Code of Practice

for Authorized Seller of Poisons

獲授權毒藥銷售商執業守則

Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局
2021

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Introduction
引言

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

此獲授權毒藥銷售商執業守則(本守則)載述獲授權毒藥銷售商經營藥劑業務的最低標準。本守則旨在向獲授權毒藥銷售商提供其在註冊處所內從事零售藥劑業務的實務指引及指示，從而保障病人和公眾人士的利益，以及推動獲授權毒藥銷售商以安全和有效的方式經營藥劑業務。

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

藥劑業及毒藥管理局根據《藥劑業及毒藥條例》(第138章)第13條向獲授權毒藥銷售商發出處所註冊證明書的其中一項條件，是獲授權毒藥銷售商須遵從本守則的規定。獲授權毒藥銷售商必須依循本守則載述的所有標準，並須注意不遵從本守則有可能構成不當行為，因而導致須按《藥劑業及毒藥條例》(第138章)第16(2)條接受紀律研訊。

Definition
定義

"antibiotics" means the substances to which the Antibiotics Ordinance (Cap.137) applies.	"抗生素"指《抗生素條例》(第137章)適用的物質。
"authorized seller of poisons" or "ASP" means a registered pharmacist, body corporate or unincorporated body of persons (seller) that is authorized to carry on a business of retail sale of poisons if the actual sale of poisons is conducted on premises registered in respect of the seller under section 13 of the Pharmacy and Poisons Ordinance (Cap.138) by a registered pharmacist or in his presence and under his supervision.	"獲授權毒藥銷售商"指註冊藥劑師、法人團體或並非法團的團體(銷售商)獲授權經營零售毒藥的業務，而毒藥的實際銷售是由註冊藥劑師或在其在場監督的情況下在根據《藥劑業及毒藥條例》(第138章)第13條妥為註冊的處所內進行。
"controlled medicines" means any substance which is specified in Part 1 of Schedule 10, i.e. Poisons List, to the Pharmacy and Poisons Regulations (Cap.138A), any substance to which the Antibiotics Ordinance (Cap.137) applies, or any substance specified in Part I of the First Schedule to the Dangerous Drugs Ordinance (Cap.134).	"受管制藥物"指《藥劑業及毒藥規例》(第138A章)附表10第1部指明的任何物質、《抗生素條例》(第137章)適用的任何物質，或《危險藥物條例》(第134章)附表1第1部指明的任何物質。
"dangerous drugs" means any of the drugs or substances specified in Part I of the First Schedule to the Dangerous Drugs Ordinance (Cap.134).	"危險藥物"指《危險藥物條例》(第134章)附表1第1部指明的任何藥物或物質。

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

"配發"、"配藥"指按照註冊醫生、註冊牙醫或註冊獸醫開出的處方供應藥物或毒藥；亦指將物質（包括毒藥）合成或混合，以及供應該等物質。

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

"督察"指為施行《藥劑業及毒藥條例》(第138章)而獲藥劑業及毒藥管理局主席以書面授權出任督察的公職人員。

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

"標籤"指構成盛載藥劑製品以供銷售的容器一部分的或附貼在該等容器上的任何說明，而在符合根據《藥劑業及毒藥條例》(第138章)訂立的規例的規定下，該等說明可以英文或中文印製。

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

"藥物"的涵義與"藥劑製品"的定義中該詞的涵義相同。

"pharmaceutical product" -

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

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

"藥劑製品" -

(a) 指符合以下說明的物質或物質組合 -

(i) 對該物質或物質組合的表述或其狀況顯示，該物質或物質組合具有的特性，使其可用於治療或預防人類或動物的疾病；或

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

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

(B) making a medical diagnosis; and

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

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

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

(ii) 可應用或施用於人類或動物，以期 –

(A) 透過藥理、免疫或新陳代謝作用，恢復、矯正或改變生理機能；或

(B) 作出醫學診斷；及

(b) 包括先進療法製品[1]。

"毒藥"指由根據《藥劑業及毒藥條例》(第138章)第29條訂立的規例訂明的毒藥表內指明的物質。

"精神藥物"指"按聯合國《1971年精神藥物公約》屬於精神藥物的毒藥列表"(見附錄B)指明的任何物質，而該表由衞生署藥物辦公室按照聯合國《1971年精神藥物公約》備存和更新。

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

[1] 先進療法製品指任何以下用於人類的製品 – (a) 基因療法製品；(b) 體細胞療法製品；(c) 組織工程製品。《藥劑業及毒藥條例》(第138 章) 第2 條列明了先進療法製品、基因療法製品、體細胞療法製品及組織工程製品的相關定義。

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

“註冊藥劑師”指姓名已根據《藥劑業及毒藥條例》(第138章)第5 條載入藥劑師名冊內並可親自控制獲授權毒藥銷售商的註冊處所的人。

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

“註冊處所”指獲授權毒藥銷售商用作存放毒藥以供零售的處所，該處所已根據《藥劑業及毒藥條例》(第138章)第13 條註冊。

"sell" includes -

(a) offer or expose for sale;

(b) supply without payment; and

(c) offer or expose for supply without payment, and "sold" and "seller" shall be construed accordingly.

“售”、“銷售”包括－

(a) 要約出售或為出售而展出；

(b) 無償供應；及

(c) 要約無償供應或為無償供應而展出，而“銷售商”亦須據此解釋。

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

“以批發經營方式銷售”指將貨品售予獲《藥劑業及毒藥條例》(第138章)授權將該等貨品轉售的人。

Section 1 : Premises
第 1 節 : 處所

1.1 REGISTERED PREMISES OF AUTHORIZED SELLER OF POISONS

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

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

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

c. The Certificate of Registration of Premises, the name and the registration certificate of the registered pharmacist responsible for the professional activity of the ASP and a

1.1 獲授權毒藥銷售商的註冊處所

獲授權毒藥銷售商的註冊處所在各方面均須得到妥善管理，使能提供及協助締造一個安全而有成效的工作環境。獲授權毒藥銷售商須確保其註冊處所適合進行藥物零售業務，並符合所有相關法例和政府部門不時發出的所有相關指引。

a. 註冊處所內所有地方的裝飾必須得到妥善維修。註冊處所內的牆壁、天花板及鋪地物料須符合任何相關法例規定，並由相關政府部門，包括屋宇署和環境保護署，就衞生、安全及環境方面發出的任何規定。

b. 註冊處所須保持清潔整齊，並提供足夠的照明、通風及空氣調節。溫度及濕度須加以控制，並必須充分顧及藥劑製品須貯存在若干指明溫度範圍內的規定(若有)。

c. 處所註冊證明書、負責獲授權毒藥銷售商專業活動的註冊藥劑師的姓名和註冊證明書，以及列出獲授

notice setting out the opening hours of the ASP and the attendance hours of the registered pharmacist must be displayed in a conspicuous place on the registered premises.

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

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

f. Medicine sales counters must not be cluttered.

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

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

權毒藥銷售商的開放時間及藥劑師當值時間的告示，須在註冊處所的顯眼處展示。

d. 註冊處所須提供安全及暢通易達的入口。公眾可進出的地方須保持暢通，不受存貨和任何障礙物阻塞。

e. 獲授權毒藥銷售商須為其每一個註冊處所提供直線電話，供公眾查詢。

f. 藥物銷售櫃枱不得雜亂無章。

g. 註冊處所須設有可盡量減低所貯存的受管制藥物及載有顧客資料的記錄被破壞或盜竊的機會的保安系統。

h. 獲授權毒藥銷售商須確保其工作環境能夠讓註冊藥劑師可履行其專業職務。獲授權毒藥銷售商須使其註冊藥劑師能容易地在內部報告有關註冊處所工作環境任何不足之處。獲授權毒藥銷售商須確保工作環境備有所需的設施、配備及材料，使註冊處所得以提供達至專業認可標準的藥劑服務。

1.2 DISPENSING AREA

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

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

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

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

1.2 配藥區

由於獲授權毒藥銷售商大部分的專業配藥活動都在配藥區進行，因此配藥區須提供足夠的空間，以便安全和妥善地貯存、處理、合成及配製藥劑製品。

a. 配藥區須保持狀況完好。配藥區地板須保持清潔，而所有表面必須乾淨、整潔、平坦、防污和防潮。

b. 配藥區須有充足光線和設有空調裝置，以確保存貨在適合有關藥劑製品性質及穩定性的環境下貯存。配藥區內的固定裝置和設備須充分切合預定的用途。配藥區應設有洗滌設備，包括供水、洗手盆及完備的排水設施，並必須安裝蒸餾水或沸水的供水設施，專用作配藥用途。

c. 配藥區須設有可上鎖的盛器，該等盛器須符合安全貯存受管制藥物的法定要求。

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

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

d. 配藥區只限作配藥用途使用。配藥區須與處所的其他部分劃開或以其他方式分隔開，以防止有人在未經邀請或未獲授權的情況下進入。配藥區必須禁止顧客進入。

e. 在處置藥劑廢物(包括過期或不可使用的藥物)時，須符合相關法例及環境保護署或其他政府部門發出的相關指引。不論是過期存貨或是由病人退回的藥物廢物，都必須與仍可使用的藥物分開貯存，並由註冊藥劑師監管，直至該些藥物被移走銷毀。處置任何危險藥物之前，必須先通知衞生署，並且由督察見證銷毀任何危險藥物的過程。

1.3 DISPENSING FACILITIES

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

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

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

1.3 配藥的設備

獲授權毒藥銷售商的註冊處所須備有各類適當的運作配備，使其註冊處所能提供各種藥劑服務。配藥的配備須存放於配藥區內，並妥為保養，同時須確保該等配藥的配備合適、方便取用、妥為保養和清潔，以免對所處理的藥劑製品的素質造成任何不良影響。

a. 配藥區須備有合適的配備，例如量器、研缽和搗棒、刮刀等，以供即場配藥。配藥的配備只限用於預備和配發藥物，並須保持清潔，妥為保養和貯存，以免藥劑製品受到污染。

b. 配藥區須設置一個適用而溫度維持於攝氏2 至8 度的雪櫃，指定用作貯存藥劑製品。該雪櫃須可上鎖，而且容量足以貯存所有須冷藏的藥物，並須定期清潔和適當保養，以確保貯存狀況良好。雪櫃內須放置溫度計，以監察溫度，確保冷鏈系統持續運作。該指定用作貯存藥劑製品的雪櫃，不得存放食物和飲品。

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

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

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

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

g. Adequate up-to-date reference books, statutes and regulations pertaining to the practice of ASP and to the sale and supply of pharmaceutical products must be provided for staff. Such references should include either hard or soft copy of the following and must be accessible by all staff during business hours:

c. 專門留作貯存受管制藥物的可上鎖盛器，須存放於配藥區內。該等盛器的容量須足以安全地貯存所有存放的受管制藥物。

d. 配藥所需用的一系列容器須隨時備妥，以便安全和適當地供應藥劑製品。在任何情況下，容器均不得重複使用。

e. 註冊處所內須備有足夠的配藥標籤設備，以符合第3.1節及附錄A有關標籤的要求。

f. 配藥區內須備有合適的配備，以點算藥片和藥丸的數目，這些點算配備須定期進行清潔，以預防藥劑製品交叉污染。

g. 獲授權毒藥銷售商須為員工提供關於獲授權毒藥銷售商實務與藥劑製品銷售和供應的最新參考書、法規和規定，並須提供足夠數量。這些參考資料應包括以下各項的印刷本或電子存本，並須讓所有員工可在營業時間內使用：

- Martindale (current or most previous edition);
- medical dictionary;
- Compendium of Pharmaceutical Products issued by the Drug Office of the Department of Health;
- list of registered medical practitioners in Hong Kong published in the Gazette or maintained by the Medical Council of Hong Kong;
- the Pharmacy and Poisons Ordinance and Regulations (Cap.138);
- the Antibiotics Ordinance and Regulations (Cap.137);
- the Dangerous Drugs Ordinance and Regulations (Cap.134);
- the Undesirable Medical Advertisements Ordinance (Cap.231);
- the Drug News and Safety Alerts issued by the Drug Office of the Department of Health; and
- the Product List referred to in paragraph c of Section 3.3.

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

- Martindale (最新一期或前一期)；
- 醫學字典；
- 衞生署藥物辦公室出版的《藥劑製品目錄》；
- 刊登於憲報的香港註冊醫生名單，或由香港醫務委員會備存的註冊醫生列表；
- 《藥劑業及毒藥條例》及規例(第138章)；
- 《抗生素條例》及規例(第137章)；
- 《危險藥物條例》及規例(第134章)；
- 《不良廣告(醫藥)條例》(第231章)；
- 衞生署藥物辦公室發出的《藥物情報》及《安全警示》；以及
- 在第3.3節c段中所提及的“製品列表”。

h. 所有須保存的登記冊、簿冊和紀錄，包括危險藥物登記冊、處方冊、毒藥冊、抗生素記錄冊及精神藥物記錄冊，須保存在配藥區內。

1.4 STORAGE AND STOCK

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

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

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

1.4 貯存及存貨

獲授權毒藥銷售商須設有一套全面的系統，按不同管制層次貯存及管理藥物。

a. 所有第1部毒藥、抗生素、精神藥物及危險藥物，必須鎖在配藥區的盛器內，該等盛器的鎖匙必須由註冊藥劑師保管。危險藥物須分開存放在專門用作貯存危險藥物的已上鎖盛器內。貯存供出售的受管制藥物的可上鎖盛器，須由處所內的註冊藥劑師親自控制。

b. 獲授權毒藥銷售商須確保所有獲取及供應的藥劑製品符合法律規定，並已在香港註冊，以及只由持牌及／或信譽良好的藥商供應。獲授權毒藥銷售商也須確保製品的包裝及在註冊處所內出現與製品相關的廣告(例如單張、招牌等)，符合《不良廣告(醫藥)條例》(第231章)的規定。

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

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

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

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

c. 藥劑製品的存貨須貯存在適合有關產品的性質及穩定性的環境中。獲授權毒藥銷售商須特別留意，避免存貨受污染及防止陽光、紫外光、水分和極端溫度。藥劑製品不得貯存在存放、準備或吃喝食物和飲品的地方附近，並須保持原廠包裝。在接收供應商的任何製品時，如發現包裝已破損或褪色，必須把有關製品隔離並退還供應商。

d. 存放註冊處所內的所有藥物存貨，必須展示批號和有效期。須避免將相同製品但批號不同的存貨混合存放於同一容器內。

e. 外用和內服的藥物應分開貯存。

f. 為盡量減少發生錯配藥物，貯存包裝相似的不同藥物或包裝相似但劑量不同的藥物時，必須特別小心。

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

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

g. 獲授權毒藥銷售商須主動參與任何不合標準藥物的回收過程。在收到製造商、批發商或衞生署發出的真確資訊及回收通知後，獲授權毒藥銷售商須展開回收行動，立刻檢查存貨，把供銷售及陳列的回收藥物移走，並貯存在指定的地方；如須回收的藥物為受管制藥物，則須貯存在由註冊藥劑師控制的地方，並盡快退還供應商或以適當的方式處置(如適用的話)。獲授權毒藥銷售商須向顧客提供如何安全處置須回收藥物的適當資訊。有關回收行動的開展、進度及完成細節，必須有完備記錄。

h. 獲授權毒藥銷售商接收送來的藥物時，須檢查發票或送貨單內是否有受管制藥物。如送來的藥物有受管制藥物，須立即分開處理受管制藥物，並鎖在貯存該等藥物的盛器內，然後記入相關的登記冊、簿冊或紀錄上(如適用)。接收受管制藥物必須由註冊藥劑師親自處理和簽收，收據其後須交回供應商。

Section 2 : Management and Staff
第 2 節 ：管理及員工

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

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

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

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

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

獲授權毒藥銷售商須確保受管制藥物的零售是在註冊處所內進行，並由註冊藥劑師或在其在場監督的情況下進行。

a. 獲授權毒藥銷售商須於每年一月向藥劑業及毒藥管理局秘書送交一份名單，列明其每一個註冊處所的地址，以及親自控制該等處所的註冊藥劑師的姓名。

b. 獲授權毒藥銷售商須確保受管制藥物的零售及貯存只限於註冊處所內進行。獲授權毒藥銷售商必須先獲得藥劑業及毒藥管理局批准，方可更改該等處所的地址或陳設。

c. 獲授權毒藥銷售商或任何由獲授權毒藥銷售商指派為主管其業務運作的人(主管)，必須是藥劑業及毒藥管理局認為適當進行毒藥零售業務的人選。

d. 獲授權毒藥銷售商必須先取得藥劑業及毒藥管理局的批准，方可更改其所有權、合夥關係、董事或主管。

e. An ASP must ensure that all processes and activities conducted on its registered premises are carried out in a manner compliant with the relevant legislations, which include but are not limited to:

- the Pharmacy and Poisons Ordinance (Cap.138);
- the Dangerous Drugs Ordinance (Cap.134);
- the Antibiotics Ordinance (Cap.137);
- the Radiation Ordinance (Cap.303);
- the Public Health and Municipal Services Ordinance (Cap.132);
- the Undesirable Medical Advertisements Ordinance (Cap.231);
- the Chinese Medicine Ordinance (Cap.549)
- the Waste Disposal Ordinance (Cap.354);
- the Trade Descriptions Ordinance (Cap.362); and
- the Personal Data (Privacy) Ordinance (Cap.486)

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

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

e. 獲授權毒藥銷售商須確保在其註冊處所內進行的所有過程及活動，均以符合相關法例的方式進行，當中包括但不限於：

- 《藥劑業及毒藥條例》(第138章)；
- 《危險藥物條例》(第134章)；
- 《抗生素條例》(第137章)；
- 《輻射條例》(第303章)；
- 《公眾衞生及市政條例》(第132章)；
- 《不良廣告(醫藥)條例》(第231章)；
- 《中醫藥條例》(第549章)；
- 《廢物處置條例》(第354章)；
- 《商品說明條例》(第362章)；以及
- 《個人資料(私隱)條例》(第486章)。

f. 獲授權毒藥銷售商須採取一切合理步驟，確保其業務按照本守則運作。

g. 獲授權毒藥銷售商須確保在註冊處所開放營業的每一日內，其註冊藥劑師有不少於三分之二的時間在場控制和監督受僱於該處所內工作的人。

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

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

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

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

h. 獲授權毒藥銷售商不得試圖不當地影響、指使、控制或干擾其註冊藥劑師的專業事務或其執行法定職責，包括親自控制和監督受僱於該獲授權毒藥銷售商的員工處理藥劑製品，以及在其註冊處所銷售受管制藥物。

i. 獲授權毒藥銷售商應鼓勵其註冊藥劑師，向醫護專業人員和衞生署匯報任何懷疑藥品不良反應個案。這點相當重要，因為此舉可能會影響日後對病人的治療，或日後某種藥物的使用。

j. 獲授權毒藥銷售商須在其註冊藥劑師協助下，制定程序並為其全體員工提供培訓，以確保他們按照現行的法例處理藥劑製品。

k. 獲授權毒藥銷售商須確保所有涉及藥劑製品銷售的員工都獲提供適當時期的入門訓練，確定他們熟悉有關藥劑製品在銷售、交收及貯存方面的法例規定。

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

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

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

l. 獲授權毒藥銷售商須確保所有在其註冊處所涉及藥劑製品銷售的員工，都曾接受培訓執行該等職務，並有足夠能力履行委派給他們的職務，尤其是他們適合進行藥物零售，以及能夠與處所內的顧客有效地溝通。獲授權毒藥銷售商有責任檢查所有其聘用的人過往的受僱記錄，其註冊處所內也須保存涉及藥劑製品銷售的全體員工的培訓記錄。

m. 獲授權毒藥銷售商須確保任何在註冊處所提供的專業藥劑服務或藥劑製品的廣告和宣傳活動均為合法、正當及真確，而且該等活動符合《不良廣告(醫藥)條例》(第231章)的規定。

n. 獲授權毒藥銷售商須在督察執行其法定職務時給予充分合作，而且在督察正式提出要求時，不得阻止其員工向督察提供資料及與業務擁有人身分有關的詳情。

Section 3 : Services and System of Operation
第 3 節 ：服務及運作制度

3.1 SALE AND SUPPLY OF MEDICINES

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

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

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

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

3.1 藥物銷售及供應

獲授權毒藥銷售商的註冊處所應主要用作藥物零售，而該業務須按照《藥劑業及毒藥條例》(第138章)及其他有關法例的規定進行，當中包括：

a. 受管制藥物只可在註冊處所由註冊藥劑師或在其在場監督的情況下銷售。

b. 附表3 毒藥、危險藥物和抗生素，只可按照註冊醫生、註冊牙醫或註冊獸醫所簽發的處方配發。有關處方只可由註冊藥劑師在註冊處所配發，或由註冊藥劑師在場監督的情況下配發。

c. 除非所供應的藥劑製品上附有正確標籤，並按醫生處方的指示須以確實數量配發，或由註冊藥劑師按其專業評估配發，否則藥劑製品須以原裝包裝供應，以免在再包裝的過程中出錯。

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

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

f. An ASP may only supply controlled medicines by way of wholesale dealing to a purchaser for the purpose of his trade, business or profession if a written order signed by the purchaser is obtained before the completion of the sale. Where the controlled medicines supplied are Part 1 Schedule 1 Poisons, the medicines may also be supplied in accordance with the record keeping requirements as set out in Section 3.4(d). For supply of controlled medicines on written order, the following particulars must be stated in the written order:
   - the date on which it is written;
   - name and address of the purchaser;
   - trade, business or profession of the purchaser;

d. 受管制藥物不得讓顧客自行揀選，而且須存放於註冊處所的配藥區內。

e. 第1部附表1毒藥只可售予適當的購買人。獲授權毒藥銷售商須在毒藥冊中記入有關第1部附表1毒藥的銷售，由購買人簽署，並由負責銷售或監督該項銷售的註冊藥劑師加簽，方可交付該毒藥。

f. 獲授權毒藥銷售商須於銷售完成前，取得由購買人簽署的書面訂單，方可以批發經營的方式，將受管制藥物供應給購買人，供其為本身的行業、業務或專業使用。如所供應的受管制藥物為第1部附表1毒藥，則該等藥物亦可按第3.4 節d 段有關備存記錄的規定供應給購買人。如受管制藥物是按書面訂單供應，書面訂單須註明以下資料：
   - 發出書面訂單的日期；
   - 購買人的姓名及地址；
   - 購買人的行業、業務或專業；

- name and quantity of the product to be purchased;
- the purpose for which it is required; and
- the signature of the purchaser.

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

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

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

- 擬購買製品的名稱及數量；
- 購買該製品的原因；以及
- 購買人的簽署。

g. 購買人如為本身的行業、業務或專業而急需獲供應第1部附表1的毒藥，但購買人未能在交付毒藥前提供已簽署的書面訂單，或前往註冊處所並在毒藥冊的記項上簽署，則在獲授權毒藥銷售商合理地信納，購買人因某些緊急情況而需要該第1部附表1毒藥，而購買人承諾在交付毒藥後48小時內提供已簽署的書面訂單的情況下，該毒藥可交付予購買人。

h. 獲授權毒藥銷售商在配發藥物時，須嚴格遵守附錄A所載有關配發藥物標籤的強制性規定。

i. 出售的藥物須按法定要求加上足夠標籤，而該等標籤須貼在藥物包裝上適當的位置。

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

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

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

j. 附貼於藥物上的標籤須為清晰可讀的中文或英文。如有關藥物為不含第1部毒藥的藥物，則其用量、用法及用藥頻率須以中文及英文加上標籤。標籤應盡可能照顧某些有特別需要的病人，如視力欠佳者。

k. 如藥物以原裝供應，加上標籤附貼的時候須讓下述說明清晰可見，即任何出現在原裝藥物上並對病人來說是重要的說明，包括藥物的批號、貯存條件、失效日期，以及藥物的名稱和劑量。

l. 獲授權毒藥銷售商須向顧客提供適當和充分的意見，以便他們能夠安全和有效地使用購得的藥物。

3.2 DISPENSING MEDICINES UNDER THE AUTHORITY OF A PRESCRIPTION

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

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

b. Prescription-only medicines must not be dispensed unless the prescription complies with the statutory requirements which include the following:
   (i) the name and address of the prescriber is specified;
   (ii) it is in writing and is signed and dated by the prescriber; where the medicine prescribed contain dangerous drugs, it must be written in ink or otherwise so as to be indelible;
   (iii) the name, address and, where the medicines prescribed contain dangerous drugs, identity card number of the person to whom the medicines are to be supplied are specified;

3.2 在處方授權下配發藥物

在按處方配發藥物的過程中，確保病人的安全至為重要。所配發的藥物須經評估為適合獲供應該等藥物的病人，並務必於交付該等藥物時，力求在收取、覆檢、裝配、核對及記錄處方各程序中，小心謹慎。

a. 藥物的配發須由註冊藥劑師進行或由其在場監督的情況下進行，而該註冊藥劑師須親自控制其執業所在的註冊處所。

b. 除非處方符合包括下列的法定要求，否則不得配發醫生處方藥物。處方須：
   (i) 指明開方人的姓名及地址；
   (ii) 以書面開出，由開方人簽署及註明日期；危險藥物的處方須用墨水書寫或以其他不能去掉的方法書寫；
   (iii) 如藥物含有危險藥物，指明獲供應藥物的人的姓名、地址及身分證號碼；

(iv) if given by a registered veterinary surgeon, the name of the person to whom the medicine is to be delivered is specified;

(v) the total amount of the medicines to be supplied is indicated;

(vi) the dose to be taken or administered is specified;

(vii) if the drugs prescribed are dangerous drugs and some or all of them are preparations,

- the total amount of the preparation or of each preparation, as the case may be, is specified; or
- when the preparation is packed in ampoules, it is specified as aforesaid or the total amount of the preparation or of each preparation, as the case may be, intended to be administered or injected is specified;

(viii) if given by a registered dentist, the statement "For dental treatment only 祇限牙科醫療用" or, where the medicine prescribed contains dangerous drugs, the statement "For local dental treatment only 僅供本地牙科治療之用" is written on it; and

(iv) 如處方由註冊獸醫開出，指明將獲交付藥物的人的姓名；

(v) 說明藥物的總供應量；

(vi) 指明服食或施用的劑量；

(vii) 如開出的藥物屬危險藥物，而當中部分或所有危險藥物屬製劑，則 –

- 視屬何情況而定，該處方須指明製劑的總量或每一製劑的總量；或
- 如製劑是以小玻璃管包裝，視屬何情況而定，該處方須作出一如前述的指明，或指明擬供施用或注射的製劑總量或每一製劑的總量；

(viii) 如處方由註冊牙醫開出，須寫上 "For dental treatment only 祇限牙科醫療用" 的字句；或如藥物含有危險藥物，須寫上 "For local dental treatment only 僅供本地牙科治療之用" 的字句；以及

(ix) if given by a registered veterinary surgeon, the statement "For animal treatment only 祇限醫治禽畜用" or, where the medicine prescribed contains dangerous drugs, the statement "For animal treatment only 僅供動物治療之用" is written on it.

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

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

(ix) 如處方由註冊獸醫開出，須寫上"For animal treatment only 祇限醫治禽畜用"的字句；或如藥物含有危險藥物，須寫上"For animal treatment only 僅供動物治療之用"的字句。

c. 除非開方人已指示可依照述明的次數或在述明的相隔期間按照該處方配藥，否則不得按照有關的處方配藥超過一次。在處方註明的日期前，不得按照處方配藥。

d. 開方人如在處方上指明某品牌的製品，註冊藥劑師必須配發所指明的製品。如未經諮詢有關的開方人，註冊藥劑師不得供應不同品牌但成分相同的製品，惟如藥劑師與有關開方人事先簽訂的品牌替代協議已包括這項供應，則屬例外。

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

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

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

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

e. 開方人如只在處方上指明藥物的學名，註冊藥劑師須在處方上記錄所配發藥物的品牌名稱及其香港註冊編號。

f. 獲授權毒藥銷售商不得供應任何有效期已屆滿的藥物。如有關藥物在其所指明的有效期屆滿後，療程仍可能繼續，該等藥物也不得供應。

g. 在按照處方完成配藥後，處方須根據相關法例獲批簽，即在處方上開方人的簽名位置上列明獲授權毒藥銷售商的名稱和註冊處所的地址，以及供應藥物的日期。獲授權毒藥銷售商須把有關處方(如屬重複處方，則指處方副本)，由配藥日期起計，在註冊處所內保存兩年。

h. 每宗配藥的記錄須根據法例規定在註冊處所備存。

3.3 PROCUREMENT AND INVENTORY SYSTEM

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

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

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

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

3.3 採購及存貨系統

獲授權毒藥銷售商須制訂並維持一套安全而有效的運作採購及存貨管理系統。

a. 藥劑製品只可購自持牌的藥商。

b. 向製造商、批發商或其他零售商購買受管制藥物，須以書面訂單(例如電子訂單)提出。

c. 對於貯存於配藥區的藥劑製品，須按照《藥劑業及毒藥條例》(第138章)、《抗生素條例》(第137章)、《危險藥物條例》(第134章)，以及載於附件B的屬於精神藥物的毒藥列表中所採用的的分類方法備存一份“製品列表”。“製品列表”上須列明製品銷售及供應方面的限制，以及貯存的要求。在必要時，“製品列表”應予以檢視和更新，使涉及處理藥劑製品的員工知悉製品的法律分類，以及在接收、供應及貯存製品上的相關要求。

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

d. 所有從供應商收取的受管制藥物，須按書面訂單加以核對，確保收取的藥物正確。藥物的數量、批次編號及失效日期，須按發票加以核實。如發現上述資料有任何不符，須通知供應商，並採取適當的補救措施。

3.4 RECORD KEEPING

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

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

b. Dangerous Drugs Register
   (i) A dangerous drugs register must be kept solely for recording the true particulars with respect to every quantity of dangerous drugs obtained and supplied. The entries in the register must be recorded in chronological sequence in the form specified in the First Schedule to the Dangerous Drugs Regulations (Cap.134A) as set out in Appendix C. A separate page within the register or separate part of the register must be used for entries made with respect to different dangerous drugs and different strengths of preparations comprised within the class of dangerous drugs to which that register or separate part relates and the balance of the amount of the dangerous drugs kept must be

3.4 保存記錄

妥善保存記錄對有效監管藥物十分重要。獲授權毒藥銷售商須按照《藥劑業及毒藥條例》(第138章)、《抗生素條例》(第137章)、《危險藥物條例》(第134章)及本守則的規定，制定合適的程序以備存登記冊、簿冊、記錄及文件。

a. 須保存的登記冊、簿冊或記錄須以釘裝記錄冊方式備存。

b. 危險藥物登記冊
   (i) 獲授權毒藥銷售商須備存一份危險藥物登記冊，專用於記錄有關獲得和供應危險藥物的每一分量的真實資料。登記冊的記項須按日期先後次序，以《危險藥物規例》(第134A章)附表1指明的格式(見附錄C)記錄。獲授權毒藥銷售商須以登記冊內或登記冊不同的部分內的分頁來登記組成某類別危險藥物的不同危險藥物及不同濃度的製劑，而該危險藥物類別是該登記冊或該不同的部分所關乎的，並須備存所保存的危險藥物數量的餘額。危險

maintained. The class of the dangerous drug and, where applicable, the particular dangerous drug and the particular strength of the preparation comprised within such class to which the entries on the page relate must be specified at the top of that page. Each entry must be made on the day of receipt or supply of the dangerous drugs, or, if it is not reasonably practicable, on the following day.

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

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

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

c. Prescription Book

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

藥物類別，以及(如適用的話)組成該類別的個別危險藥物及製劑的個別濃度，須在每一頁與該頁的記項有關的頂端指明。有關記項須在收取或供應危險藥物當日記入危險藥物登記冊上；如在當日記入該記項並非合理切實可行，則須在該日期的翌日記入危險藥物登記冊上。

(ii) 危險藥物登記冊上的任何記項均不得予以取消、塗去或更改。更正只准用旁註或腳註方式作出，並須指明作出更正的日期。

(iii) 每一項記項或更正須用墨水書寫，或以其他不能擦掉的方法書寫。

(iv) 在同一時間，只准在每一註冊處所就同一類別的危險藥物，備存一本登記冊。

c. 處方冊

獲授權毒藥銷售商須備存一份處方冊，以記錄配發藥物的詳情。註冊藥劑師須在配發藥物當日，如在當日記入該記項並非合理切實可行，則須在該日期的翌日，把下列資料記入處方冊上：

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

d. Poisons Book

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

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

- 配發藥物的日期；
- 藥物的成分及所供應的藥量；以及
- 開方人的姓名、獲開給處方的人的姓名及地址；以及開出處方的日期。

d. 毒藥冊

獲授權毒藥銷售商須保存一份毒藥冊，專用於記錄銷售第1部附表1毒藥，而該等毒藥並非附表3所載的毒藥。在不抵觸第3.1節f段的規定下，獲授權毒藥銷售商在交付該等毒藥予購買人之前，須把下列資料記入毒藥冊上：

- 銷售日期；
- 出售毒藥的名稱及數量；
- 購買人的姓名；
- 購買人的身分證號碼；
- 購買人的地址；
- 購買人的業務、行業或職業；
- 購買人所述的購買該毒藥的用途；
- 按照《藥劑業及毒藥條例》(第138章)第22(1)(a)條獲發出證書的人的姓名和地址(如適用)；
- 購買人的簽署；以及
- 註冊藥劑師的簽署。

e. Antibiotics Record
Antibiotics record must be kept for recording every transaction of antibiotics except when the antibiotics are dispensed in accordance with a prescription and the prescription is properly retained in accordance with the relevant legislation. Registered pharmacist must enter the following particulars into the antibiotics record:
- the name and address of person from whom or to whom the antibiotics are received or supplied;
- if the antibiotics are received from or supplied to the holder of an Antibiotics permit, the serial number of such permit;
- the name and quantity of the antibiotics received or supplied; and
- the date on which the antibiotics are received or supplied.

f. Psychotropic Substances Book
Psychotropic substances book must be kept for recording every transaction of psychotropic substances, including those supplied on and in accordance with a prescription. Registered pharmacist must keep a psychotropic substances book according to the specified format in Appendix D with the following particulars entered therein:
- the date on which the psychotropic substances were received or supplied;
- the name and address of person from whom or to whom the psychotropic substances are received or supplied;

e. 抗生素記錄冊
獲授權毒藥銷售商須保存一份抗生素記錄冊，以記錄每宗抗生素交易，但如根據處方配發抗生素，而有關處方已按照相關法例妥為保存，該等交易則屬例外。註冊藥劑師須把下列資料記入抗生素記錄冊上：
- 他從而獲取抗生素或獲他供應抗生素的人的姓名或名稱及地址；
- 如屬從持有抗生素許可證的人獲取抗生素或向該人供應抗生素，則須包括該許可證的編號；
- 所獲取或供應的抗生素的名稱及數量；以及
- 獲取或供應抗生素的日期。

f. 精神藥物記錄冊
獲授權毒藥銷售商須保存一份精神藥物記錄冊，以記錄每宗精神藥物交易，包括按照處方供應的精神藥物。註冊藥劑師須按照附錄D的指明格式，連同下列資料，備存精神藥物記錄冊：
- 獲取或供應精神藥物的日期；
- 他從而獲取精神藥物或獲他供應精神藥物的人的姓名或名稱及地址；

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

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

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

- 獲取或供應精神藥物的數量；
- 發票號碼(如適用)；以及
- 所保存精神藥物的餘額。獲授權毒藥銷售商須以登記冊內或登記冊不同的部分內的分頁來登記組成某類別精神藥物的不同精神藥物及不同濃度的製劑，而該精神藥物類別是該登記冊或該不同的部分所關乎的，並須備存所保存的精神藥物數量的餘額。精神藥物類別，以及(如適用的話)組成該類別的個別精神藥物及製劑的個別濃度，須在記錄冊每一頁與該頁的記項有關的頂端指明。有關記項須在收取或供應精神藥物當日記入精神藥物記錄冊上；如在當日記入該記項並非合理切實可行，則須在該日期的翌日記入精神藥物記錄冊上。

g. 所有須備存的登記冊、簿冊、記錄及文件須保存於註冊處所內，以供有關當局在合理時間查閱。

h. 所有登記冊、簿冊及記錄須從在其內作出的最後一項記項的日期起計保存兩年。

i. Entries made in registers, books and records must be supported by relevant transaction documents. In the case of antibiotics record, entries made must be supported by invoice, order note or other voucher and such supporting documents must be kept for a period of two years from the date of the transaction and be open for inspection. Documents in support of entries made in the dangerous drugs register are required to be kept for a period of two years from the date on which they are issued or made. Prescriptions relating to entries made in the prescription book must, except in the case of a prescription which may be dispensed again, be retained and kept for a period of two years on the premises on which it was dispensed in such a manner that they may be readily available for inspection. Documents in support of entries made in the poisons book and the psychotropic substances book are required to be kept for a period of two years from the date of the transaction.

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

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

i. 登記冊、簿冊及記錄上作出的記項，須有相關交易證明文件支持。就抗生素記錄冊而言，冊上的記項須由發票、訂單或其他憑單支持，而這些支持文件須由交易當日起計保存兩年，以備查閱。對於危險藥物登記冊，支持冊上記項的文件，須從發出或編製該文件的日期起計保留兩年。有關處方冊上的記項的處方，除可重複配藥的處方外，須保留兩年，並以可供隨時查閱的方式存放在按照該處方配藥的處所內。至於毒藥冊及精神藥物記錄冊，支持冊上記項的文件，則須由交易當日起計保存兩年。

j. 所有採購受管制藥物的書面訂單及相應的銷售發票，須自交易日起計保存兩年，以供查閱。

k. 獲授權毒藥銷售商及其註冊藥劑師在處理顧客資料時，須確保遵守《個人資料(私隱)條例》(第486章)的規定。註冊藥劑師與病人之間所建立的信任與保密關係，不得受到破壞。

Appendix A : Mandatory Requirements for Labeling of Dispensed Medicines

附錄 A : 配發藥物標籤的強制性規定

1. The following types of medicines are required to be labeled:
   (a) all medicines dispensed against "prescriptions" of registered medical practitioners, dentists or registered veterinary surgeon;
   (b) all "Part 1 Schedule 1" poisons dispensed by registered pharmacists, other than on prescription, except those supplied in their original and properly-labeled packaging*; and
   (c) all medicines, other than types (a) and (b) above, dispensed by or in the presence of registered pharmacists, except those supplied in their original and properly-labeled packaging*.
   * Original and properly-labeled packaging means packaging in which the medicine is supplied by the drug manufacturer or wholesaler.

2. All labeling should contain the following essential information:
   (a) name of patient;
   (b) date of dispensing;
   (c) name and address of the dispensary;
   (d) trade name or pharmacological name of the medicine;
   (e) dosage per unit;
   (f) method and dosage of administration; and
   (g) precautions where applicable.

3. Exemptions to the above are only allowed when the patients' consulting doctors/dentists so specified in the prescriptions.

1. 以下類別的藥物必須加上標籤：
   (a) 所有根據註冊醫生、註冊牙醫或註冊獸醫的"處方"而配發的藥物；
   (b) 所有由註冊藥劑師配發，而並非根據處方配發的"第 1 部附表1"毒藥，除非有關藥物以已加上適當標籤的原裝供應*；以及
   (c) 除上文(a)及(b)類藥物外，所有由註冊藥劑師配發，或於他在場的情況下配發的藥物，除非有關藥物以已加上適當標籤的原裝供應*。
   * 加上適當標籤的原裝是指藥物製造商或批發商供應的藥物的包裝。

2. 所有標籤應包含以下基本資料：
   (a) 病人姓名；
   (b) 配發日期；
   (c) 藥房的名稱和地址；
   (d) 藥物的品牌或藥理學名稱；
   (e) 單位劑量；
   (f) 用法及用量；以及
   (g) 注意事項(如適用)。

3. 上述規定只有在為病人診症的醫生／牙醫在處方上指明的情況下，方可獲豁免。

Appendix B
附錄 B

List of poisons which are psychotropic substances based on the United Nations 1971 Convention on Psychotropic Substances
按聯合國《1971 年精神藥物公約》屬於精神藥物的毒藥列表

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
甲乙呱酮
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
呱苯甲醇
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

Forms in Appendix C
附錄 C

FORM SPECIFIED IN THE FIRST SCHEDULE TO THE DANGEROUS DRUGS REGULATIONS (CAP. 134A)
《危險藥物規例》(第134A章)附表1所指明的格式

Date of receipt/supply 收取／供應日期	Name and address of person* or firm from whom received/ to whom supplied 供應／獲供應的有關人士*或商號的姓名或名稱及地址	Patient's identity card number# 病人的身分證號碼#	Amount 數量		Invoice No. 發票號碼	Balance 餘額
			Received 收取	Supplied 供應		

*Only cross reference of the person to whom supplied may be made, in which case, only the reference number of the person's treatment record needs to be given.
只有獲供應危險藥物的人士的相互參照，在這情況下，只須提供該人士的治療記錄編號。

#For a patient who is not resident in Hong Kong, the reference number of any proof of identity, other than an identity card, specified in section 17B(1) of the Immigration Ordinance (Cap.115) must be inserted.
如病人並非居於香港，則須填寫《入境條例》(第115章)第17B(1)條指明的任何身分證明文件(身分證除外)的編號。

Forms in Appendix D
附錄 D

FORMAT OF PSYCHOTROPIC SUBSTANCES BOOK
精神藥物記錄冊的樣式

Name of Preparation 製劑名稱			Unit of Quantity 數量單位	
Date 日期	Supplier or to whom supplied 供應者或獲供應者	Invoice No. 發票號碼／Order Note No. 訂單號碼／Prescription No. 處方號碼	Quantity 數量	Balance 餘額

Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局
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