CODE OF PRACTICE FOR AUTHORIZED SELLER OF POISONS

2021
PHARMACY AND POISONS BOARD OF HONG KONG

TABLE OF CONTENT

INTRODUCTION

This code of practice for authorized seller of poisons (the Code) sets out the minimum standards of pharmacy practice for authorized sellers of poisons (ASPs). Its purpose is to provide to ASPs practical guidance and direction for conducting retail pharmacy business in their registered premises with the aim of safeguarding the interest of patients and the public, and promoting safe and effective pharmacy practice of ASP.

Compliance with the Code is one of the conditions upon which the Pharmacy and Poisons Board issues a Certificate of Registration of Premises to an ASP under section 13 of the Pharmacy and Poisons Ordinance (Cap. 138). An ASP must observe the standards set out in the Code and be aware that non-compliance with the Code may constitute misconduct and lead to disciplinary inquiry under section 16(2) of the Pharmacy and Poisons Ordinance (Cap. 138).

DEFINITION

"antibiotics" means the substances to which the Antibiotics Ordinance (Cap. 137) applies.

"authorized seller of poisons" or "ASP" means a registered pharmacist, body corporate or unincorporated body of persons (seller) that 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 under section 13 of the Pharmacy and Poisons Ordinance (Cap. 138) by a registered pharmacist or in his presence and under his supervision.

"controlled medicines" means any substance which is specified in Part 1 of Schedule 10, i.e. Poisons List, to the Pharmacy and Poisons Regulations (Cap. 138A), any substance to which the Antibiotics Ordinance (Cap. 137) applies, or any substance specified in Part I of the First Schedule to the Dangerous Drugs Ordinance (Cap. 134).

"dangerous drugs" means any of the drugs or substances specified in Part I of the First Schedule to the Dangerous Drugs Ordinance (Cap. 134).

"dispense" means supplying a medicine or poison on and in accordance with a prescription given by a registered medical practitioner, a registered dentist or a registered veterinary surgeon; and also means the compounding or mixing of substances, including poisons, and the supplying of the same.

"inspector" means the public officer authorized by the Chairman of the Pharmacy and Poisons Board in writing to be an inspector for the purposes of the Pharmacy and Poisons Ordinance (Cap. 138).

"label" means any statement forming part of or affixed to a container in which pharmaceutical products are sold, which statement may, subject to any regulations made under the Pharmacy and Poisons Ordinance (Cap. 138), be printed in English or Chinese.

"medicine" has the same meaning as in the definition of "pharmaceutical product".

"pharmaceutical product" -

(a) means a substance or combination of substances that—

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

(ii) may be used in or administered to human beings or animals with a view to—

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

(B) making a medical diagnosis; and

(b) includes an advanced therapy product[1].

"poison" means a substance which is specified in the Poisons List prescribed by under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138).

"psychotropic substance" means any substance specified in the "List of poisons which are psychotropic substances based on the United Nations 1971 Convention on Psychotropic Substances" in Appendix B which is maintained and updated by the Drug Office of the Department of Health in accordance with the United Nations 1971 Convention on Psychotropic Substances.

"registered pharmacist" means a person whose name has been entered on the register of pharmacists under section 5 of the Pharmacy and Poisons Ordinance (Cap. 138) and who has personal control of the registered premises of an authorized seller of poisons.

"registered premises" means premises of an authorized seller of poisons, where poisons are kept for the purposes of retail sale, registered under section 13 of the Pharmacy and Poisons Ordinance (Cap. 138).

[1] "advanced therapy product" means any of the following products that is for human use – (a) a gene therapy product; (b) a somatic cell therapy product; (c) a tissue engineered product. The relevant definitions of advanced therapy product, gene therapy product, somatic cell therapy product and tissue engineered product are set out in section 2 of the Pharmacy and Poisons Ordinance (Cap. 138).

“sell” includes-

(a) offer or expose for sale;

(b) supply without payment; and

(c) offer or expose for supply without payment,

and “sold” and “seller” shall be construed accordingly.

"sale by way of wholesale dealing" means the sale of goods to a person who is authorized by the Pharmacy and Poisons Ordinance (Cap. 138) to resell such goods.

SECTION 1: PREMISES

1.1 REGISTERED PREMISES OF AUTHORIZED SELLER OF POISONS

All aspects of the registered premises of an ASP must be well maintained to enable and facilitate a safe and effective working environment. An ASP must ensure that its registered premises are suitable for conducting retail sale of medicines and comply with all relevant legislation and all relevant guidelines issued from time to time by government departments.

a. Decor in all areas of the registered premises must be in good repair. The wall, ceiling and floor covering of the registered premises must be compliant with any relevant statutory requirements and any health, safety and environmental requirements issued by the relevant government departments including the Buildings Department and the Environmental Protection Department.

b. The registered premises must be maintained in a clean and orderly condition. Adequate lighting, ventilation and air conditioning must be provided. Temperature and humidity must be controlled with due regard to the requirements, if any, for the storage of pharmaceutical products within certain specified temperature parameters.

c. The Certificate of Registration of Premises, the name and the registration certificate of the registered pharmacist responsible for the professional activity of the ASP and a notice setting out the opening hours of the ASP and the attendance hours of the registered pharmacist must be displayed in a conspicuous place on the registered premises.

d. A safe and accessible entrance to the registered premises must be provided. Publicly accessible areas must be clear of stock and any obstructions.

e. An ASP must provide a telephone line for public enquiry for each set of its registered premises.

f. Medicine sales counters must not be cluttered.

g. The registered premises must have a security system that could minimize sabotage or theft of controlled medicines kept and of records containing information of its customers.

h. An ASP must ensure that the working environment of its registered premises enables compliance with the professional responsibilities of its registered pharmacist. An ASP must facilitate internal reporting by its registered pharmacist of any deficiency in the working environment of its registered premises. An ASP must ensure that the requisite facilities, equipment and materials are available to enable the provision of pharmacy service in its registered premises to the professionally accepted standards.

1.2 DISPENSING AREA

As most of the professional dispensing activities of an ASP take place in the dispensing area, the dispensing area must be of sufficient size to enable safe and proper storage, handling, compounding and preparation of pharmaceutical products.

a. The dispensing area must be maintained in good order. It must have clean floor covering and all surfaces must be clean, uncluttered, smooth and impervious to dirt and moisture.

b. The dispensing area must be well-lit and air-conditioned to ensure that the stock is stored under conditions appropriate to the nature and stability of the pharmaceutical products kept. The fixtures and fittings of the dispensing area must be adequate for the purpose for which they are intended. Washing facilities including water, sink and adequate drain should be available. A source of distilled or boiled water must be installed for the sole-purpose of dispensing.

c. The dispensing area must have lockable receptacles compliant with the statutory requirements for the safe storage of controlled medicines.

d. Dispensing area must be reserved for dispensing purpose only. It must be partitioned off or otherwise separated from other parts of the registered premises to avoid uninvited or unauthorized access. Customers are not permitted to have access to the dispensing area.

e. Disposal of pharmaceutical wastes (including expired or unserviceable medicines) must be conducted in a manner compliant with the relevant statutory requirements and the relevant guidelines issued by the Environmental Protection Department or other government departments. Waste medicines, whether expired stock or patient returns, must be stored separately from serviceable products and under the control of the registered pharmacist until removed for destruction. The Department of Health must be notified before disposal of any dangerous drug and the destruction process of any dangerous drug must be witnessed by an inspector.

1.3 DISPENSING FACILITIES

An ASP's registered premises must be equipped with a suitable operational range of equipments to enable provision of the range of pharmacy services it will provide in its registered premises. Equipments for dispensing must be kept in the dispensing area and properly maintained. The suitability, accessibility, maintenance and cleaning of dispensing equipments must be ensured to prevent any adverse impact on the quality of pharmaceutical products processed.

a. The dispensing area must have suitable equipments such as measures, mortar and pestle, spatula etc. for extemporaneous dispensing. The dispensing equipments must be for the sole purpose of preparing and dispensing medicines. They must be clean and properly maintained and stored in order to prevent contamination of pharmaceutical products.

b. An appropriate refrigerator that can maintain temperature between 2°C and 8°C must be designated solely for storage of pharmaceutical products in the dispensing area. The refrigerator must be lockable and large enough to store all medicines that need refrigeration. It must be cleaned regularly and appropriately maintained to ensure the integrity of storage conditions. A thermometer must be placed inside the refrigerator to monitor the temperature so as to ensure sustainability of the cold chain system. Food and beverage must never be stored in such a designated refrigerator.

c. Lockable receptacles reserved solely for storage of controlled medicines must be maintained in the dispensing area. The capacity of the receptacles must be sufficient to safely store all controlled medicines kept.

d. A suitable range of containers for dispensing must be available for the safe and appropriate supply of pharmaceutical products. Containers must not be reused under any circumstances.

e. Adequate labeling facilities must be present on site to enable compliance with the labeling requirements set out in Section 3.1 and in Appendix A.

f. Suitable equipment for counting tablets and capsules must be available in the dispensing area. Such counting equipment must be cleaned regularly to prevent cross-contamination of pharmaceutical products.

g. Adequate up-to-date reference books, statutes and regulations pertaining to the practice of ASP and to the sale and supply of pharmaceutical products must be provided for staff. Such references should include either hard or soft copy of the following and must be accessible by all staff during business hours:
    - Martindale (current or most previous edition);
    - medical dictionary;
    - Compendium of Pharmaceutical Products issued by the Drug Office of the Department of Health;
    - list of registered medical practitioners in Hong Kong published in the Gazette or maintained by the Medical Council of Hong Kong;
    - the Pharmacy and Poisons Ordinance and Regulations (Cap. 138);
    - the Antibiotics Ordinance and Regulations (Cap. 137);
    - the Dangerous Drugs Ordinance and Regulations (Cap. 134);
    - the Undesirable Medical Advertisements Ordinance (Cap. 231);
    - the Drug News and Safety Alerts issued by the Drug Office of the Department of Health; and
    - the Product List referred to in paragraph c of Section 3.3.

h. All registers, books and records required to be kept, including the dangerous drugs register, the prescription book, the poisons book, the antibiotics record and the psychotropic substances book, must be maintained in the dispensing area.

1.4 STORAGE AND STOCK

A comprehensive system must be put in place for the storage and maintenance of medicines subject to different level of control.

a. All Part 1 poisons, antibiotics, psychotropic substances and dangerous drugs must be kept in locked receptacles in the dispensing area and the key of which must be kept by the registered pharmacist. Dangerous drugs must be stored separately in a locked receptacle designated for storage of dangerous drugs only. The lockable receptacles where controlled medicines are kept for the purposes of sale must be under the personal control of the registered pharmacist present at the premises.

b. An ASP must ensure that all pharmaceutical products obtained and supplied conform to legal requirements and are registered in Hong Kong and supplied by licensed and/or reputable pharmaceutical traders only. An ASP must also ensure that the product package and the related advertisement of the products (e.g. pamphlets, signboards, etc) present on its registered premises comply with the requirements under the Undesirable Medical Advertisements Ordinance (Cap. 231).

c. Stocks of pharmaceutical products must be stored under conditions appropriate to the nature and stability of the product concerned. Particular attention must be paid to protection from contamination, sunlight, UV rays, moisture, and extreme temperature. Pharmaceutical products must not be stored in close proximity to areas where food and beverages are kept, prepared or consumed and must be stored in the manufacturer's original packaging. Any product received from the supplier which is found to be in packaging that is damaged or discolored must be quarantined and returned to the suppliers.

d. All stock of medicines kept in the registered premises must exhibit batch numbers and expiry dates. Mixing of stock of the same product from different batches in the same container must be avoided.

e. Medicines for external use should be stored separately from those for internal use.

f. Particular care must be exercised in storing different medicines with similar packaging or different strengths of medicines in similar packaging to minimize the occurrence of dispensing errors.

g. An ASP must proactively participate in the recall process for any substandard medicines. Upon receiving authentic information and recall notifications from the manufacturers, wholesalers or the Department of Health, an ASP must initiate the recall and immediately inspect its stock kept, remove the recalled medicine from sale and display and store them in a designated area which is, where the recalled medicine is a controlled medicine, under the control of the registered pharmacist, for return to the suppliers or for disposal (if applicable) as soon as possible in an appropriate manner. Appropriate information must be provided to customers on how to safely dispose of recalled medicines. The initiation, progress and completion of the recall must be well documented.

h. When a delivery of medicines is received by an ASP, the invoice or delivery note must be examined for the presence of controlled medicines. If there are controlled medicines among the medicines delivered, they must be separated immediately and locked in the receptacle for storage of such medicines and, where applicable, appropriate entry must be made in the relevant register, book or record. The receipt of the controlled medicines must be attended to and signed by the registered pharmacist and thereafter returned to the suppliers.

SECTION 2: MANAGEMENT AND STAFF

An ASP must ensure that the retail sale of controlled medicines is conducted on registered premises by a registered pharmacist or in his presence and under his supervision.

a. An ASP must in the month of January in each year send to the Secretary of the Pharmacy and Poisons Board a list showing the address of each set of its registered premises together with the name of the registered pharmacist having personal control of such premises.

b. An ASP must ensure that retail sale and storage of controlled medicines are confined to its registered premises only. An ASP must obtain the approval of the Pharmacy and Poisons Board prior to any change in the address or layout of such premises.

c. An ASP or any person assigned by an ASP as the person-in-charge of running its business (PIC) must be a person considered fit and proper by the Pharmacy and Poisons Board to carry on the retail sale of poisons.

d. An ASP must obtain the approval of the Pharmacy and Poisons Board prior to any change in its proprietorship, partnership, directorship or PIC.

e. An ASP must ensure that all processes and activities conducted on its registered premises are carried out in a manner compliant with the relevant legislations, which include but are not limited to:
   - the Pharmacy and Poisons Ordinance (Cap. 138);
   - the Dangerous Drugs Ordinance (Cap. 134);
   - the Antibiotics Ordinance (Cap. 137);
   - the Radiation Ordinance (Cap. 303);
   - the Public Health and Municipal Services Ordinance (Cap. 132);
   - the Undesirable Medical Advertisements Ordinance (Cap. 231);
   - the Chinese Medicine Ordinance (Cap. 549)
   - the Waste Disposal Ordinance (Cap. 354);
   - the Trade Descriptions Ordinance (Cap. 362); and
   - the Personal Data (Privacy) Ordinance (Cap. 486)

f. An ASP must take all reasonable steps to ensure that its business is being operated in a manner which is in compliance with the Code.

g. An ASP must ensure that for not less than two-thirds of the hours of each day the premises are open for business its registered pharmacist is present at the premises and exercises control and supervision over the persons employed therein.

h. An ASP must not seek to unduly influence, direct, control or interfere in the professional practice of or performance of statutory duties by its registered pharmacist, including his exercise of personal control and supervision over the staff employed by the ASP in handling pharmaceutical products and the sale of controlled medicines conducted by him on its registered premises.

i. An ASP should encourage its registered pharmacist to report to the healthcare professionals and the Department of Health any suspected adverse drug reactions. This is important as it may have an effect on the future treatment of patients or the future use of a particular medicine.

j. An ASP must, with the assistance from its registered pharmacist, establish procedures and provide training for all its staff to ensure that they act in accordance with the law in force at the time when handling pharmaceutical products.

k. An ASP must ensure that all its staff involved in sale of pharmaceutical products are provided with a suitable period of orientation training and are familiar with the statutory requirements on the sale, receipt and storage of pharmaceutical products.

l. An ASP must ensure that all its staff involved in sale of pharmaceutical products on its registered premises are trained to carry out such duties and are competent to fulfill the duties assigned to them, in particular that they are fit to conduct the retail sale of medicines and that they are able to communicate effectively with the customers attending the premises. It is the ASP's responsibility to carry out checks on previous employment records of all individuals employed. A training record of all its staff involved in sale of pharmaceutical products must be kept on its registered premises.

m. An ASP must ensure that any advertising and promotional activities of professional pharmacy services or of pharmaceutical products on the registered premises are lawful, decent and truthful and that such activities comply with the Undesirable Medical Advertisements Ordinance (Cap. 231).

n. An ASP must provide full co-operation to the inspector in his carrying out of the statutory duties and must not prevent its staff, whenever they are duly requested to do so, from providing to the inspector information and particulars relating to the identity of its owner.

SECTION 3: SERVICES AND SYSTEM OF OPERATION

3.1 SALE AND SUPPLY OF MEDICINES

The registered premises of an ASP should be used mainly for retail sale of medicines and such business must be conducted in accordance with the requirements under the Pharmacy and Poisons Ordinance (Cap. 138) and other relevant legislation, which include the following:

a. Controlled medicines must only be sold on the registered premises by the registered pharmacist or in his presence and under his supervision.

b. Dispensing of Schedule 3 poisons, dangerous drugs and antibiotics must only be conducted in accordance with a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. The prescription must only be dispensed on the registered premises by the registered pharmacist or in his presence and under his supervision.

c. Pharmaceutical products must be supplied in their original packing to avoid errors in the repacking process, unless the pharmaceutical products to be supplied are properly labeled and are either dispensed in accordance with a prescription requiring dispensing in exact quantity or are dispensed by a registered pharmacist according to his professional assessment.

d. Controlled medicines must not be made available for self selection by customers and must be kept within the dispensing area of the registered premises.

e. Part 1 Schedule 1 poisons must only be sold to a purchaser who is a fit and proper person. An ASP must not deliver Part 1 Schedule 1 poisons until an entry has been made in the poisons book and the entry has been signed by the purchaser and countersigned by the registered pharmacist who is responsible for or supervises the sale.

f. An ASP may only supply controlled medicines by way of wholesale dealing to a purchaser for the purpose of his trade, business or profession if a written order signed by the purchaser is obtained before the completion of the sale. Where the controlled medicines supplied are Part 1 Schedule 1 Poisons, the medicines may also be supplied in accordance with the record keeping requirements as set

out in Section 3.4(d). For supply of controlled medicines on written order, the following particulars must be stated in the written order:

- the date on which it is written;
- name and address of the purchaser;
- trade, business or profession of the purchaser;
- name and quantity of the product to be purchased;
- the purpose for which it is required; and
- the signature of the purchaser.

g. Where a Part 1 Schedule 1 poison is supplied urgently to a purchaser for the purpose of his trade, business or profession, and the purchaser is unable before delivery either to furnish a signed written order or to attend the registered premises and sign the entry in the poisons book, the Part 1 Schedule 1 poison may be delivered to the purchaser on the condition that it is reasonably satisfied that the purchaser requires the poison by reason of some emergency and that the purchaser undertakes to furnish a written signed order within 48 hours after the delivery.

h. An ASP must comply strictly with the mandatory requirements for labeling of dispensed medicines set out in Appendix A in dispensing medicines.

i. Medicines for sale must be adequately labeled in accordance with the statutory requirements and the labels affixed to the pack of the medicines must appear in a proper position.

j. The label affixed to the medicines must be clear and legible in English or Chinese. Where the medicines are not medicines containing Part 1 poisons, the dosage and the route and frequency of administration must be labeled in both English and Chinese. The special needs of certain patients such as those with poor eyesight must be accommodated as far as possible.

k. If medicines are supplied in their original packing, the label must be affixed in such a manner that any statements appearing on the original packing that are important to the patient, including the batch number, the storage conditions of the medicines, the expiry date, and the name and strength of the medicines, are left visible.

l. An ASP must provide appropriate and sufficient advice to a customer to facilitate his safe and effective use of the medicine purchased.

3.2 DISPENSING MEDICINES UNDER THE AUTHORITY OF A PRESCRIPTION

Ensuring patient's safety is the primary focus of the process of medicine dispensing upon a prescription. Medicines dispensed must be assessed as appropriate for the persons to whom the medicines are supplied and delivered in a manner that ensures diligence and care in the receipt, review, assembling, checking and recording of the prescription.

a. Dispensing of medicines must be carried out by or in the presence and under the supervision of the registered pharmacist having the personal control of the registered premises where the registered pharmacist practices his profession.

b. Prescription-only medicines must not be dispensed unless the prescription complies with the statutory requirements which include the following:
   (i) the name and address of the prescriber is specified;
   (ii) it is in writing and is signed and dated by the prescriber; where the medicine prescribed contain dangerous drugs, it must be written in ink or otherwise so as to be indelible;
   (iii) the name, address and, where the medicines prescribed contain dangerous drugs, identity card number of the person to whom the medicines are to be supplied are specified;
   (iv) if given by a registered veterinary surgeon, the name of the person to whom the medicine is to be delivered is specified;
   (v) the total amount of the medicines to be supplied is indicated;
   (vi) the dose to be taken or administered is specified;
   (vii) if the drugs prescribed are dangerous drugs and some or all of them are preparations,
      - the total amount of the preparation or of each preparation, as the case may be, is specified; or
      - when the preparation is packed in ampoules, it is specified as aforesaid or the total amount of the preparation or of each preparation, as the case may be, intended to be administered or injected is specified;
   (viii) if given by a registered dentist, the statement "For dental treatment only 祇限牙科醫療用" or, where the medicine prescribed contains dangerous drugs, the statement "For local dental treatment only 僅供本地牙科治療之用" is written on it; and
   (ix) if given by a registered veterinary surgeon, the statement "For animal treatment only 祇限醫治禽畜用" or, where the medicine prescribed contains dangerous drugs, the statement "For animal treatment only 僅供動物治療之用" is written on it.

c. Prescription must not be dispensed more than once unless the prescriber has directed that it could be dispensed a stated number of times or at stated intervals. Prescription must not be dispensed before the date specified in the prescription.

d. Where a prescriber specifies a particular branded product on the prescription, the registered pharmacist is required to dispense the product specified. The registered pharmacist cannot supply a different equivalent brand without consulting the prescriber concerned, except where such supply is covered by a brand substitution agreement entered into in advance by both the pharmacist and the prescriber concerned.

e. Where a prescriber only specifies the generic name of a medicine on the prescription, the brand name and the Hong Kong registration number of the medicine dispensed must be recorded on the prescription.

f. An ASP must not supply any expired medicine or such medicine where it is likely that the course of treatment will continue beyond the expiry date specified on the medicine.

g. When the dispensing of a prescription is completed, the prescription must be endorsed as per the relevant legislation with the name and address of the registered premises of the ASP and the date of supply of the medicines above the signature of the prescriber appearing on the prescription. The prescription or, where the prescription is a repeat prescription, a copy of the prescription must be retained and kept by the ASP on the premises for two years from the date of dispensing.

h. Records of each dispensing must be maintained on the registered premises in accordance with statutory requirements.

3.3 PROCUREMENT AND INVENTORY SYSTEM

An ASP must develop and maintain a safe and effective operational procurement and inventory management system.

a. The pharmaceutical products must be purchased from licensed pharmaceutical traders only.

b. Acquisition of controlled medicines from the manufacturers, wholesalers or other retailers must be by way of a written order such as an electronic order.

c. A product list (the Product List) for pharmaceutical products stored in dispensing area must be maintained in accordance with the classification of pharmaceutical products adopted by the Pharmacy and Poisons Ordinance (Cap. 138), the Antibiotics Ordinance (Cap. 137), the Dangerous Drugs Ordinance (Cap. 134) and the List of poisons which are psychotropic substances in Appendix B. The Product List must specify the restrictions on the sale, supply and requirements on storage of the products. It must be reviewed and updated when necessary so that staff involved in the handling of pharmaceutical products are aware of the legal classification and the corresponding requirements on receipt, supply and storage of the products.

d. All controlled medicines received from suppliers must be checked against the written order to ensure correctness of the medicines delivered. The quantity, batch number and expiry date of the medicines must be verified against the sales invoices. Any discrepancies of such information must be brought to the notice of the supplier and suitable rectifications must be done.

3.4 RECORD KEEPING

Proper record keeping is important for effective control of medicines. An ASP must devise suitable procedures to keep and to maintain registers, books, records and documents in accordance with the requirements under the Pharmacy and Poisons Ordinance (Cap.138), the Antibiotics Ordinance (Cap.137), the Dangerous Drugs Ordinance (Cap.134) and the Code.

a. Registers, books or records required to be kept must be maintained by way of bound record books.

b. Dangerous Drugs Register

(i) A dangerous drugs register must be kept solely for recording the true particulars with respect to every quantity of dangerous drugs obtained and supplied. The entries in the register must be recorded in chronological sequence in the form specified in the First Schedule to the Dangerous Drugs Regulations (Cap. 134A) as set out in Appendix C. A separate page within the register or separate part of the register must be used for entries made with respect to different dangerous drugs and different strengths of preparations comprised within the class of dangerous drugs to which that register or separate part relates and the balance of the amount of the dangerous drugs kept must be maintained. The class of the dangerous drug and, where applicable, the particular dangerous drug and the particular strength of the preparation comprised within such class to which the entries on the page relate must be specified at the top of that page. Each entry must be made on the day of receipt or supply of the dangerous drugs, or, if it is not reasonably practicable, on the following day.

(ii) No cancellation, obliteration or alteration of any entry on the dangerous drugs register is allowed. A correction can only be made by way of a marginal note or footnote specifying the date of such correction.

(iii) Each entry or correction must be made in ink or other indelible form.

(iv) Only one register is allowed to be kept at one time in respect of each class of dangerous drug on each set of registered premises.

c. Prescription Book

A prescription book must be kept for recording the details of dispensing medicines. Registered pharmacist must enter the following particulars into the prescription book on the day on which the medicine is dispensed, or, if it is not reasonably practicable, on the following day:

- the date on which the medicine was dispensed;
- the ingredients of the medicine and the quantity of the medicine supplied;
- the name of the prescriber, the name and the address of the person to whom the prescription was given, and the date on which the prescription was given.

d. Poisons Book

A poisons book must be kept for recording only the sale of Part 1 Schedule 1 poisons save those poisons included in Schedule 3. Subject to Section 3.1(f), an ASP must make an entry in the poisons book with the following particulars before delivery of such poisons to the purchaser:

- date of sale;
- name and quantity of poison sold;
- name of purchaser;
- identity card number of the purchaser;
- address of the purchaser;
- business, trade or occupation of the purchaser;
- purpose for which it was stated to be required by the purchaser;
- name and address of the person by whom a certificate under s.22(1)(a) of the Pharmacy and Poisons Ordinance (Cap.138) was given (if applicable);
- signature of the purchaser; and
- signature of the registered pharmacist.

e. Antibiotics Record

Antibiotics record must be kept for recording every transaction of antibiotics except when the antibiotics are dispensed in accordance with a prescription and the prescription is properly retained in accordance with the relevant legislation. Registered pharmacist must enter the following particulars into the antibiotics record:

- the name and address of person from whom or to whom the antibiotics are received or supplied;
- if the antibiotics are received from or supplied to the holder of an Antibiotics permit, the serial number of such permit;
- the name and quantity of the antibiotics received or supplied; and
- the date on which the antibiotics are received or supplied.

f. Psychotropic Substances Book

Psychotropic substances book must be kept for recording every transaction of psychotropic substances, including those supplied on and in accordance with a prescription. Registered pharmacist must keep a psychotropic substances book according to the specified format in Appendix D with the following particulars entered therein:

- the date on which the psychotropic substances were received or supplied;
- the name and address of person from whom or to whom the psychotropic substances are received or supplied;
- the amount of the psychotropic substances received or supplied;
- the invoice number (if applicable); and
- the balance of the amount of the psychotropic substances kept.

A separate page within the book or separate part of the book must be used for entries made with respect to different psychotropic substances and different strengths of preparations comprised within the class of psychotropic substances to which that book or separate part relates and the balance of the amount of the psychotropic substance kept must be maintained. The class of the psychotropic substances and, where applicable, the particular psychotropic substance and the particular strength of the preparation comprised within such class to which the entries on the page of the book relate must be specified at the top of that page. Each entry must be made on the day of receipt or supply of the psychotropic substances, or, if it is not reasonably practicable, on the following day.

g. All registers, books, records and documents required to be maintained must be kept in the registered premises and made available for inspection at reasonable times.

h. Registers, books and records must be kept for a period of two years from the date of the last entry therein.

i. Entries made in registers, books and records must be supported by relevant transaction documents. In the case of antibiotics record, entries made must be supported by invoice, order note or other voucher and such supporting documents must be kept for a period of two years from the date of the transaction and be open for inspection. Documents in support of entries made in the dangerous drugs register are required to be kept for a period of two years

from the date on which they are issued or made. Prescriptions relating to entries made in the prescription book must, except in the case of a prescription which may be dispensed again, be retained and kept for a period of two years on the premises on which it was dispensed in such a manner that they may be readily available for inspection. Documents in support of entries made in the poisons book and the psychotropic substances book are required to be kept for a period of two years from the date of the transaction.

j. All written orders for acquisition of controlled medicines and corresponding sales invoices must be kept for inspection for a period of two years from the date of the transaction.

k. An ASP and its registered pharmacist must ensure compliance with the Personal Data (Privacy) Ordinance (Cap. 486) in handling customer information. The trust and confidence established between the registered pharmacist and the patient must not be dishonored.

APPENDIX A
MANDATORY REQUIREMENTS FOR LABELING OF DISPENSED MEDICINES

1. The following types of medicine are required to be labeled:

   (a) all medicines dispensed against “prescriptions” of registered medical practitioners, dentists or registered veterinary surgeon;
   (b) all “Part 1 Schedule 1” poisons dispensed by registered pharmacists, other than on prescription, except those supplied in their original and properly-labeled packaging*; and
   (c) all medicines, other than types (a) and (b) above, dispensed by or in the presence of registered pharmacists, except those supplied in their original and properly-labeled packaging*.

   * Original and properly-labeled packaging means packaging in which the medicine is supplied by the drug manufacturer or wholesaler.

2. All labeling should contain the following essential information:

   (a) name of patient;
   (b) date of dispensing;
   (c) name and address of the dispensary;
   (d) trade name or pharmacological name of the medicine;
   (e) dosage per unit;
   (f) method and dosage of administration; and
   (g) precautions where applicable.

3. Exemptions to the above are only allowed when the patients’ consulting doctors/dentists so specify in the prescription.

Pharmacy and Poisons Board of Hong Kong
2021

APPENDIX B
LIST OF POISONS WHICH ARE PSYCHOTROPIC SUBSTANCES BASED ON THE UNITED NATIONS 1971 CONVENTION ON PSYCHOTROPIC SUBSTANCES

1.	Allobarbital	阿洛巴比妥	14.	Meprobamate	甲丙氨酯
2.	Amineptine	阿米庚酸	15.	Methylphenobarbital	甲苯比妥
3.	Amobarbital	异戊巴比妥	16.	Methyprylon	甲乙哌酮
4.	Buprenorphine	丁丙諾啡	17.	Pemoline	匹莫林
5.	Butalbital	布他比妥	18.	Pentazocine	噴他佐辛
6.	Butobarbital	丁巴比妥	19.	Pentobarbital	戊巴比妥
7.	Cyclobarbital	環己巴比妥	20.	Phenobarbital	苯巴比妥
8.	Ethchlorvynol	乙氯維諾 (乙氯戊烯炔醇)	21.	Pipradrol	哌苯甲醇
9.	Ethinamate	炔己蟻胺	22.	Pyrovalerone	吡咯戊酮
10.	Fencamfamin	芬坎法明	23.	Secbutabarbital	仲丁比妥
11.	Glutethimide	格魯米特	24.	Vinylbital	乙烯比妥
12.	Lefetamine	勒非他明	25.	Zolpidem	唑吡坦
13.	Mazindol	馬吲哚	26.	any salt or preparation of any of the above 任何上述物質之鹽類或製劑	

APPENDIX C
FORM SPECIFIED IN THE FIRST SCHEDULE TO THE DANGEROUS DRUGS REGULATIONS (CAP. 134A)

Date of receipt/ supply	Name and address of person* or firm from whom received/ to whom supplied	Patient's identity card number #	Amount		Invoice No.	Balance
			received	supplied		

* *Only cross reference of the person to whom supplied may be made, in which case, only the reference number of the person's treatment record needs to be given.*

\# *For a patient who is not resident in Hong Kong, the reference number of any proof of identity, other than an identity card, specified in section 17B(1) of the Immigration Ordinance (Cap 115) must be inserted.*

APPENDIX D
FORMAT OF PSYCHOTROPIC SUBSTANCES BOOK

Name of Preparation			Unit of Quantity	
Date	Supplier or to whom supplied	Invoice No./ Order Note No./ Prescription No.	Quantity	Balance