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Website: http//www.ppa.hk E-mail: info@ppa.hk Fax: 3003 0112

17 April 2012

Dr Heston Kwong
Assistant Director
Department of Health
HKSAR

RE: Urgent Request for Consultation on the revised Code of Practice for Authorized Seller of Poisons

Dear Dr Kwong,

On behalf of The Practising Pharmacists Association of Hong Kong, we would like to formally request for the opportunity to be invited by the Hong Kong Department of Health in the consultation meetings for developing a revised version of the Code of Practice for Authorized Seller of Poisons (ASP).

We are of the view that in order for the government to properly conduct a consultation process in reviewing any government policy, regulations, and/or legislations to be effective in collecting meaningful feedback, gain consensus on the majority of stakeholders' views, and to facilitate the successful implementation of the new policies, it is important that the government will take all actions to ensure that key stakeholders, that will be affected by the policy changes, be given an opportunity to have a formal and proper consultation by the government.

We would like to raise our concerns regarding the fact that The Practising Pharmacists Association of Hong Kong, as one of the largest pharmacy professional bodies in Hong Kong and as the only association representing the views of the vast majority of pharmacists working in the community sector, had not been given the opportunity to be invited to the consultation meetings held by the government to review and make recommendations to the Authorised Seller of Poisons Code of Practice.

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We would like to bring to the attention of the government due to the fact that the pharmacist practising in the community is one of the most important stakeholders in the Authorized Seller of Poisons (ASP) operations and also due to the fact that the Authorized Seller of Poisons Code of Practice sets the standards for the roles and responsibility of the pharmacist working in the Authorised Seller of Poisons operations, any changes to the Authorized Seller of Poisons Code of Practice requirements has a direct impact on current pharmacy practice in the community pharmacy setting, it is important for the government to understand that the professional views of the majority of community pharmacists is absolutely necessary to be included in the consultation process relating to any changes in the Authorised Seller of Poisons Code of Practice.

We are seriously concerned that if the government does not have a good comprehension of the views of the majority of pharmacists that will be asked to comply with the standards set forth by the revised Authorised Seller of Poisons Code of Practice, the revised Authorised Seller of Poisons Code of Practice will be ineffective in delivering its stated purpose and thus public interests will not be effectively protected.

We would like to advise the government that is in the case if the standards of an ineffective Authorised Seller of Poisons Code of Practice be adopted by the government and community pharmacists find that the new standards to be ineffective to provide the necessary level of protection to ensure for public safety, it will be necessary for the community pharmacy sector to hold our first strike activity in the history of Hong Kong as a demonstration of our ethical duty as a practising pharmacist to warn the public at large of the risks involved in accepting the ineffective standards of the newly proposed Authorised Seller of Poisons Code of Practice.

Finally, it has also come to our attention that the attached “Draft Authorised Seller of Poisons Code of Practice ” document may have been disseminated by the government without the knowledge of the majority of pharmacists working in the Authorised Seller of Poisons operations.

As the attached document has been forwarded to our Association from an non-government organization, we would like to confirm with the Department of Health if this is the actual document that the government has developed for discussion with all stakeholders of the pharmacy profession.

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We have been informed by a third party that the deadline to provide feedback on the Authorised Seller of Poisons Code of Practice is 20 April 2012. We believe that this deadline is unreasonably short and a proper consultation process to collect the views of all key stakeholders would not be achievable.

We would also like to have the official confirmation from the government regarding the deadline for the consultation process for the revised Authorised Seller of Poisons Code of Practice. We would expect the period for consultation to be of a more reasonable time frame and at least three months from the date the government officially requests for our Association's consultation.

We would like to express our regret that members of the pharmacy profession are experiencing a high level of distress and confusion as a result of the dissemination of such document by the government to a few selected stakeholders of the pharmacy profession and without providing a proper communication to pharmacists, currently working in the Authorised Seller of Poisons, to inform them of the proposed changes to the Authorised Seller of Poisons Code of Practice. .

The Practising Pharmacists Association of Hong Kong is of the view that pharmacist should be entitled to basic rights as any other Hong Kong citizen and we would like to exercise our "Right to Know" and the " Right to Express our Views " through proper consultation processes conducted by the government in regards to the changes to the Authorised Seller of Poisons Code of Practice.

We sincerely hope that the government of Hong Kong will continue to respect the rights of pharmacists in Hong Kong in the same manner that other pharmacists practising in other countries are respected by their respective governments and to continue to respect the role of The Practising Pharmacists Association of Hong Kong to represent the majority voice of the pharmacists working in the community sector as we have been respected in the past 40 years since our establishment in 1972.

As The Practising Pharmacists Association of Hong Kong have professional members working in all sectors of pharmacy practice, it is the expectation of our members that the government would include the representatives of The Practising Pharmacists Association of Hong Kong in the formal consultation processes to represent our members' views in regards to any changes to be made in the future relating to pharmacy practice and law

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requirements in all sectors.

In view of the urgency of the situation, we hope to have your kind confirmation and reply within seven days of this letter in regards to the matters relating to the revision of the Authorised Seller of Poisons Code of Practice.

Yours faithfully,

Iris Chang
President
The Practising Pharmacists Association of Hong Kong

Encl.

CC:
Dr PY Lam, Director of Health, Department of Health, HKSAR
Ms Linda Woo, Chief Pharmacist, Department of Health, HKSAR
Hong Kong General Chamber of Pharmacy
The Health Panel, LEGCO

CODE OF PRACTICE FOR AUTHORIZED SELLER OF POISONS

2012
PHARMACY & POISONS BOARD OF HONG KONG

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INTRODUCTION

The code of practice for authorized seller of poisons (the Code) sets out the standards for authorized seller of poisons (the ASP) and registered pharmacists employed or engaged in relation to carrying on a retail pharmacy business at the premises of authorized seller of poisons (registered premises). These standards are set to protect patients and the public from professional misconduct 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. It is important for ASP to supply pharmaceutical products of assured quality, to provide appropriate information and advice to the patients or public and to monitor the effects of uses.

The ASP and registered pharmacists who are responsible for providing pharmacy services within the registered premises must make sure that all the standards set out in the Code are met.

The purpose of the Code is to provide practical guidance and direction to the ASP and registered pharmacists employed or engaged in the practice of pharmacy at the registered premises which determines minimum standards of good pharmacy practice as well as minimum conduct and requirements of pharmacy profession. 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. **ALL** ASP and registered pharmacists shall study the Code carefully, in order to avoid the danger of transgressing accepted standards of pharmacy practice or conduct for pharmacy profession. Breach of the Code is regarded as infringement of the licensing conditions which may render themselves liable for disciplinary proceedings by the Disciplinary Committee under Section 16(2) of Pharmacy & Poisons Ordinance, Cap. 138.

Note:

**Authorized seller of poisons: is currently defined in section 2(1) of the Pharmacy & Poisons Ordinance Cap. 138 to mean "a business authorized to sell poisons under section 11". In order to reflect the usage of this term throughout Cap. 138 and its subsidiary legislations to mean "an entity who carries on a business", the definition of "Authorized seller of poisons" is revised accordingly to mean a registered pharmacist, a body corporate or an unincorporated body of persons that is authorized to carry on a business comprising the retail sale of poisons under section 11 of the Pharmacy & Poisons Ordinance Cap, 138 and referred to as "authorized seller of poisons" throughout the Code.*

SECTION 1: PREMISES

1.1 PREMISES OF AUTHORIZED SELLER OF POISONS

All aspects of the registered premises shall be well maintained to reflect the professional role of the registered pharmacist employed or engaged therein in the partnership delivery of pharmaceutical services. 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 surfaces are clean, uncluttered, smooth and impervious to dirt and moisture.

b. The design of the dispensing area shall discourage uninvited and unauthorized access. Public access to the dispensing area shall be prohibited. 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 and sinks shall be clean with running water and adequate drain. A source of distilled or boiled water shall also be available.

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.

e. Disposal of pharmaceutical waste (including expired or unserviceable pharmaceutical products) 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 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 solely in the custody of the registered pharmacist at all time.

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 drugs 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

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 legitimate stock which is held within prescribed storage conditions and facilities.

a. An appropriate control shall be in place to ensure the control, accessibility, receipt, storage and maintenance of stock.

b. There shall be adequate security provisions in place to safeguard the pharmaceutical products from sabotage, theft, and contamination.

c. Controlled medicines including all Part I poisons, antibiotics, psychotropic substances and dangerous drugs must be locked in receptacles in the dispensing area and appropriately stored in locations preventing misuse and errors. Dangerous drugs shall be stored separately in a receptacle for storage of dangerous drugs only. The lockable receptacles where controlled medicines are kept and the keys to the receptacles shall be under the personal control of a registered pharmacist present at the premises. The keys of the lockable receptacles shall be in the sole custody of the registered pharmacist at all time.

d. 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 (e.g. pamphlets, signboards, etc) found in the premises of the products it supplied shall comply with the provision of The Undesirable Medical Advertisement Ordinance.

e. 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.

f. 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.

g. Medicines for external use shall preferably be stored separately from those meant for internal use. 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.

h. A record (paper record or computer system) of the expiry date of the medicines in stock shall be in place. The expiry dates of the stocks shall be checked regularly. All stock which has reached expiry date shall be removed for disposal or destruction.

i. 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. The initiation, progress and completion of the recall shall be well documented and in compliance with the pharmaceutical products recall guidelines published by the Department of Health. All pharmaceutical products returned to the ASP for recall or destruction shall be immediately removed from all inventory sources to prevent further dispensing or distribution. They shall be stored in a designated area, under the control of the registered pharmacist, for 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.

j. 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 controlled medicines, they shall be removed 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 retails sale of medicines, and complies with all relevant legislation and appropriate guidance issued.

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 take reasonable steps to ensure that the business is being operated in accordance with the Code, and that appropriate policies, management and record keeping are in place.

i. 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 open for business. The ASP or the PIC shall ensure that all sale of controlled medicines are conducted by the registered pharmacist or in his presence and under his supervision.

j. The ASP shall not intervene the registered pharmacist in exercising personal control and supervision over all sale of controlled medicines conducted in the registered premises as well as the persons employed therein.

k. 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.

l. 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.

m. 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.

n. The ASP shall ensure that any advertising and promotional activity for professional services or pharmaceutical products in the registered premises is legal, decent and truthful. It should also comply with the Undesirable Medical Advertisements Ordinance.

o. The ASP shall ensure that the registered premises is fully equipped with a suitable operational range of equipment to safely provide for the range of pharmaceutical services provided.

p. The ASP shall ensure that full co-operation be provided to the inspector, to disclose all requests for information which he is duly required and particulars sufficient to identify the owner of the business.

q. 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.

r. 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.

s. The ASP may be subjected to inquiry by the Disciplinary Committee of the Pharmacy and Poisons Board when the ASP or his employee is convicted of a drug-related offence or found guilty of misconduct.

2.2 REGISTERED PHARMACIST

Registered pharmacist refers to the registered pharmacist employed or engaged at the premises of an ASP who is responsible for the supervision or the actual sale of poisons conducted at registered premises as stipulated by section 11 of the Pharmacy & Poisons Ordinance Cap 138 and the duties specified in this section. Accordingly, the registered pharmacist accepts the legal responsibility in performing professional activity of the ASP which includes dispensing and compounding of medicines, and the provision of all pharmacy services. The professional activities should be conducted in the presence and under the supervision of the registered pharmacist, for the time period within which that registered pharmacist is present. Additional responsibilities and accountabilities will be required of a registered pharmacist fulfilling supervisory professional role.

a. The registered pharmacist shall be accountable for all professional activities carried out in the ASP.

b. The registered pharmacist shall be responsible for conducting or supervising the actual sale of poisons in the registered premises

c. The registered pharmacist shall be responsible for exercising personal control of each set of registered premises where poisons are kept for the purpose of retail sale.

d. The registered pharmacist shall be present at the registered premises and exercise control and supervision over the persons employed therein for not less than two-thirds of the hours of each day the premises are open for business.

e. The registered pharmacist shall be responsible for assisting the ASP to establish procedures for the ASP and all employees to ensure that they act in accordance with the current law and best practice at all time.

f. The registered pharmacist shall not at the same time be engaged in employment with another authorized seller of poisons unless he has obtained the written authority of the Pharmacy and Poisons Board.

g. The registered pharmacist shall provide proper training to all personnel operating within an ASP to ensure they are aware of the limits and scope applicable to the management of the professional services provided.

h. The registered pharmacist shall ensure that this code and any guidance issued by the Pharmacy and Poisons Board and the Department of Health are adhered to.

i. The registered pharmacist shall ensure that full co-operation be provided to the inspector, and all requests for information which he is duly required.

j. The registered pharmacist shall ensure that the environment within which he practice enables compliance with his professional responsibility. Any registered pharmacist operating in an environment which is not in accordance with safe practice shall formally notify the ASP of the apparent deficiency. The registered pharmacist shall ensure that the requisite facilities, equipment and materials are available to enable the provision of the service to professionally accepted standards.

k. The registered pharmacist shall report 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.

l. The safety of patients and the public shall be the prime consideration of a registered pharmacist, over-riding any personal or commercial loyalties.

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 sited 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 (which can be either:- (i) the name of the medicine as it is registered with the Pharmacy and Poisons Board of Hong Kong as shown in the Compendium of Pharmaceutical Products published by the Department of Health; or (ii) the generic, chemical or pharmacological name of the medicine);
- Dosage per unit;
- Method and dosage of administration; and
- Precaution where applicable.

g. The label is to 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. The label shall be placed to leave visible any of the manufacturer's statements that may be important to the patient if supplied in original packaging, 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, unable before delivery either to furnish a signed written order or to attend to the registered premises or 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 DISPENSED 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. The patient is the primary focus of the dispensing process, and 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.

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. ASP shall not dispense any prescription only medicines 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 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, ASP shall not dispense a prescription more than once unless it is a repeat prescription specifying it could be dispensed a stated number of times or at stated intervals. ASP shall not dispense the prescription before the date specified in the prescription.

d. It is a best practice that the registered pharmacist shall receive the prescription

and ensure the particulars of the patient as stated on the prescription are clear, legible and complete. The registered pharmacist shall clarify the particulars of the patient if necessary and shall ensure that the person presenting the prescription is authorized to do so. The prescription shall be legible and the registered pharmacist must be satisfied that they are in a position to safely and correctly interpret the identity of the product prescribed. There must be no ambiguity in respect of product, method of use or dosage regime. If no specific directions for use are stated by the prescriber, the registered pharmacist shall first ascertain whether these have been verbally transmitted to and understood by the patient. If this is not the case, then the prescriber shall be contacted and any alteration shall be authorized by prescriber in writing.

e. It is a best practice that the registered pharmacist shall make a clinical assessment as to the appropriateness of the prescribed medicine therapy for the individual to whom the prescription is issued. This shall include screening for any potential drug therapy problems, including therapeutic duplication, drug-drug interactions (including with OTC medicines), food-drug interactions, incorrect drug dosage or duration of treatment, known drug allergies and clinical misuse/abuse. When deemed necessary, the registered pharmacist should act in consultation with the prescriber. Records of the details of the notification to the prescriber shall be maintained in conjunction with the dispensing records of the patient.

f. 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.

g. 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.

h. 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.

i. Before the patient leaves the registered premises, it is a best practice that the registered pharmacist shall offer to counsel the patient or their representative on matters which should include (but not limit to) the followings:
   - the nature and use of the medicine,
   - the directions for use, including how to take/administer it and duration of treatment,
   - potential side effects that are likely to be experienced and how to deal with them,
   - any special precautions to be taken while on the medication, e.g. foods, drinks or other medicines to be avoided,
   - the appropriate storage of the medicine,
   - what to do with any residual medicine as appropriate,
   - if a patient's usual medication is changed, then the registered pharmacist shall draw the patient's attention to it, and counsel them on any new medications being introduced.

j. Where the dispensing of a prescription is complete, 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 case of a repeat prescription is dispensed, the copy of the prescription) shall be retained on 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. .

k. Where a prescriber only specifies the generic name of a medicine on the prescription, the brand name of the medicine dispensed and the corresponding HK Registration No. shall be recorded on the prescription.

l. Appropriate and required 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 shall be developed and maintained in 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 pharmaceutical products from the manufacturers, wholesalers or other retailers shall be on a written order.

c. A “Product List” shall be maintained 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 specifying 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.

d. All 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 pharmaceutical product concerned whichever period is longer.

3.4 RECORD KEEPING

An ASP must recognize the importance of record keeping. Suitable procedures shall be provided that allow for records to be maintained that are compliant and satisfy 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 so as to be at all times available for inspection. 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 document, they shall be retained for a period of two years from the date on which it is made or the transaction occurred.

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 confidentiality 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 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 that is not reasonably practicable, on the day next following that 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 made 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;
- quantity 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 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 and dangerous drugs are supplied by way of wholesale dealing or sale of a poison to a person 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.

Where a poison is supplied from an ASP to a purchaser for the purpose of his trade, business or profession urgently and a signed written order from the purchaser was unable to obtain before delivery, it is necessary to obtain the signed written order from the purchaser within 48 hours after the transaction.

j. All signed written orders and corresponding sales invoices shall be maintained in registered premises for two years from the date on which issued or made or not less than the expiry date of the pharmaceutical product 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 PB 10/70

Tel No.: 961 8652
電 話

圖文傳真 *Fax No.:* 891 7946

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-label led 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. Allobarbital 阿洛巴比妥
2. Amineptine 阿米庚酸
3. Amobarbital 异戊巴比妥
4. Buprenorphine 丁丙諾啡
5. Butalbital 布他比妥
6. Butobarbital 丁巴比妥
7. Cyclobarbital 環己巴比妥
8. Ethchlorvynol 乙氯維諾(乙氯戊烯炔醇)
9. Ethinamate 炔己蟻胺
10. Fencamfamin 芬坎法明
11. Glutethimide 格魯米特
12. Lefetamine 勒非他明
13. Mazindol 馬吲哚
14. Meprobamate 甲丙氨酯
15. Methylphenobarbital 甲苯比妥
16. Methyprylon 甲乙哌酮
17. Pemoline 匹莫林
18. Pentazocine 噴他佐辛
19. Pentobarbital 戊巴比妥
20. Phenobarbital 苯巴比妥
21. Pipradrol 哌苯甲醇
22. Pyrovalerone 吡咯戊酮
23. Secbutabarbital 仲丁比妥
24. Vinylbital 乙烯比妥
25. Zolpidem 唑吡坦
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 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 registered pharmacist, a body corporate or an unincorporated body of persons that is authorized to carry on a business comprising the retail sale of poisons under section 11 of the Pharmacy & Poisons Ordinance (Cap. 138).

"Controlled medicines" means any substance which is specified in the Part I 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" 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.