
CODE OF PRACTICE FOR AUTHORIZED SELLER OF POISONS

2012
PHARMACY & POISONS BOARD OF HONG KONG

(DRAFT VERSION)

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INTRODUCTION

The code of practice for authorized seller of poisons (the Code) sets out the standards of professional practice for all authorized seller of poisons (the ASP) conducting retail pharmacy business at the premises of authorized seller of poisons (registered premises). These standards are set to protect patients and the public and to promote the safe and effective practice of pharmacy at the registered premises. The core of the pharmacy activity is to help patients make the best use of medicines.

The ASP must make sure that all the standards set out in the Code are met.

The purpose of the Code is intended to provide practical guidance and direction to the ASP in conducting retail pharmacy business at the registered premises and to set the minimum standards of good pharmacy practice for all ASPs. Compliance to the Code is one of the licensing conditions when issuing Certificate of Registration of Premises under Section 13 of Pharmacy & Poisons Ordinance to an ASP. Non-compliance to the code may constitute misconduct and the ASP may be liable to disciplinary proceedings by the Disciplinary Committee under Section 16(2) of Pharmacy & Poisons Ordinance, Cap. 138.

SECTION 1: PREMISES

1.1 PREMISES OF AUTHORIZED SELLER OF POISONS

All aspects of the registered premises shall be well maintained. The registered premises shall enable and facilitate a safe and effective working environment.

- a. Decor in all area of the registered premises shall be in good repair, the wall, ceiling and floor covering shall be compliant with any legislative requirements and in accordance with all health, safety and environmental requirements.
- b. The registered premises shall be maintained in a clean and orderly condition, adequate lighting, ventilation and air conditioning shall be provided. Temperature and humidity shall be controlled with due regard to the requirements to store pharmaceutical products within certain specified temperature parameters.
- c. The Certificate of Registration of Premises, notice relating to opening hours and attendance hours of pharmacist, the name and the registration certificate of the registered pharmacist responsible for the professional activity of the ASP shall be displayed in a conspicuous place to the public.
- d. A safe and accessible entrance to the registered premises shall be provided. Publicly accessible areas shall be clear of stock and any other obstructions.
- e. The registered premises shall operate with a telephone line for public enquiry.
- f. Medicine sales counters shall not be cluttered.
- g. The registered premises shall have a security system that could minimize sabotage or theft of stocks, records and other assets.

1.2 DISPENSING AREA

As majority of the professional dispensing activity of the ASP occurs in the dispensing area, the dispensing area shall be of sufficient size for the safe and proper storage, handling, compounding and preparation of pharmaceutical products.

- a. The dispensing area shall be maintained in good order. The dispensing area shall be free from all sources of contamination, have clean floor covering and all surfaces shall be clean, uncluttered, smooth and impervious to dirt and moisture.
- b. The dispensing area shall be well-lit and air-conditioned to ensure the stock is stored under suitable conditions, appropriate to the nature and stability of the product concerned. The fixtures and fittings in the dispensing area shall be adequate for the purpose for which they are intended. Hand washing facilities with water, sink and adequate drain should be available. A source of distilled or boiled water shall also be available for the sole-purpose of dispensing if necessary.
- c. The dispensing area shall have lockable receptacles compliant with legislative requirements for the safe storage of Part I poisons, dangerous drugs and antibiotics.
- d. Dispensing area should be reserved for dispensing purpose only. It shall be partitioned off or otherwise separated from the remainder of the premises to discourage uninvited or unauthorized access. Customers are not permitted to have access to the dispensing area.
- e. Disposal of pharmaceutical waste (including expired or unserviceable controlled medicines) shall be conducted in a manner complying with legislation and guidelines of the relevant departments (such as Environmental Protection Department). Waste medicines, whether expired stock or patient returns, shall be stored separately from serviceable products and under the control of the registered pharmacist until removed for destruction. The Department of Health shall be notified before disposal of any dangerous drug and the destruction process shall be witnessed by inspector.

1.3 EQUIPMENT

Equipment for dispensing shall be located in the dispensing area and properly maintained. The suitability and accessibility, maintenance and cleaning of equipment shall be ensured to prevent any adverse impact on the quality of pharmaceutical products processed therein.

- a. The dispensing area shall have a suitable range of equipment for extemporaneous dispensing if necessary such as balance, measures, mortar & pestle, funnels, tile and spatula etc. The dispensing equipment shall be for the sole purpose of preparing and dispensing medicines. They shall be clean and properly maintained, and stored in order to prevent contamination of products.
- b. An appropriate refrigerator that could be maintained between 2°C and 8°C shall be designated for storage of pharmaceutical products. The refrigerator shall be lockable and large enough to store refrigerated medicines while adequate airflow and uniform temperature in the interior are maintained. It shall be cleaned regularly and appropriately maintained to ensure the integrity of storage conditions. A thermometer shall be placed to monitor temperature to ensure the sustainability of cold chain system. Food and beverage shall never be stored in the refrigerator designated for the storage of pharmaceutical products.
- c. Lockable receptacles solely for storage of controlled medicines shall be maintained in the dispensing area. The capacity of the receptacles shall be sufficient to safely store all controlled medicines. The lockable receptacles where controlled medicines are kept for the purposes of sale shall be under the personal control of a registered pharmacist present at the premises. The keys to the receptacles shall be kept only by the registered pharmacist.
- d. A suitable range of containers for dispensing shall be available for the safe and appropriate supply of product. Containers shall not be reused under any circumstances.
- e. Adequate labeling facilities shall be present on site. All written information and instructions on labels for dispensed medicines shall be clear and legible to customers. Refer to section 3.1 and Appendix A for the labeling requirements.
- f. A suitable means of counting tablets and capsules shall be available. This equipment shall be cleaned regularly and routinely to prevent

cross-contamination of products.

- g. Adequate references shall be provided for staff and shall be adequately stocked with up-to-date reference books, journals and statutory regulations pertaining to the practice of ASP and to the sale and supply of pharmaceutical products. Essential references shall also be prepared. They should include either hard or soft (including electronic) copy of the followings which shall be accessible by all personnel 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;
 - Gazette of registered medical practitioners in Hong Kong or list of registered doctors maintained by the Medical Council of Hong Kong;
 - The Pharmacy & Poisons Ordinance and Regulations (Cap. 138);
 - The Antibiotics Ordinance and Regulations (Cap. 137);
 - The Dangerous Drugs Ordinance and Regulation (Cap. 134);
 - The Undesirable Medical Advertisements Ordinance (Cap. 231);
 - The News Bulletin and Alerts on Drugs issued by the Drug Office of the Department of Health and
 - A product list specifying forensic classification of the pharmaceutical products stocked in the dispensing area to ensure relevant personnel are aware of the statutory restrictions on the sale and supply of these products.
- h. Adequate record books meeting the requirements set down in The Pharmacy & Poisons Ordinance, The Antibiotics Ordinance, The Dangerous Drug Ordinance and condition specified on Certificate of Registration of Premises in respect of all psychotropic substances scheduled under the 1971 Convention of Psychotropic Substances shall be maintained.

1.4 STORAGE AND STOCK

A comprehensive system shall be in place for the control and maintenance of appropriate level of controlled medicines which is held within prescribed storage conditions and facilities.

- a. All Part I poisons, antibiotics, psychotropic substances and dangerous drugs shall be kept in locked receptacles in the dispensing area, the key to which shall be kept only by the registered pharmacist. Dangerous drugs shall be stored separately in a receptacle for storage of dangerous drugs only.
- b. ASP shall ensure all pharmaceutical products obtained and supplied must be registered in Hong Kong and conform to legal requirements. ASP shall not purchase or supply any pharmaceutical products, unless the quality, safety, efficacy and genuineness can be assured. ASP shall ensure all the products supplied are from reputable traders and exercise reasonable diligence to avoid obtaining counterfeit/unregistered pharmaceutical products or products adulterated with unlabelled western medicines. ASP shall also ensure the product package and the related advertisement of the products (e.g. pamphlets, signboards, etc) found in the premises shall comply with the provision of The Undesirable Medical Advertisement Ordinance.
- c. Stocks of pharmaceutical products shall be stored under suitable conditions, appropriate to the nature and stability of the product concerned. Particular attention shall be paid to protection from contamination, sunlight, UV rays, moisture, and extreme temperature. They shall not be stored in close proximity to areas where food and beverages are stored, prepared or consumed. During storage, pharmaceutical products shall be retained in the manufacturer's original packaging. Any product received in packaging that is damaged or discolored shall be quarantined and returned to suppliers.
- d. All stock of medicines in the registered premises shall have batch numbers and expiry dates. Mixing of stock of the same product from different batches in same container shall be avoided.
- e. Medicines for external use shall preferably be stored separately from those meant for internal use.
- f. Particular care shall be exercised in the storage of different medicines presented

in similar packaging, and of different strengths of medicines presented in similar packaging. To minimize the incidence of a dispensing error, similarly packaged pharmaceutical products shall not be stored adjacent to each other on the shelves or receptacles in the dispensing area. The problem of inadvertent dispensing of the wrong medicine due to similar packaging can be overcome by educating staff, and by making sure all staffs are aware of products which are prone to such dispensing errors.

- g. The ASP shall proactively participate in the recall process for any substandard medicines. All such recalls shall be initiated upon receiving authentic information and recall notifications from the manufacturers, wholesalers or the Department of Health. ASP shall immediately inspect and remove stock from shelves and refrigerators. They shall be stored in a designated area, under the control of the registered pharmacist (for controlled medicines only), for return to suppliers or disposal (if applicable) as soon as possible in an appropriate manner. Appropriate information shall be provided to patients on how to safely dispose of expired or unwanted medicines. The initiation, progress and completion of the recall shall be well documented.

- h. When a delivery is received by the ASP, the invoice or delivery note shall be examined for the presence of controlled medicines. If there are Part I poisons, antibiotics, psychotropic substances or dangerous drugs, they shall be separated immediately, entered into the relevant register (if applicable) and locked in receptacle for storage of medicines. The receipt of these medicines shall be attended to and signed by the registered pharmacist. The signed document shall be returned to the suppliers no later than 48 hours from the date of receipt of the medicines if a signed written order had not been forwarded to the supplier before the completion of the sale.

SECTION 2: STAFF AND SUPERVISION

2.1 AUTHORIZED SELLER OF POISONS

The ASP must comply with the legal requirements and requirements of the Code in conducting retail sale of controlled medicines on registered premises. The ASP shall ensure the retail sale of controlled medicines is conducted on registered premises by a registered pharmacist or in his presence and under his supervision.

- a. The ASP shall pay a prescribed fee for the initial registration and for renewal of registration of premises each year.
- b. The ASP shall in the month of January in each year send to the Secretary of the Pharmacy and Poisons Board a list showing the addresses of all sets of registered premises together with the name of the registered pharmacist having personal control of each such set of premises.
- c. The ASP shall ensure that retail sale and storage of controlled medicines are confined to the registered premises only. The ASP shall obtain the approval of the Pharmacy & Poisons Board prior to any change in the address or layout of such premises.
- d. The ASP or any other person assigned by an ASP as person-in-charge of running the business (PIC) must be a fit and proper person to the satisfaction of the Pharmacy and Poisons Board.
- e. The ASP shall obtain the approval of the Pharmacy and Poisons Board prior to any change in the proprietorship, partnership, directorship, or PIC of the ASP.
- f. The ASP shall ensure that the registered premises is suitable for the purpose of conducting the retail sale of medicines, and complies with all relevant legislation and appropriate guidance issued. In addition, the registered premises shall be fully equipped with a suitable operational range of equipment to safely provide for the range of pharmacy services provided.
- g. The ASP shall ensure that all processes and activities conducted in the registered premises are carried out in a manner compliant with applicable legislation including, but not limited to:
 - Pharmacy and Poisons Ordinance (Cap. 138);

- Dangerous Drugs Ordinance (Cap. 134);
 - Antibiotics Ordinance (Cap. 137);
 - Radiation Ordinance (Cap. 303);
 - Public Health and Municipal Services Ordinance (Cap. 132);
 - Undesirable Medical Advertisements Ordinance (Cap. 231);
 - Chinese Medicine Ordinance (Cap. 549)
 - Waste Disposal Ordinance (Cap. 354);
 - Trade Descriptions Ordinance (Cap. 362); and
 - Personal Data (Privacy) Ordinance (Cap. 486)
- h. The ASP shall only deal in radioactive substances if it holds a radioactive substance licence and shall comply with the Guidelines of Good Practices for Preparation of Radiopharmaceutical Products in Authorized Seller of Poisons.
- i. The ASP shall take reasonable steps to ensure that the business is being operated in accordance with the Code.
- j. The ASP shall ensure each set of registered premises where controlled medicines are kept for the purpose of retail sale is under the personal control of a registered pharmacist who is engaged in or employed and present at the registered premises for at least two-thirds of the hours of each day the premises are opened for business.
- k. The ASP or the PIC shall ensure that all sales of controlled medicines are conducted in the registered premises by the registered pharmacist or in his presence and under his supervision.
- l. The ASP shall ensure the registered pharmacist is responsible for exercising personal control of each set of registered premises where poisons are kept for the purpose of retail sale.
- m. The ASP shall not interfere with the registered pharmacist in exercising personal control and supervision over the persons employed therein and the sale of all controlled medicines conducted in the registered premises.
- n. The ASP shall ensure the environment within which the registered pharmacist practice enables compliance with his professional responsibility. The ASP shall facilitate the registered pharmacist in reporting any apparent deficiency in an

environment which is not in accordance with safe practice. The ASP shall ensure that the requisite facilities, equipment and materials are available to enable the provision of pharmacy service to accepted standards

- o. The ASP shall encourage the registered pharmacist reports to the healthcare professional and the Department of Health for any suspected adverse drug reactions (ADRs). This is important as it may have an effect on the future treatment of the patients, or the future use of the particular medicine.
- p. The ASP shall not seek to unduly influence, direct, control or interfere with the legal duties of the registered pharmacist. Any non-compliance will be regarded as a failure on the part of the ASP to provide a proper standard of professional services.
- q. The ASP shall seek assistance from the registered pharmacist in establishing procedures and providing training for all employees to ensure that they act in accordance with the current law at all time.
- r. The ASP shall ensure that all staff members are provided with a suitable period of orientation training, and familiar with the legislative requirements on the sale, receipt and storage of all pharmaceutical products in particular controlled medicines.
- s. The ASP shall ensure that all personnel employed to carry out duties under the registered premises are trained and 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 clients attending the premises. It is the ASP's responsibility to carry out prior reference checks in respect of all individuals employed. A training record shall be kept in the registered premises.
- t. The ASP shall ensure that any advertising and promotional activities for professional services or pharmaceutical products in the registered premises are legal, decent and truthful. It should also comply with the Undesirable Medical Advertisements Ordinance.
- u. The ASP shall provide full co-operation to the inspector and ensure all his employees giving information which they are duly required and particulars sufficient to identify the owner of the business.

- v. In the case of proceedings against a person under the Pharmacy & Poisons Ordinance Cap. 138 for or in connection with the sale, exposure for sale or supply of a poisons effected by an employee-
 - (i) it shall not be a defence that the employee acted without the authority of the ASP; and
 - (ii) any material fact known to the employee shall be deemed to have been known to the ASP.

- w. The ASP may be subjected to inquiry by the Disciplinary Committee of the Pharmacy and Poisons Board when-
 - (i) the ASP or his employee is convicted of a drug-related offence; or
 - (ii) a complaint is received by the Board regarding the conduct of the ASP or his employee.

SECTION 3: SERVICES AND SYSTEM OF OPERATION

3.1 SALE AND SUPPLY OF MEDICINES FROM AUTHORIZED SELLER OF POISONS

An ASP should mainly involve in the business of retail sale of medicines in accordance with the provisions of the Pharmacy & Poisons Ordinance Cap. 138 and other relevant statutory provisions which includes the following:

- a. All Part I poisons shall be sold in the registered premises by the registered pharmacist or in his presence and under his supervision.
- b. All Third Schedule poisons, dangerous drugs and antibiotics shall only be supplied or dispensed in accordance with a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon. The prescription must be dispensed by the registered pharmacist present at the registered premises or in his presence and under his supervision. (Refer to Section 3.2 Dispensed Medicines Under the Authority of a Prescription)
- c. Pharmaceutical products shall be supplied in their original packing to avoid errors in the repacking process, except when it was supplied on and in accordance with a prescription which is required by law to be dispensed in exact quantity as directed or it is dispensed by the registered pharmacist according to his professional assessment with proper labeling.
- d. Part I poisons (other than those poisons included in the First and Third Schedule) shall not be available for self selection by a customer and shall be kept in dispensing area of the registered premises.
- e. All Part I First Schedule Poisons shall only be sold if the purchaser is a fit and proper person. Furthermore, the seller shall not deliver the poisons until he has made an entry in the poisons book and the entry is signed by the purchaser and countersigned by the registered pharmacist who is responsible for or supervises the sale.
- f. An ASP shall comply strictly with the guideline on mandatory labeling of all dispensed medicine as directed by the Pharmacy & Poisons Board (enclosed in Appendix A) in supplying dispensed medicines. Labeling of all the dispensed medicines should contain the following information:

- Name of patient;
 - Date of dispensing;
 - Name, address and telephone number of the registered premises;
 - Name of the medicine;
 - Dosage per unit;
 - Method and dosage of administration; and
 - Precaution where applicable.
- g. The label shall be firmly attached to the immediate container unless the immediate container is so small or is so constructed that the label would compromise the patient's ability to use the medicine; metered aerosols and some eye drops are examples. In such instances, the pharmacist should exercise professional judgment to decide whether the label shall be attached to the primary pack or alternatively, purpose-designed labeling tags may be used.
- h. The label shall be clear and legible with unambiguous and understandable English or Chinese; other languages that are accurate translations appropriate to the patients may be used additionally. The special needs of patients such as those with poor eyesight shall be accommodated if possible.
- i. If medicines are supplied in original packaging, the label shall be affixed appropriately so that any of the manufacturer's statements that may be important to the patient are left visible. including the manufacturer's name and address, expiry date (unless inappropriate e.g. reconstituted antibiotic mixtures and eye drops), batch number, storage conditions and where possible, the name and strength of the medicine.
- j. Patients shall receive appropriate and sufficient advice to facilitate the safe, effective use of the medicine and ensure they are empowered in the management of their own health status.
- k. The ASP shall only supply Part I poisons, antibiotics and dangerous drugs by way of wholesale dealing if a written order signed by the purchaser is obtained before the completion of the sale.
- l. Where a poison is supplied urgently to a purchaser for the purpose of his trade, business or profession, who is unable before delivery either to furnish a signed written order or to attend to the registered premises and sign the entry in the

Poisons book, the poisons 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 the purchaser furnish a written signed order within 48 hours after the transaction.

3.2 DISPENSING MEDICINES UNDER THE AUTHORITY OF A PRESCRIPTION

Dispensing means supplying prescription only medicines (which includes Part I Third scheduled poisons, antibiotics and dangerous drugs) on and in accordance with a prescription. Ensuring patient's safety is the primary focus of the dispensing process, the prescribed medicines must be assessed as appropriate for that individual; and delivered in a manner which reflects diligence and care in the receipt, review, assembling, checking and recording of the prescription.

- a. All dispensing of medicines shall be carried out by or in the presence and under the supervision of the registered pharmacist having the personal control of the registered premises who bears the associated legal liability and professional responsibility for the dispensing.
- b. Prescription only medicines shall not be dispensed unless the prescription complies with the statutory requirements. The prescription shall :
 - contain the name and address of the prescriber;
 - be in writing, signed and dated by the prescriber;
 - contain the name, address and identity card number (applicable to a prescription containing dangerous drugs) of the person to whom the poisons is to be supplied;
 - contain the name of the person to whom the medicine is to be delivered if the prescription is given by a registered veterinary surgeon;
 - contain the total quantity of the poisons supplied;
 - contain the dosage to be administered and if any, direction or instruction for such purpose; and
 - have written the words “For dental treatment only 祇限牙科醫療用” (“For local dental treatment only 僅供本地牙科治療之用” in case of dangerous drugs) if given by a registered dentist; or
 - have written the words “For animal treatment only 祇限醫治禽畜用” (“For animal treatment only 僅供動物治療之用” in case of dangerous drugs) if given by a registered veterinary surgeon.
- c. As a general rule, Prescription shall not be dispensed more than once unless it is a repeat prescription specifying it could be dispensed a stated number of times or at stated intervals. Prescription shall 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 prescriber concerned.

- e. ASP shall not supply any medicine after its expiry date or any short-dated medicine where it is likely that the course of treatment will continue beyond the expiry date specified on the medicine.
- f. All dispensed medicines shall be properly labeled in accordance with the guidelines on mandatory labeling of all dispensed medicines as directed by the Pharmacy & Poisons Board in Appendix A and information on the labels shall be clear and legible.
- g. When the dispensing of a prescription is completed, it shall be endorsed as per relevant legislation, with the name and address of the registered premises and the date of supply on the prescription above the signature of the prescriber. The prescription (in the case of a repeat prescription is dispensed, a copy of the prescription) shall be preserved by the ASP in the premises for two years from the date of its last dispensing. The prescription shall be dispensed in its entirety as instructed by the prescriber and no prescription shall be dispensed more than once unless the prescription expressly states that it may be dispensed a stated number of times or at stated intervals. .
- h. Where a prescriber only specifies the generic name of a medicine on the prescription, the brand name of the medicine dispensed and the corresponding Hong Kong registration number shall be recorded on the prescription.
- i. Records of each dispensing must be maintained in the registered premises in accordance with legislative requirements. (Refer to Section 3.4 Record Keeping for records requirements)

3.3 PROCUREMENT AND INVENTORY SYSTEM

A safe, effective and operational procurement and inventory management system shall be developed and maintained by an ASP.

- a. The pharmaceutical products shall be purchased from licensed pharmaceutical traders only. ASP shall exercise reasonable diligence to avoid obtaining counterfeit/unregistered pharmaceutical products or products adulterated with unlabelled western medicines.
- b. Acquisition of controlled medicines from the manufacturers, wholesalers or other retailers shall be on a written order.
- c. A "Product List" shall be maintained for pharmaceutical products stored in dispensing area with corresponding classification in accordance with Pharmacy & Poisons Ordinance, Antibiotics Ordinance, Dangerous Drugs Ordinance and List of poisons which are psychotropic substances in Appendix B. The list shall specify the restriction on the sale and supply as well as items required to be stored in lockable receptacles in dispensing area. The Product List shall be reviewed and updated when necessary so that relevant personnel aware of the forensic classification and corresponding requirements on receipt, supply and storage.
- d. All controlled medicines received from suppliers shall be checked for correctness of identity against the written order and verified the quantity, batch number and expiry date against the invoices. Any anomalies shall be brought to the notice of the supplier and suitable rectifications shall be done.
- e. The signed written orders and corresponding sale invoices shall be retained for two years from the date of which they are issued or made or not less than the expiry date of the controlled medicines concerned whichever period is longer.

3.4 RECORD KEEPING

An ASP must recognize the importance of record keeping. Suitable procedures shall be provided that allows records to be maintained in compliance with requirements set out in the law, the Code and other relevant guidelines.

- a. Record keeping requirements for the dispensing of prescriptions and other supplies or receipt of controlled medicines are set down in the Pharmacy and Poisons Ordinance, Antibiotics Ordinance, Dangerous Drugs Ordinance and Guidelines for Psychotropic Substances. These records are preferably maintained in bound record books except otherwise required by law.
- b. All the registers and documents shall be kept at the registered premises available for inspection at all times. The registers and records shall be kept for a period of two years from the date on which the last entry is made. In the case of any other documents, they shall be retained for a period of two years from the date on which it is made or the transaction occurred except otherwise specified.
- c. The registered pharmacist and the ASP shall be aware of the Personal Data (Privacy) Ordinance (Cap. 486) and ensure that they are familiar with the practical implications. The trust and confidential relationship shared between the registered pharmacist and the patient must not be dishonored.
- d. **Dangerous Drug Register**
Dangerous drug register must be a book used solely for recording the true particulars with respect to every quantity of dangerous drugs obtained and supplied in chronological sequence in form specified in First Schedule of Dangerous Drugs Regulations (see appendix C). Each product/ strength must be entered on a separate page within the register or separate part of the register and balances must be maintained. The name and strength of the dangerous drug must be specified at the top of each page to which the entries on that relate. Entries must be made in the dangerous drug register on the day of receipt or supply of dangerous drugs, unless it is not reasonably practicable, the entry must be made on the following day.

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

Each entry or correction must be made in ink or other indelible form. Therefore, a register stored electronically in a computer will not fulfill the requirement.

The dangerous drug register must be used only for recording transaction of dangerous drugs. Only one register is allowed to be kept in respect of the same dangerous drug at the same registered premises.

e. Prescription book

Prescription book shall be kept for recording the details of prescription dispensed. Registered pharmacist must enter the following particulars into the prescription book on the day on which the medicine is dispensed, unless it is not reasonably practicable, the entry must be made on the following day:

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

f. Poisons book

Poisons book shall be kept for recording every sale of Part I First Schedule only poisons, other than those poisons included in the Third schedule. The seller of the Part I First schedule poisons shall make an entry in the Poisons book with the following particulars before delivery of the medicines to purchaser:

- date of sale;
- name and quantity of poison sold;
- name of purchaser;
- identity card number of purchaser;
- address of purchaser;
- business, trade or occupation of purchaser;
- purpose for which stated to be required by purchaser;
- date of certificate (if applicable);
- name and address of person giving certificate (if applicable);
- signature of purchaser, or reference number of signed order in case of wholesale; and
- signature of registered pharmacist.

g. Antibiotics Record

Antibiotics record shall be kept for recording every transaction of antibiotic

except when antibiotics are dispensed in accordance with a prescription and that the prescription book and the prescription are properly maintained. Registered pharmacist shall enter the following particulars into the Antibiotics record:

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

h. Psychotropic Substances Record Book

Psychotropic substances record book is used for recording every transaction of psychotropic substances, including those supplied under the authority of a prescription. Registered pharmacist shall keep a psychotropic substances record book according to specified format in Appendix D of the Code with the following particulars:

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

Each product/ strength of the psychotropic substance shall be entered on a separate page within the record book or separate part of the record book and balances shall be maintained. The name and strength of the psychotropic substances shall be specified at the top of each page to which the entries on that relate. Entries shall be made in the record book on the day of receipt or supply of psychotropic substances, unless it is not reasonably practicable, the entry shall be made on the following day.

i. Signed Order

When Part I poisons, antibiotics or dangerous drugs are supplied by way of wholesale dealing to authorized purchasers for the purpose of his trade, business or profession, a written order signed by the purchaser shall be obtained before the completion of the sale, the following particulars shall be stated:

- 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 article to be purchased;
- the purpose for which it is required; and
- a reference number that allows the written order to be distinguished from other written orders used by the person ordering the pharmaceutical products.

If an authorized purchaser urgently requires a Part I poison for the purpose of his trade, business or profession and by reasons of some emergency, unable before delivery either to furnish to the ASP a signed written order or attend to the registered premises and sign the entry in the Poisons Book, the ASP could deliver the Part I Poison to the authorized purchasers on an undertaking by the purchaser to furnish such an order within 48 hours after the transaction.

- j. All signed written orders and corresponding sales invoices shall be readily available for two years from the date of the transaction, or not less than the expiry date of the controlled medicines concerned whichever period is longer for inspection. If maintained electronically, adequate secure backups shall be in place.

APPENDIX A

MANDATORY LABELING OF ALL DISPENSED MEDICINES

PHARMACY & POISONS BOARD

HONG KONG

香港藥劑業及毒藥管理局

Your Ref.:
貴處檔號

Our Ref.:
本局檔號

Tel No.: 961 8652
電話

圖文傳真 Fax No.: 891 7946

PB 10/70

Wu Chung House, 17th floor
213 Queen's Road East
Wan Chai, Hong Kong

香港灣仔皇后大道東 213 號
胡忠大廈 17 樓

19 December 1994

All Pharmacists registered with the
Pharmacy and Poisons Board of Hong Kong

Dear Registered Pharmacist,

Mandatory Labelling of all Dispensed Medicines

Subsequent to the issuance of my letter of 25 October 1994 on the captioned subject, the Pharmacy and Poisons Board of Hong Kong has further considered the matter. I am now directed by the Board to write to you again to clarify some details which are to be included in the labeling and also the types of medicine that are covered by this mandate. This letter-therefore supersedes my earlier circular letter of 25 October 1994.

New Disciplinary Provision

With effect from 1 January 1995, all registered pharmacists are required to properly label the following types of medicine:-

- (1) all medicines dispensed against "prescriptions" of registered medical practitioners and/or dentists;
- (2) all "Part I First Schedule" poisons dispensed by registered pharmacists, other than on prescription, except those supplied in their original and properly-labelled packaging*; and
- (3) all medicines, other than types (1) and (2) above, dispensed by or in the presence of registered pharmacists, except those supplied in their original and properly-labelled packaging*.

*[Original and properly-labelled packaging meaning packaging in which the medicine is supplied by the drug manufacturer or whole-saler]

Communications to be addressed to the Secretary
來函請寄秘書收

All labelling 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) precaution where applicable.

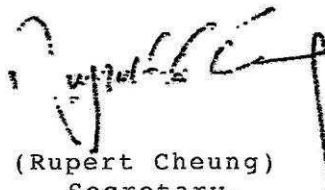
Exemptions to the above are only allowed when the patients' consulting doctors/dentists so specify in the prescription forms.

I am further directed by the Pharmacy and Poisons Board to remind you that any failure on your part to comply with the above disciplinary provision may render yourself liable for disciplinary proceedings, in accordance with provisions of the Pharmacy and Poisons Ordinance, Cap. 138 of the Laws of Hong Kong.

Enquiries

Should you have any queries, please contact the Pharmaceutical Service Head Office of the Department of Health at telephone no. 961 8754 or your own professional societies.

Yours sincerely,



(Rupert Cheung)
Secretary,

Pharmacy & Poisons Board of Hong Kong

APPENDIX B

LIST OF POISONS WHICH ARE PSYCHOTROPIC SUBSTANCES

| | | | |
|------------------|--------------|---|--------------|
| 1. Allobarbitol | 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. Methypylon | 甲乙哌酮 |
| 4. Buprenorphine | 丁丙诺啡 | 17. Pemoline | 匹莫林 |
| 5. Butalbitol | 布他比妥 | 18. Pentazocine | 喷他佐辛 |
| 6. Butobarbital | 丁巴比妥 | 19. Pentobarbital | 戊巴比妥 |
| 7. Cyclobarbitol | 环己巴比妥 | 20. Phenobarbital | 苯巴比妥 |
| 8. Ethchlorvynol | 乙氯维诺(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. Secbutabarbitol | 仲丁比妥 |
| 11. Glutethimide | 格鲁米特 | 24. Vinylbital | 乙烯比妥 |
| 12. Lefetamine | 勒非他明 | 25. Zolpidem | 唑吡坦 |
| 13. Mazindol | 马吗啉 | 26. any salt or preparation of any of the above | 任何上述物质之盐类或制剂 |

APPENDIX C

FORM SPECIFIED IN FIRST SCHEDULE OF DANGEROUS DRUGS ORDINANCE

| 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 | | |
| | | | | | | |

* 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) shall be inserted.

APPENDIX D

FORMAT OF PSYCHOTROPIC SUBSTANCES RECORD BOOK

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

GLOSSARY

“Antibiotics” means the substances to which Antibiotics Ordinance (Cap. 137) applies.

“Authorized seller of poisons” mean a business comprising the retail sale of poisons carried on by a registered pharmacist or by a body corporate or an unincorporated body of persons where the actual sale of poisons is conducted on premises duly registered under section 11 of the Pharmacy & 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 the Part I & Part II of the Poisons List Regulations (Cap. 138B), any substance to which Antibiotics Ordinance (Cap. 137) applies and any substance specified in Part I of the First Schedule of Dangerous Drugs Ordinance (Cap. 134).

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

“Dispense” has the meaning assigned to it by Section 2 of Pharmacy & Poisons Ordinance (Cap. 138).

“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 Pharmacy and Poisons Ordinance.

“Label” has the meaning assigned to it by Section 2 of Pharmacy and Poisons Ordinance (Cap. 138).

“Pharmaceutical Product” or “Medicine” has the meaning assigned to it by Section 2 of Pharmacy and Poisons Ordinance (Cap. 138).

“Poison” means a substance which is specified in the Poisons List under Poisons List Regulations (Cap. 138B).

“Psychotropic substance” means any substance specified in the “List of poisons which are psychotropic substances” (see appendix A) maintained and updated by Pharmaceutical Service of Department of Health in accordance with the Convention on Psychotropic Substances, 1971.

“Registered” has the meaning assigned to it by Section 2 of Pharmacy & Poisons Ordinance (Cap. 138).

“Registered pharmacist” means the pharmacist having personal control of the registered premises of the Authorized Seller of Poisons where actual sale of poisons is conducted by him or in his presence and under his supervision.

“Registered premises” means premises of an authorized seller of poisons where it is authorized to sell poisons under Section 11 of Pharmacy and Poisons Ordinance (Cap. 138).

“Sell” has the meaning assigned to it by Section 2 of Pharmacy & Poisons Ordinance (Cap. 138).

"Sale by way of wholesale dealing" has the meaning assigned to it by Section 2 of Pharmacy & Poisons Ordinance.