinese medicines awarded by a university in Hong Kong

on completion of a 120 hour course;

(ii) hold a certificate in Chinese medicines awarded by the Vocational Training Council on completion of a 120 hour course; or

(iii) have a qualification which, in the opinion of the Medicines Board, is equivalent to that mentioned in subparagraph (i) or (ii),

and have 3 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong; or

(f) have 5 years' practical experience in manufacturing proprietary Chinese medicines in Hong Kong.

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SCHEDULE 2 [s. 31]

Offences and Penalties

| Column 1 Section | Column 2 Fine | Column 3 Imprisonment |
|---|---|---|
| 7(h)(i) or (ii) | level 6 | 2 years |
| 7(k) | level 6 | -- |
| 8(1), (2) or (3) | level 6 | -- |
| 9(1) or (2) | level 6 | -- |
| 10 | level 6 | 2 years |
| 11(g)(iv), (v) or (vi) | level 6 | -- |
| 12 | level 6 | 2 years |
| 13(1), (2) or (3) | level 6 | -- |
| 14(1), (2) or (3) | level 6 | -- |
| 17(1), (2) or (3) | level 6 | -- |
| 18(1) or (2) | level 6 | -- |
| 19(1), (2) or (3) | level 6 | -- |
| 21(1), (2) or (3) | level 6 | -- |
| 23(1) | level 6 | 2 years |
| 24 | level 6 | 2 years |
| 26(1) | level 6 | 2 years |

SCHEDULE 3 [s. 38]

Certificate of Sale of Proprietary Chinese Medicine

Chinese Medicine Ordinance

(Chapter 549)

Certificate of Sale of Proprietary Chinese Medicine

Name of the proprietary Chinese medicine: (Chinese)

(English)

Dose form:

Packing specification:
Names and quantities of its active ingredients (as set out in a package insert of the medicine required to be supplied for its sales in Hong Kong):

Manufacturer(s) name:
Address:

It is certified that---
(a) the proprietary Chinese medicine specified in this Certificate is registered under section 121 of the Chinese Medicine Ordinance;
Certificate no.:
Date of registration:
(b) the premises in Hong Kong in which the proprietary Chinese medicine is manufactured are subject to regular inspections;
(c) other statements (if applicable):

The proprietary Chinese medicine is allowed to be sold in Hong Kong.
This Certificate is valid until _____.
Date of issue: _____
for Chinese Medicines Board
Hong Kong Special Administrative Region

SCHEDULE 4 [s. 39]
Manufacturer Licence
Chinese Medicine Ordinance
(Chapter 549)
Manufacturer Licence
_____ of

is licensed to manufacture proprietary Chinese medicines at

from _____ to (both dates inclusive),
subject to the conditions specified in this licence.
Dated this _____ day of _____
for Chinese Medicines Board
Hong Kong Special Administrative Region
CONDITIONS

SCHEDULE 5 [s. 40]

Certificate for Manufacturer

Chinese Medicine Ordinance

(Chapter 549)

Certificate for Manufacturer

(Good manufacturing practice in respect of proprietary Chinese medicines)

It is hereby certified that of

(1) is the holder of a manufacturer licence---

(a) Licence no.:

(b) Duration of licence:

(c) Date of issue: ;

(2) is licensed to manufacture proprietary Chinese medicines;

(3)

(the address of the premises in Hong Kong in which proprietary Chinese medicines are manufactured) is subject to regular inspections and the inspections show that the manufacturer follows the requirements of good practices in manufacture and quality control of proprietary Chinese medicines.

This Certificate is valid until _____.

Date of issue: _____

for Chinese Medicines Board

Hong Kong Special Administrative Region

Dr. TSE Chi-wai, Daniel

Chairman,

Chinese Medicine Council of Hong Kong

30 October 2002

Explanatory Note

This Regulation is made under section 161 of the Chinese Medicines Ordinance (Cap. 549)("the Ordinance"). The main purpose of the Regulation is to provide for the further regulation and supervision of the sale and manufacture of Chinese herbal medicines and proprietary Chinese medicines.

2. Part 1 comprising sections 1 and 2 is preliminary and, in section 2, the terms used in the Regulation are defined.

3. Part 2 provides for the licensing requirements in respect of applications for retailer, wholesaler and manufacturer licences (sections 3 to 6 and Schedule 1).

4. Part 3 specifies the duties of a holder of a retailer licence in Chinese herbal

medicines (sections 7 to 10).
5. Part 4 specifies the duties of a holder of a wholesaler licence in Chinese herbal medicines (sections 11 to 14).
6. Part 5 deals with particulars required to be registered for a proprietary Chinese medicine (section 15).
7. Part 6 specifies the duties of a holder of a manufacturer licence in proprietary Chinese medicines (sections 16 to 19).
8. Part 7 specifies the duties of a holder of a wholesaler licence in proprietary Chinese medicines (sections 20 and 21).
9. Part 8 provides for the requirements regarding the labelling of containers and packages of Chinese herbal medicines and proprietary Chinese medicines---
(a) section 22 provides for the manner in which a label is to be attached to or printed on a container of Chinese herbal medicines for the purposes of section 142 of the Ordinance;
(b) section 23 provides for the requirements in respect of a label attached to or printed on a container of Schedule 1 medicines by a wholesale dealer in Chinese herbal medicines;
(c) section 24 provides for the requirements in respect of a label attached to or printed on a container of Schedule 2 medicines by a wholesale dealer in Chinese herbal medicines;
(d) section 25 provides for the manner of labelling of packages of proprietary Chinese medicines for the purposes of section 143 of the Ordinance;
(e) section 26 provides for the requirements in respect of labels on packages of proprietary Chinese medicines to be sold in Hong Kong; and
(f) section 27 provides for the requirements in respect of labels on packages of proprietary Chinese medicines manufactured in Hong Kong which are to be exported.
10. Part 9 specifies the requirements of package inserts of proprietary Chinese medicines to be sold in Hong Kong for the purposes of section 144 of the Ordinance (section 28).
11. Part 10 specifies the duration of certain licences and certificates (sections 29 and 30).
12. Part 11 provides for offences and penalties in respect of contraventions of certain provisions of the Regulation (section 31 and Schedule 2).
13. Part 12 sets out the exemption provisions. Section 32 sets out the circumstances under which applications for retailer licences are exempt from section 114(2)(b) of the Ordinance. Sections 33 to 37 provide exemptions for certain proprietary Chinese medicines from the application of sections 119 (proprietary Chinese medicines to be registered), 143 (proprietary Chinese medicines to be labelled) and 144 (package

inserts for proprietary Chinese medicines) of the Ordinance.

14. Part 13 (sections 38 to 40) and Schedules 3, 4 and 5 prescribe the forms of a certificate of sale of proprietary Chinese medicines, a manufacturer licence and a certificate for manufacturer.