


Code of Practice

for Holder of Wholesale Dealer Licence

批發商牌照持有人執業守則





Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局
2015

The code can be downloaded from the website of
Pharmacy and Poisons Board of Hong Kong:
本守則可在香港藥劑業及毒藥管理局網頁下載：

http://www.ppbhk.org.hk

Code of Practice

for Holder of Wholesale Dealer Licence

批發商牌照持有人執業守則

Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

2015

Table of Content
目錄

INTRODUCTION
引言

Under section 4B of the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance), the Pharmacy and Poisons Board (the Board) may issue codes of practice that it considers suitable for providing practical guidance in respect of the Ordinance.

根據《藥劑業及毒藥條例》(第138章)第4B條，藥劑業及毒藥管理局可發出該局認為適合就該條例提供實務指引的執業守則。

Pursuant to such power under section 4B of the Ordinance, the Board issues this Code of Practice for Holder of Wholesale Dealer Licence (the Code) for the purpose of providing guidance on the roles and responsibilities of the holders of Wholesale Dealer Licence (WDL) and setting out the minimum standards that a WDL holder has to meet in the distribution of pharmaceutical products. Distribution includes the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, and the delivery of pharmaceutical products from the premises of a WDL holder to other premises.

根據上述條例第4B給予的權力，批發商牌照持有人執業守則(本守則)的發出是旨在為批發商牌照持有人的角色和責任，以及批發商牌照持有人在分銷藥劑製品時所須符合的最低標準提供指引。分銷包括採購、購買、持有、貯存、銷售、供應、進口、出口藥劑製品，以及把藥劑製品從批發商牌照持有人的處所運送至其他處所。

WDL holders shall comply with the Ordinance and the Code, as well as any other requirements related to pharmaceutical products imposed under the Laws of Hong Kong, including but not limited to:

批發商牌照持有人須遵從《藥劑業及毒藥條例》(第138章)和本守則的規定，以及根據香港法例施加關乎藥劑製品的任何其他規定，包括但不限於：

a. Dangerous Drugs Ordinance (Cap. 134);

a. 《危險藥物條例》(第134章)；

b. Antibiotics Ordinance (Cap. 137);

b. 《抗生素條例》(第137章)；

c. Import and Export Ordinance (Cap. 60);

c. 《進出口條例》(第60章)；

d. Public Health and Municipal Services Ordinance (Cap. 132);

e. Undesirable Medical Advertisements Ordinance (Cap. 231);

f. Trade Descriptions Ordinance (Cap. 362); and

g. Waste Disposal Ordinance (Cap. 354).

Contravention of the Code may lead to revocation or suspension of the WDL for such period as the Pharmacy and Poisons (Wholesale Licences) Committee (the Committee) thinks fit.

The Board has engaged the assistance of the Department of Health in implementing the various requirements under the Code.

The Code does not apply to the trade in non-medicinal poisons, for example chemical reagents, hair-dyes, and industrial chemicals such as cyanide and sulphuric acid. However, all WDL holders shall ensure that their operations comply with the legal requirements stipulated in the Ordinance, and its subsidiary regulations.

d. 《公眾衞生及市政條例》(第132章);

e. 《不良廣告(醫藥)條例》(第231章);

f. 《商品説明條例》(第362章);以及

g. 《廢物處置條例》(第354章)。

違反本守則可能導致藥劑業及毒藥(批發牌照)委員會(委員會)撤銷批發商牌照,或在委員會認為適當的期間內暫時吊銷該牌照。

藥劑業及毒藥管理局已邀請衞生署協助執行守則下的各種要求。

本守則不適用於非藥用毒藥行業,例如化學試劑、染髮劑和工業化學品(如氰化物和硫酸)。然而,所有的批發商牌照持有人應確保其業務運作符合《藥劑業及毒藥條例》(第138章)及其附屬法例的規定。

SECTION 1 : GENERAL RESPONSIBILITIES OF HOLDER OF WHOLESALE DEALER LICENCE
第 1 節 : 批發商牌照持有人的一般責任

1.1 A WDL holder shall furnish any information relating to its licence as reasonably required by the Committee.

1.1 批發商牌照持有人須按委員會的合理要求，提供有關其牌照的任何資料。

1.2 A WDL holder shall nominate in writing a person to take charge of poisons and/or pharmaceutical products, and may nominate in writing one or more deputies to act during the temporary absence of the person in charge. A WDL holder shall obtain approval from the Committee prior to any change in the person in charge of the poisons and/or pharmaceutical products or his deputies and the Committee shall not approve the change unless it considers the person nominated fit and proper.

1.2 批發商牌照持有人須以書面指定一名負責人掌管毒藥及/或藥劑製品，以及可以以書面指定一名或多於一名代理在該負責人暫時缺勤時代司其職。批發商牌照持有人須先取得委員會批准，方可更改掌管毒藥及/或藥劑製品負責人或他的代理，而除非委員會認為獲提名人是適當人選，否則不會批准有關更改。

1.3 A WDL holder shall notify the Committee in writing of any change in its proprietor, partner(s) or director(s) within one month from the date of change.

1.3 所有東主、合伙人或董事如有任何更改，批發商牌照持有人須於更改日期起計一個月內，以書面通知委員會。

1.4 A WDL holder shall not sell or deal in any listed psychotropic substances set out in Appendix A unless under the supervision of a registered pharmacist.

1.4 批發商牌照持有人不得銷售或經營任何列載於附錄A的精神藥物，但如在註冊藥劑師的監督下進行，則屬例外。

1.5 A WDL holder shall ensure that all activities relating to pharmaceutical products or poisons are conducted in a manner that complies with applicable legislation and the Code.

1.5 批發商牌照持有人須確保所有關乎藥劑製品或毒藥的事務，均以符合適用法例和本守則的方式進行。

SECTION 2 : STORAGE FACILITY
第 2 節 ：貯存設施

2.1 A WDL holder shall provide designated storage facility for storing pharmaceutical products. All storage facilities of pharmaceutical products shall be approved by the Committee prior to the commencement of use. A WDL holder shall ensure that the storage facility is commensurate with or suitable for the amount and nature of the pharmaceutical products handled.

2.1 批發商牌照持有人須提供專門用作貯存藥劑製品的貯存設施。所有貯存藥劑製品的設施須先獲委員會批准，方可啟用。批發商牌照持有人應確保貯存設施配合或適合所處理藥劑製品的數量及性質。

2.2 Precautions shall be taken to prevent unauthorized persons from accessing the storage area of pharmaceutical products.

2.2 須採取預防措施，防止未經授權人士進入藥劑製品貯存區。

2.3 All Part I poisons shall be properly locked in the storage facility.

2.3 所有第 I 部毒藥須妥為鎖在貯存設施內。

2.4 Poisons shall only be kept in a container impervious to the poison stored and sufficiently stout to prevent leakage from the container arising from the ordinary risks of handling.

2.4 毒藥須貯存在不會讓毒藥滲透，且堅固程度足以防止因處理過程中的一般風險而引致洩漏的容器內。

2.5 Radioactive materials, dangerous drugs, psychotropic substances and cytotoxic drugs shall be stored subject to the implementation of appropriate additional safety and security measures.

2.5 放射性物質、危險藥物、精神藥物和細胞毒害藥物須加設適當的安全和保安措施。

2.6 Storage area of poisons and/or pharmaceutical products shall have adequate lighting facilities and ventilation.

2.6 貯存區須有充足的照明設施和通風。

2.7 Toilet facility shall not be connected directly to the storage area of pharmaceutical products.

2.7 廁所設施不得與藥劑製品貯存區直接相連。

2.8 No food shall be stored in those parts of the premises where poisons and/or pharmaceutical products are stored.

2.8 貯存毒藥或藥劑製品的處所部分，不得貯存食物。

2.9 Pharmaceutical products shall be stored off the ground and away from direct sunlight and suitably spaced.

2.9 藥劑製品須離地貯存，保持適當的間距，並避免陽光直接照射。

2.10 Measures shall be taken to prevent contamination of pharmaceutical products and mixing up of different products. There shall be segregated storage areas for different categories of pharmaceutical products, namely products in quarantine and products released, rejected, returned, or recalled. The different products and areas concerned shall be appropriately identified.

2.10 須採取措施，預防污染藥劑製品和混淆不同製品。不同類別的藥劑製品，即被隔離的製品，以及已放行、拒收、退回或回收的製品，須有分隔的貯存區。不同製品和有關的貯存區，須適當地加以識別。

2.11 Storage facility shall be maintained at a temperature and humidity within the range specified in the storage instructions of the pharmaceutical products kept. A WDL holder shall measure the temperature and humidity at different locations of the storage facility to ensure uniformity across the area. Based on the readings obtained, calibrated thermometer,

2.11 貯存設施的温度和濕度，須維持在所存藥劑製品貯存指示的指明範圍內。批發商牌照持有人須量度貯存設施不同位置的温度和濕度，以確保整區的温度和濕度均勻。根據所得讀數，須在温度和濕度波幅

hygrometer or equivalent equipment shall be placed in those location(s) of the storage facility with the highest fluctuation in temperature and humidity for daily monitoring of the storage condition. The monitoring records, such as the daily maximum and minimum temperature and humidity, shall be kept. The equipment shall be calibrated at defined interval for the required operating range and the calibration records shall be maintained.

最高的位置，放置經校正的温度計、濕度計或同等儀器，以每天監察貯存狀況。須備存監察記錄，例如每天最高及最低温度和濕度。須定期把儀器按照所需的操作範圍進行校正，並保存校正記錄。

2.12 Cold room or refrigerator for the storing of temperature-sensitive pharmaceutical products shall be installed with an alarm or alert system to alert staff to any temperature excursions. The alarm system shall be tested periodically and testing records shall be kept. Backup power shall be available to maintain the storage conditions of the pharmaceutical product in the event of power failure. Any backup generators used shall be subject to periodic testing. Alternative back-up plans that provide equivalent storage conditions and monitoring system in case of unavailability of backup generator or malfunction of the cold room or refrigerator shall be put in place. A WDL holder shall provide justification(s) for the Committee's consideration if some other contingency measures are proposed to safeguard against inappropriate storage conditions.

2.12 用作貯存易受温度影響藥劑製品的冷藏室或雪櫃，須裝設警報或預警系統，以警示員工注意任何温度偏差。警報系統須定期測試，並須備存測試記錄。須備有後備電源，萬一發生電力故障，藥劑製品的貯存狀況也得以維持。所使用的任何後備發電機須定期測試。也須制定其他後備方案，以在沒有後備發電機，或冷藏室或雪櫃出現故障的情況下，提供同等的貯存狀況和監察系統。如持牌人希望提出一些其他應急措施以防止不適當的貯存狀況，他須提供充分的理據給委員會考慮。

2.13 Storage facility shall be clean and free of litter and dust. Cleaning records shall be kept.

2.13 貯存設施須保持清潔，且無垃圾和塵埃。須備存清潔記錄。

2.14 There shall be pest control measures to prevent pest infestation. Records of any pest control measures taken shall be kept.

2.14 應採取防治蟲鼠措施，以防蟲鼠侵擾。須備存所採取的任何防治蟲鼠措施記錄。

2.15 Procedures for temperature and humidity monitoring, cleaning, and pest control shall be audited. The audit records shall be reviewed regularly. In the event of irregularities and/or deficiencies found in the procedures, the causes of irregularities and/or deficiencies shall be investigated and any corrective and preventive actions taken shall be documented.

2.15 須審核温度和濕度監察、清潔及防治蟲鼠的程序。須定期覆核審核記錄。如發現上述程序有不當情況及／或不足之處，須查明原因，所採取的任何糾正行動和預防措施，須一一記錄在案。

SECTION 3 : OPERATIONS
第 3 節 : 運作

Procurement, Import and Export of Pharmaceutical Products

採購、進口和出口藥劑製品

3.1 A WDL holder shall exercise due diligence to ensure that pharmaceutical products are procured from reputable or licensed wholesalers or manufacturers so that the quality of the products acquired may be ensured.

3.1 批發商牌照持有人須作出應盡的努力，確保從信譽良好或持牌的批發商或製造商採購藥劑製品，以保證所採購產品的質素。

3.2 A WDL holder shall exercise due diligence to ensure that pharmaceutical products for export can be legally exported to the receiving countries.

3.2 批發商牌照持有人須作出應盡的努力，確保藥劑製品可合法出口至收貨國家。

3.3 A WDL holder shall report to the DH the actual import and export of pharmaceutical products within 14 days of the arrival and departure of the shipment of the products upon the implementation of the DH's online import/export licence issuing system.

3.3 當衞生署的網上進口/出口許可證發證系統實施後，批發商牌照持有人須在付運貨物抵港或離港14天內，向衞生署呈報實際進口或出口付運的藥劑製品。

3.4 For pharmaceutical products imported for export purpose, a WDL holder shall export the products within 1 year from the date of importation unless otherwise approved by the DH.

3.4 就進口作出口用途的藥劑製品而言，批發商牌照持有人須在進口日期起計一年內出口有關製品，但如獲衞生署批准，則屬例外。

Receipt and Storage of Pharmaceutical Products

3.5 Each incoming delivery of pharmaceutical products shall be physically checked upon receipt for tampering and damage. Label description, type and quantity of the incoming products shall be verified against the relevant purchase order. All pharmaceutical products shall be accompanied by batch release certificates or certificates of analysis issued by the manufacturers and these certificates shall be checked to ensure the quality of the products delivered. The checking and verification conducted shall be supported by documentary records.

3.6 Pharmaceutical products, especially temperature-sensitive products, shall be immediately identified upon receipt and stored under the storage conditions specified in the instructions indicated on the product label.

3.7 A WDL holder who sells or supplies drugs imported from overseas manufacturer must make available to the DH within a reasonable time frame after a drug incident concerning such drug a batch sample of the drug concerned so as to enable any investigation into the incident required by the DH.

接收和貯存藥劑製品

3.5 收貨後，須以人手檢查每批送來的藥劑製品有否被擅動或損壞。送來製品的標籤說明、種類和數量，須按相關購貨訂單加以核實。所有藥劑製品須附有製造商所發出的批次放行許可證書或分析證明書，而該等證明書亦須予查核，以確保送來製品的質素。所進行的查核及核實須有文件記錄支持。

3.6 在接收藥劑製品時，須即時識別易受溫度影響的製品，並按照製品標籤上指示的貯存條件貯存。

3.7 從事銷售或供應從海外製造商進口的藥物的批發商牌照持有人，須在藥物事故後的合理時限內提供相關的藥物的批次樣本給予衞生署，以便衞生署需要時就該藥物事故進行任何調查。

3.8 Periodic stock reconciliation shall be performed by comparing the actual and recorded stock. Significant stock discrepancies shall be investigated to ensure that there has been no mixing up, incorrect issue and/or misappropriation of pharmaceutical products.

3.8 須定期進行存貨盤點，比對實際和記錄的存貨量。存貨如有重大差異，須進行調查，確保沒有混淆、錯誤發出及／或挪用藥劑製品的情況。

Supply of Pharmaceutical Products

3.9 A WDL holder must not sell or supply a poison to any person other than the following:

a. a licensed wholesale dealer;

b. a licensed manufacturer;

c. an authorized seller of poisons;

d. a registered pharmacist;

e. a registered medical practitioner, a registered dentist or a registered veterinary surgeon;

f. persons who require the poison for the purpose of their trade or business;

g. a Government department or public officer requiring the article for the purposes of public service;

h. a person or an establishment concerned with education or scientific research, if the article is required for the purposes of such education or research;

供應藥劑製品

3.9 持有批發商牌照的人不得向任何人銷售或供應任何毒藥，但向下列的人銷售或供應毒藥則除外：

a. 另一名批發商牌照持有人；

b. 持牌製造商；

c. 獲授權毒藥銷售商；

d. 註冊藥劑師；

e. 註冊醫生、註冊牙醫或註冊獸醫；

f. 為本身的行業或業務而需要該毒藥的人；

g. 為公共服務而需要該物品的政府部門或公職人員；

h. 從事教育或科學研究的人或組織，但該物品必須是進行有關的教育或科學研究所需的；

i. an institution;

j. purchasers outside Hong Kong; or

k. a Listed Seller of Poisons (provided that only Part II poisons may be sold or supplied).

If the product handled is a dangerous drug or an antibiotic, a WDL holder must also comply with the Dangerous Drug Ordinance (Cap. 134) or the Antibiotics Ordinance (Cap. 137) in its sale or supply of the product.

3.10 When a verbal order for pharmaceutical products that contain Part I poisons, dangerous drugs or antibiotics is received from a purchaser, a WDL holder shall obtain an order in writing from the purchaser before completion of a sale of Part I poisons, dangerous drugs or antibiotics in order to avoid ambiguity or miscommunication which may otherwise lead to wrongful delivery.

Written orders in paper format or by means of an electronic message, such as email, are acceptable.

i. 任何機構；

j. 香港以外地方的購買人；或

k. 列載毒藥銷售商（但只可銷售或供應第II部毒藥）。

如所處理的產品是危險藥物或抗生素，批發商牌照持有人必須在符合危險藥物條例（第134章）或抗生素條例（第137章）下銷售或供應該產品。

3.10 為避免因為歧義或溝通出錯而可能引致送貨出現錯誤，當批發商牌照持有人於接到購買人的口頭訂單購買含有第I部毒藥、危險藥物和抗生素的藥劑製品後，須於完成銷售第I部毒藥、危險藥物和抗生素前，取得由購買人發出的書面訂單。

以紙張形式或透過電子媒介（如電郵）所作的書面訂單均可被接受。

A WDL holder may accept an order of medicines placed by a representative of the purchaser but shall exercise due diligence to ensure the authenticity of the order.

購買人可以指派他的代表向批發商牌照持有人訂購藥物，但批發商牌照持有人須作出應盡的努力以確保訂單的真確性。

3.11 Particulars of registered pharmaceutical products sold or distributed in Hong Kong shall correspond exactly with those registered with the Pharmacy and Poisons Board.

3.11 於香港銷售或分銷的註冊藥劑製品詳情，須與向藥劑業及毒藥管理局註冊的詳情完全相符。

3.12 A WDL holder shall not supply pharmaceutical products with broken seals, damaged packaging, suspected tampering or contamination or which have been stored in undesirable storage condition and shall properly segregate such products. Should such a defect exist, a WDL holder shall investigate into the cause of the defect, take relevant corrective and preventive measures and document the measures taken.

3.12 批發商牌照持有人不得供應封口破裂、包裝損壞、懷疑被擅動或污染，或曾貯存於不良貯存狀況的藥劑製品，並應妥為分隔。如有上述情況，批發商牌照持有人須查明出現任何上述問題的原因，以及採取糾正和預防措施，並一一記錄在案。

3.13 Pharmaceutical products shall not be supplied after their expiry dates or at a time that is so close to their expiry dates that the pharmaceutical products will soon expire by the time of consumption.

3.13 不得供應已過期的藥劑製品，或其時已非常接近使用期限因而很可能在服用時已過期的藥劑製品。

3.14 A system shall be in place to ensure that the pharmaceutical products will be distributed on a "first expired first out" (FEFO) basis. Exceptions may be justified provided that adequate controls are in place to prevent distribution of expired products.

3.14 須設有一套系統，確保藥劑製品會以"先到期先出"的準則分銷。但如有足夠管控，防止分銷過期製品，則有理由支持作例外處理。

Transportation

3.15 A WDL holder shall not consign any poison for transport unless the poison is sufficiently stoutly packed to avoid leakage arising from the ordinary risks of handling and transport.

3.16 Pharmaceutical products shall be transported in such a manner that will:

a. ensure their identification;

b. avoid contamination of the products;

c. protect the products from spillage, breakage or theft;

d. avoid exposure of the products to unacceptable heat, coldness, light, moisture or other adverse conditions and infestation by microorganisms or pests.

運輸

3.15 批發商牌照持有人不得託運任何毒藥，除非該毒藥有堅固的包裝，其程度足以避免因處理和運輸過程中的一般風險所引致的洩漏。

3.16 藥劑製品的運輸方式，須：

a. 確保製品得以識別；

b. 不會導致製品受到污染；

c. 保護製品，以免溢出、破損或被盜；

d. 避免製品暴露於不可接受的熱力、寒冷、光線、水分或其他不良狀況，以及受微生物或蟲鼠侵擾。

3.17 A WDL holder shall make arrangement with their transportation agents to ensure that delivery of pharmaceutical products will be carried out in a safe and secure manner and the pharmaceutical products will be kept in appropriate storage conditions during transportation, especially where the products delivered are dangerous drugs, psychotropic substances or products need to be kept under cold chain management.

3.17 批發商牌照持有人須與運輸代理作出安排，確保代理會安全而穩妥地運送藥劑製品，以及信納代理會在運輸途中把藥劑製品存放於合適的環境中，尤以危險藥物、精神藥物和藥物需要保存於冷鏈處理為然。

Handling of Returned Pharmaceutical Products

3.18 All returned pharmaceutical products shall be segregated from the saleable stock.

3.19 Pharmaceutical products returned from the market shall be destroyed unless a risk assessment has been carried out to ensure the appropriateness for the reissue or reuse of such products. The risk assessment shall be carried out in accordance with a written procedure and shall take into account the nature, condition and history of the product returned, the special storage conditions required, and the time elapsed since the product was issued.

3.20 All handling of returned pharmaceutical products including their return to saleable stock or disposal shall be approved by the person in charge of poisons or pharmaceutical products and be recorded.

處理退回的藥劑製品

3.18 所有退回的藥劑製品須與可出售的存貨分隔開。

3.19 所有從市面退回的藥劑製品，須予銷毀，除非在進行風險評估後，肯定情況合適，始應考慮重新分發或重新使用退回的藥劑製品。須為風險評估制定書面程序，並考慮退回製品的性質、狀況和來歷、所需特別貯存條件，以及自製品分發以來經過多久。

3.20 處理全部退回的藥劑製品，包括將製品退回可出售的存貨或棄置製品，一律應獲掌管毒藥或藥劑製品負責人批准，並作出記錄。

Destruction of Pharmaceutical Products

3.21 Pharmaceutical products intended to be destroyed shall be handled in accordance with relevant legislations and guidelines, if any, issued by the Environmental Protection Department. A WDL holder shall notify the DH in advance of the destruction and, where the destruction is of dangerous drugs, the destruction shall be witnessed by a pharmacist of the DH. Record of destruction of pharmaceutical products shall be kept for inspection and investigation by the DH.

銷毀藥劑製品

3.21 擬銷毀的藥劑製品須按照相關法例和環境保護署發出的指引（如有的話）處理。批發商牌照持有人進行銷毀前，須預先通知衞生署，如要銷毀的屬危險藥物，須由衞生署藥劑師見證其銷毀。須備存銷毀藥劑製品的記錄，以供衞生署查閱。

Regular Checking and Review of Operation

3.22 All operation procedures and records related to the handling and control of pharmaceutical products shall be reviewed regularly and documented. In the event of irregularities and/or deficiencies found in the operation procedures and record keeping, the causes of irregularities and/or deficiencies shall be investigated and corrective and preventive measures shall be taken and documented.

定期查核和檢討運作

3.22 須定期檢討及記錄所有與處理和管控藥劑製品有關的運作程序。相關運作記錄亦應定期覆檢。如有不當情況及／或不足之處，須查明出現不當情況及／或不足之處的原因，以及採取糾正和預防措施，並一一記錄在案。

SECTION 4 : DOCUMENTATION
第 4 節 ：文件記錄

4.1 A WDL holder shall provide all documentation related to the licensed activities, including those required in the Code, for inspection when required by the DH.

4.2 A WDL holder shall keep record of all transactions of Part I poisons or pharmaceutical products and the records shall contain the following particulars:

a. the name of the poison or pharmaceutical product;

b. the batch number, pack size and unit of quantity of the poison or pharmaceutical product;

c. the date of the transaction;

d. the nature of the transaction;

e. the name of supplier or the person to whom the poison or pharmaceutical product is supplied;

f. the invoice number;

g. the total quantity received or supplied; and

4.1 批發商牌照持有人須在衞生署要求時，提供所有與持牌活動有關的文件記錄，包括本守則所要求的，以供查閱。

4.2 批發商牌照持有人須備存所有第 I 部毒藥或藥劑製品的交易記錄，而該等記錄須載有下列詳情：

a. 毒藥或藥劑製品名稱；

b. 毒藥或藥劑製品的批次編號、包裝大小及數量單位；

c. 交易日期；

d. 交易性質；

e. 供應人或獲供應毒藥或藥劑製品的人的姓名；

f. 發票號碼；

g. 獲取或供應的總數量；以及

h. the balance of the poison or pharmaceutical product kept after the transaction.

There shall be a separate entry in the record for each Part I poison or pharmaceutical product and every transaction shall be recorded within 72 hours after the time it took place.

All records of transactions must be in the specified form (see Appendix B) unless the Committee approves another system of recording.

Records of sales or supplies maintained under Pharmacy and Poisons Regulations shall be supported by documents signed by the purchaser. In the case of an import or export transaction, a WDL holder must retain all shipping and other documents supporting the transaction.

4.3 A WDL holder shall collect the signed receipts of sale or supply of Part I poisons or pharmaceutical products within 72 hours after the transaction.

4.4 Electronic record may only be used if it can be readily retrieved and printed out for inspection.

h. 毒藥或藥劑製品交易後的餘量。

每種第 I 部毒藥或藥劑製品須有獨立的記錄，而每項交易須在有關交易進行後 72 小時內予以記錄。

所有交易記錄，均須符合指明格式（見附錄 B），但如委員會批准使用另一種記錄制度，則屬例外。

根據《藥劑業及毒藥規例》備存的銷售或供應記錄，須有購買人所簽署的文件支持。如屬入口或出口交易，批發商牌照持有人必須保留所有支持該項交易的裝運及其他文件。

4.3 批發商牌照持有人須在第 I 部毒藥或藥劑製品交易後 72 小時內收集經簽署的銷售或供應單據。

4.4 可使用電子記錄，但必須能隨時檢索和列印有關記錄，以供查閱。

4.5 A WDL holder shall retain the supporting records and documents for each transaction of Part I poisons or pharmaceutical products, which include but are not limited to invoice, written order, signed receipt, import and export licence, import and export declaration form, batch release certificate and certificate of analysis.

4.6 A WDL holder shall state the batch number of the Part I poisons or pharmaceutical products supplied in the invoice for the transaction.

4.7 All books or other form of records and documents required to be kept or retained by a WDL holder shall be preserved in the premises in which the transaction recorded took place-

a. for a period of 2 years from the date of the last entry therein; or

b. in relation to a certificate or document, for a period of 2 years from the date of the transaction.

4.5 批發商牌照持有人須保留支持每項第I部毒藥或藥劑製品交易的記錄和文件，包括但不限於發票、書面訂單、經簽署的單據、進口及出口許可證、進口及出口報關表格、批次放行許可證書及分析證明書。

4.6 批發商牌照持有人須於發票內述明所供應第I部毒藥或藥劑製品的批次號碼。

4.7 所有須由批發商牌照持有人備存或保留的簿冊或其他形式的記錄及文件，均須保存於進行予以記錄的交易的處所內－

a. 為期兩年，由在該等簿冊或記錄記入最後的記項的日期起計；或

b. 就證明書或文件而言，為期兩年，由交易日期起計。

4.8 Any other records and documents mentioned in the Code shall be kept or retained by a WDL holder for at least two years from the date of completion of the record or document.

4.8 本守則提及的任何其他記錄和文件，批發商牌照持有人須由有關記錄或文件完成日期起計，備存或保留至少兩年。

4.9 Records and documents required to be maintained under the Code shall be reviewed regularly. In the event of irregularities and/or deficiencies found in maintaining the records and documents, the causes of irregularities and/or deficiencies shall be investigated and any corrective and preventive actions taken shall be documented.

4.9 記錄和文件須予以定期覆檢。如有發現記錄和文件不當情況及／或不足之處，須查明原因，所採取的任何糾正行動和預防措施，須一一記錄在案。

4.10 A WDL holder shall carefully review all the documents before their proper disposal to avoid mistaken destruction.

4.10 批發商牌照持有人在妥善棄置所有文件前必須先仔細覆檢，以免錯誤銷毀文件。

SECTION 5 : REPORTING OF PRODUCT COMPLAINTS, PRODUCT RECALLS, PRODUCT CHANGES AND ADVERSE DRUG REACTIONS

第 5 節 ：呈報製品投訴、製品回收、製品改變和藥物不良反應

5.1 A WDL holder shall carefully investigate and document any complaints and information concerning potentially defective pharmaceutical products supplied. In case of a complaint or problem of pharmaceutical products that leads to a recall, a WDL holder shall report the recall to the DH where the recall is not initiated by the DH and implement the recall as instructed or endorsed by the DH in accordance with the "Pharmaceutical Products Recall Guidelines" published at the following website link:

http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Pharmaceutical_Products_Recall_Guidelines.pdf

A recall of pharmaceutical products may be initiated by the DH or the manufacturer, wholesaler, importer or registration certificate holder of the pharmaceutical products recalled.

5.2 If a WDL holder is also the registration certificate holder of a pharmaceutical product, the WDL holder shall closely liaise with the local or overseas manufacturer of the product and promptly report any significant changes or

5.1 批發商牌照持有人須仔細調查及記錄任何關於可能有問題的藥劑製品的投訴和資料。如因投訴或產品有問題導致有產品需要回收，而該回收行動並非由衞生署指示下開展，則批發商牌照持有人須向衞生署呈報，並按照"藥劑製品回收指引"，執行衞生署指示或批簽的回收行動。有關指引載於以下網站連結：

http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Pharmaceutical_Products_Recall_Guidelines.pdf

藥劑製品的回收行動可由衞生署或該被回收藥劑製品的製造商、批發商、進口商或註冊證明書持有人展開。

5.2 如批發商牌照持有人亦是藥劑製品註冊證明書持有人，他們便須和海外製造商緊密聯系及在接到本地或海外製造商就有關任何

conditions which may affect the safety, efficacy or quality of the pharmaceutical products to the DH once notification of such changes or conditions from the manufacturer is received.

該藥劑製品的顯著改變或其情況可能影響該製品的安全、療效及素質時，他們須及時向衞生署呈報。

5.3 Once a WDL holder is made aware of an Adverse Drug Reactions (ADR) related to the products it has supplied, it shall investigate into, document and report the same to the Pharmacovigilance Unit of the DH in accordance with the "Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements" published at the following website link:

http://www.drugoffice.gov.hk/adr_industry.html

5.3 批發商牌照持有人在得悉其供應的產品有藥物不良反應後，須即進行調查及記錄，並按照"藥劑業界指引 - 藥品不良反應申報要求"，向衞生署藥物警戒組呈報。有關要求載於以下網站連結：

http://www.drugoffice.gov.hk/adr_industry.html

GLOSSARY
辭彙

"Adverse Drug Reaction (ADR)"

A response to a pharmaceutical product which is noxious and unintended.

" 藥物不良反應 "

藥品不良反應是指對藥劑製品與用藥目的無關的有害反應。

"antibiotics"

Substances to which the Antibiotics Ordinance (Cap. 137) applies.

" 抗生素 "

《抗生素條例》(第 137 章)適用的物質。

"authorized seller of poisons (ASP)"

This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap. 138).

" 獲授權毒藥銷售商 "

指根據《藥劑業及毒藥條例》(第 138 章)給予該詞的涵義相同。

"batch"

A defined quantity of pharmaceutical products processed in a single process or series of processes so that the products produced are expected to be homogenous.

" 批次 "

在單一或一系列製造過程中處理的經界定數量的藥劑製品，從而預期該些製品都是均質。

"The Board"

The Pharmacy and Poisons Board.

"calibration"

A set of operations that establishes under specified conditions the relationship between the values indicated by an instrument or system for measuring (especially weighing), recording, and controlling and the corresponding known values of a reference standard and for which limits for acceptance of the results of measurement are established.

"Committee"

The Pharmacy and Poisons (Wholesale Licences) Committee established by the Pharmacy and Poisons Board.

"

藥劑業及毒藥管理局。

" 校正 "

一套操作程序，用以在特定條件下，訂定測量（尤指稱量）、記錄和控制器具或系統所顯示的數值與參照標準的相應已知數值之間的關係，並就此訂定測量結果的接受範圍。

" 委員會 "

藥劑業及毒藥管理局所成立的藥劑業及毒藥（批發牌照）委員會。

“certificate of analysis”

A certificate which certifies whether or not a sample of poison or pharmaceutical product complies with certain specifications after a list of test procedures meeting specified criteria are applied to the sample.

" 分析證明書 "

對樣本進行一系列符合指明準則的測試程序後，證明該毒藥或藥劑製品樣本是否符合訂明規格的證明書。

“The Code”

The Code of Practice for Holder of Wholesale Dealer Licence.

批發商牌照持有人執業守則。

“contamination”

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a pharmaceutical product during handling, storage or transport.

" 污染 "

在處理、貯存或運輸過程中，藥劑製品意外沾染化學雜質、微生物雜質或外來異物。

"container"	**" 容器 "**
The material employed in the packaging of a pharmaceutical product. Containers include primary, secondary and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product and secondary if they are not.	包裝藥劑製品所用的物料。容器包括內、外或運輸容器。會與製品直接接觸的容器，稱為內容器，不會與製品直接接觸的容器，則稱為外容器。
"dangerous drugs"	**" 危險藥物 "**
The drugs and substances specified in Part I of the First Schedule of the Dangerous Drugs Ordinance (Cap. 134).	《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。
"DH"	
The Department of Health.	衞生署。

“distribution of pharmaceutical products”

It includes the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, and the delivery of pharmaceutical products from the premises of a WDL holder to other premises, with the exception of dispensing or supplying pharmaceutical products directly to a patient or his or her agent.

" 分銷藥劑製品 "

包括採購、購買、持有、貯存、銷售、供應、進口、出口藥劑製品，及把藥劑製品從批發商 牌照持有人的處所運送至其他處所，但不包括直接向病人或其代理人配發或提供藥劑製品。

"expiry date”

In relation to a pharmaceutical product, it is the date determined, on the basis of the product's specifications registered under Regulation 36(3)(a)(ii) of the Pharmacy and Poisons Regulations, by the manufacturer as the date after which the product should not be used, assuming that the product is stored under conditions suitable to the product.

" 使用期限 "

就任何藥劑製品而言，指符合以下說明的日期：由製造商按該製品根據藥劑業及毒藥規例第 36 (3)(a)(ii) 條註冊的規格，斷定該日期，而假設該製品是在適合該製品的情況下貯存，在該日期後便不應使用該製品。

“first expired first out” (FEFO)

A distribution procedure that ensures that the stock with the earliest expiry date is distributed and/or used before an identical stock item with a later expiry date is distributed and/or used.

" 先到期先出 "

一種分銷程序，用以確保最早到使用期限的存貨，會在較遲到使用期限的相同物品分銷及／或使用之前，分銷及／或使用。

"institution"

This includes hospital, maternity home or clinic as defined under the Pharmacy and Poisons Ordinance (Cap. 138).

" 機構 "

包括根據《藥劑業及毒藥條例》(第 138 章)界定的醫院、留產院或診療所。

"Listed Seller of Poisons"

This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap. 138).

" 列載毒藥銷售商 "

與《藥劑業及毒藥條例》(第 138 章)給予該詞的涵義相同。

"manufacture" and "manufacturer"

These have the same meaning assigned to them under the Pharmacy and Poisons Ordinance (Cap. 138).

" 製造 " 和 " 製造商 "

與《藥劑業及毒藥條例》(第 138 章)給予該兩詞的涵義相同。

"The Ordinance"

The Pharmacy and Poisons Ordinance (Cap. 138).

" 本條例 "

《藥劑業及毒藥條例》(第 138 章)。

"pharmaceutical product"

Any substance or combination of substances—

a. presented as having properties for treating or preventing disease in human beings or animals; or

b. that may be used in, or administered to, human beings or animals, either with a view to—

   i. restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

   ii. making a medical diagnosis.

" 藥劑製品 "

指符合以下説明的物質或物質組合—

a. 被表述為具有治療或預防人類或動物的疾病的特性；或

b. 可應用或施用於人類或動物，其目的是—

   i. 透過藥理、免疫或新陳代謝作用，以恢復、矯正或改變生理機能；或

   ii. 作出醫學診斷。

"Part I poison"

A substance which is specified in Part I of the Poisons List (Cap. 138A Schedule 10).

" 第 I 部毒藥 "

在毒藥表（第 138A 章附表 10）第 I 部內指明的物質。

"Part II poison"

A substance which is specified in Part II of the Poisons List (Cap. 138A Schedule 10).

" 第 II 部毒藥 "

在毒藥表（第 138A 章附表 10）第 II 部內指明的物質。

“poison”

A substance which is specified in the Poisons List (Cap. 138A Schedule 10).

" 毒藥 "

在毒藥表（第 138A 章附表 10）內指明的物質。

“procure”

Obtain, acquire or purchase pharmaceutical products from manufacturers, importers or other wholesale distributors.

" 採購 "

從製造商、進口商或其他批發分銷商獲得、取得、購買或買入藥劑製品。

“product recall”

A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product, and/or complaints of serious adverse reactions to the product and/or concerns that the product is or may be counterfeit.

" 製品回收 "

由於藥劑製品有問題、出現對製品有嚴重不良反應的投訴，以及／或關注到製品是或可能是假冒，因而從藥物分銷鏈撤回或清除藥劑製品的過程。

"psychotropic substance"

Any substances specified in the List of poisons which are Psychotropic Substances (see Appendix A) maintained and updated by the Drug Office of the Department of Health in accordance with the Convention on Psychotropic Substances, 1971.

" 精神藥物 "

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

"quarantine"

The status of pharmaceutical products when they are isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

" 隔離 "

把藥劑製品予以實體隔離或以其他有效方法隔離，以待決定應否放行、拒納或重新處理的狀況。

"registered"

This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap. 138).

" 註冊 "

與《藥劑業及毒藥條例》(第138章)給予該詞的涵義相同。

“returned pharmaceutical product”	" 退回的藥劑製品 "
Finished product sent back to a holder of Wholesale Dealer Licence.	送回批發商牌照持有人的製成品。
“specification”	" 規格 "
A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.	製造過程中所使用或獲取的製品或物料所須符合詳細規定的文件。規格是進行品質評估的依據。
“storage”	" 貯存 "
The storing of pharmaceutical products up to the point of use.	貯存藥劑製品直至使用為止的過程。
“WDL”	
The Wholesale Dealer Licence.	批發商牌照。

APPENDIX A
附錄 A

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 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

APPENDIX B
附錄 B

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

(Chapter 138)
(第 138 章)

FORM OF RECORDS OF TRANSACTIONS INVOLVING POISONS IN PART I OF THE POISONS LIST OR ANY PHARMACEUTICAL PRODUCTS TO BE KEPT BY WHOLESALE DEALERS

批發商須備存的涉及毒藥表第 I 部毒藥或任何藥劑製品的交易紀錄格式

Name of Poison/ Pharmaceutical Product 毒藥 / 藥劑製品名稱				Pack Size 包裝大小		Unit of Quantity 數量單位
Date of Transaction 交易日期	Nature of transaction 交易性質	Supplier or to whom supplied 供應人或獲供應的人	Invoice No. 發票號碼	Batch Number 批次編號	Total Quantity 總數量	Balance after transaction 交易後的餘量

Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局
2015