# 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
2021

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# 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合適的執業守則，以就該條例提供實務指引。

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 (Cap.138) 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);

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.

c.《進出口條例》(第60章)；

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.《商品說明條例》(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委任一名負責人掌管毒藥及/或藥劑製品，以及可以以書面委任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其代理，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 如東主、合伙人或董事有任何更改，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，除非在註冊藥劑師的監督下進行。

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涉及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.

2.2 Precautions shall be taken to prevent unauthorized access to the storage facility of pharmaceutical products.

2.3 All Part 1 poisons shall be properly locked in the storage facility.

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.

2.5 Radioactive materials, dangerous drugs, psychotropic substances and cytotoxic drugs shall be stored in a facility with additional safety and security measures as appropriate.

2.1 批發商牌照持有人須提供專為貯存藥劑製品而設的貯存設施。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此等貯存設施與所處理的藥劑製品的數量及性質相稱或合適。

2.2 須採取預防措施，以防止未獲授權人士進入藥劑製品貯存區 。

2.3 所有第1部毒藥須妥為鎖在貯存設施內。

2.4 毒藥須貯存在不會讓毒藥滲透的容器，而容器的堅固程度須能抵禦因處理過程所產生的一般風險而引致的洩漏。

2.5 貯存放射性物質、危險藥物、精神藥物和細胞毒害藥物的設施須加設合適的安全和保安措施。

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

2.6 貯存區須具備充足的照明設施和通風系統。

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

2.7 藥劑製品貯存區不得與廁所設施直接相連 。

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，產品之間應保持適當的間距，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 須採取措施以防藥劑製品受污染和不同產品被混淆。不同類別的藥劑製品，即被隔離、已放行、拒收、退回或回收的產品，須有分隔的貯存區。不同產品和相關的貯存區，須妥善分隔並適當地加以識別 。

2.11 Storage facility shall be maintained within the temperature and humidity 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, hygrometer or equivalent equipment shall be placed in those location(s) 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.

2.11 須根據所貯存的藥劑製品的貯存指示，將貯存設施維持在指明的溫度和濕度範圍內。批發商牌照持有人須量度貯存設施不同位置的溫度和濕度，以確保整區的溫度和濕度均勻。根據所得讀數，將經校正的溫度計、濕度計或同等儀器放置在溫度和濕度波幅最高的位置，以監察每天的貯存狀況，並備存每天最高及最低溫度和濕度等監察紀錄。須定期把儀器按照所需的操作範圍進行校正，並保存校正紀錄。

2.12 Cold room or refrigerator for the storing of temperature-sensitive pharmaceutical products shall be equipped with the following:

- Alarm or alert system to alert staff of any temperature excursions. The alarm system shall be tested periodically and testing records shall be kept.

2.12 用作貯存易受溫度影響藥劑製品的冷藏室或雪櫃須配備以下項目：

- 須備有警報或預警系統以提醒員工注意任何溫度偏差。須定期測試警報系統，並備存測試紀錄。

- Backup power 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. Justification(s) shall be provided for the Committee's consideration if some other contingency measures are proposed to safeguard against inappropriate storage conditions.

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

2.14 Pest control measures shall be in place to prevent pest infestation. Records of any pest control measures taken shall be kept.

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.

- 須備有後備電源，在萬一發生電力故障，也能維持藥劑製品的貯存狀況。須定期測試所使用的任何後備發電機。
- 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，可提供同等的貯存狀況和監察系統。如欲提出其他應急措施以防止不適當的貯存狀況，持牌人須提供充分的理據給委員會考慮。

2.13 須保持貯存設施清潔，且無垃圾和塵埃，並備存清潔紀錄。

2.14 須採取防治蟲鼠措施以防蟲鼠侵擾，並備存所採取的任何防治蟲鼠措施紀錄。

2.15 須審核溫度和濕度監察、清潔及防治蟲鼠的程序。須定期覆核此等審核紀錄 。如發現上述程序有不當及/或不足情況，須查明原因，而所採取的任何糾正和預防措施，須記錄在案 。

# 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 as to assure the quality of the products acquired.

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 In addition to the requirements by the Customs and Excise Department, a WDL holder shall report to the DH the actual import of unregistered pharmaceutical products within 14 days of the arrival of the shipment of the products.

3.3 除海關的規定外，批發商牌照持有人須在付運貨物抵港14天內，向衞生署呈報實際進口的未經註冊藥劑製品的詳情。

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 批發商牌照持有人須在進口日期起計一年內，出口所有為出口用途而進口的藥劑製品。如獲衞生署批准，則屬例外。

## Receipt and Storage of Pharmaceutical Products

## 接收和貯存藥劑製品

3.5 The followings shall be noted upon receipt of each incoming batch of pharmaceutical products:

- check whether there is any physical tampering and damage of the products.
- verify label description, type and quantity of products against the relevant purchase order.
- ensure products are accompanied by batch release certificates or certificates of analysis issued by the manufacturers, and also check these certificates to ensure the quality of the products.

All the above checking and verification shall be supported by documentary records.

3.5 接收每批藥劑製品時，須留意以下事項：

- 藥劑製品有否被擅動或損壞。
- 須按相關購貨訂單資料核實產品的標籤說明、種類和數量。
- 產品附有製造商所發出的批次放行許可證書或分析證明書，亦須檢查該證明書以確保產品的質素。

須有文件紀錄支持以上所進行的檢查及核實事項。

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

3.6 接收藥劑製品，特別是易受溫度影響的產品時，須立即識別產品並按照產品標籤上指示的貯存條件貯存。

3.7 Within a reasonable time frame after a drug incident, the WDL holder who imported those drugs from overseas manufacturer for sale or supply must make available to the DH a batch sample of the drug concerned so as to facilitate any investigation into the incident required by the DH.

3.7 在藥物事故發生後的合理時間內，曾向海外製造商進口該藥物作銷售或供應的批發商牌照持有人，須向衞生署提供相關藥物批次的樣本，以便衞生署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，比對實際存貨和紀錄上的存貨量。存貨如有重大差異，須進行調查以確保沒有混淆、錯誤發貨及／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;

i. an institution;

j. purchasers outside Hong Kong; or

## 供應藥劑製品

3.9 除向以下人士銷售或供應外，批發商牌照持有人不得向任何人銷售或供應毒藥：

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. 任何機構；

j. 香港以外地方的購買人；或

k. a Listed Seller of Poisons (provided that only Part 2 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 1 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 these products 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.

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.

k. 列載毒藥銷售商(但只可銷售或供應第2部毒藥)。

如處理的產品屬危險藥物或抗生素，批發商牌照持有人在銷售或供應該產品時必須符合危險藥物條例（第134章）或抗生素條例（第137章）。

3.10 為避免因為含糊不清或溝通問題而可能引致錯誤送貨，當批發商牌照持有人接到購買人的口頭訂單購買含有第1部毒藥、危險藥物和抗生素的藥劑製品後，須於完成銷售第1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。

可接受的書面訂單模式包括以紙張形式，或透過電子媒介（如電郵等）所作的訂單。

批發商牌照持有人可接受購買者委派代表向其訂購藥物，但批發商牌照持有人必須作出應盡的努力確保訂單的真確性 。

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的詳情，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，並應將此等產品妥為分隔。如有上述情況，批發商牌照持有人須查明出現上述問題的原因，以及採取相應的糾正和預防措施，並記錄在案。

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

3.13 不得供應已過期的藥劑製品，或非常接近其使用期限因而很可能在使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 須設有一套可確保藥劑製品能以“先到期先出”的準則的分銷系統。如有充足的管制措施防止分銷過期產品，則可能作為例外處理的理由 。

## 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.

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.

## 運輸

3.15 批發商牌照持有人不得託運任何包裝不夠堅固的毒藥，除非其包裝足以抵禦因處理和運輸所產生的一般風險所引致的洩漏。

3.16 藥劑製品的運輸方式，須：

a. 確保產品得以識別；

b. 避免產品受到污染；

c. 保護產品以免溢出、破損或被盜；

d. 避免產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 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，並信納代理會在運輸途中把藥劑製品存放於合適的貯存環境中，特別對危險藥物、精神藥物和需要貯存於冷鏈的藥物尤其重要。

## Handling of Returned Pharmaceutical Products

## 處理退回的藥劑製品

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

3.18 所有退回的藥劑製品須與可出售的存貨分隔開貯存。

3.19 Pharmaceutical products returned from the market shall be destroyed unless a risk assessment has been carried out to ensure the appropriateness for their reissue or reuse. The risk assessment shall adhere to 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.

3.19 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，確定情況合適，才可重新分發或重新使用退回的藥劑製品。應遵循書面程序進行風險評估，其考慮因素包括退回產品的性質、狀況和來歷、所需特別貯存條件，以及產品分發至退回所經歷的時間 。

3.20 The 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.

3.20 處理退回的藥劑製品，包括將產品歸回可出售的存貨或棄置，一律應獲掌管毒藥或藥劑製品負責人批准，並作出紀錄。

## Destruction of Pharmaceutical Products

## 銷毀藥劑製品

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

3.21 須按照相關法例和環境保護署發出的指引(如有)處理擬銷毀的藥劑製品。批發商牌照持有人銷毀危險藥物前，須預先通知衞生署，並由衞生署藥劑師見證其銷毀。須備存銷毀任何藥劑製品的紀錄，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. Corrective and preventive measures shall be taken and documented.

## 定期查核和檢視運作

3.22 須定期檢視所有與處理和管控藥劑製品相關的運作程序及紀錄，並予以記錄。如發現運作程序及所保存的紀錄有不當及／或不足情況，須查明原因，以及採取糾正和預防措施，並記錄在案 。

# Section 4 : Documentation
# 第 4 節 ：文件紀錄

4.1 A WDL holder shall maintain documentation related to the licensed activities, including those required in the Code, and ensure the documents are readily available for inspection when required by the DH.

4.2 A WDL holder shall keep record of all transactions of Part 1 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. for an advanced therapy product (ATP) supplied for use by a registered medical practitioner or registered dentist – the name and address of the practitioner or dentist;

4.1 批發商牌照持有人須保存所有與持牌事務有關的文件紀錄，包括本守則所要求的文件，並確保在衛生署要求時可供隨時查閱該等文件。

4.2 批發商牌照持有人須備存所有第1部毒藥或藥劑製品的交易紀錄，而該等紀錄須載有下列詳情：

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. 就供應予註冊醫生或註冊牙醫使用的先進療法製品而言—該醫生或牙醫的姓名及地址；

g. the invoice number;

h. the total quantity received or supplied; and

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

There shall be a separate entry in the record for each Part 1 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 Appendices B and C) 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 1 poisons or pharmaceutical products within 72 hours after the transaction.

g. 發票號碼；

h. 獲取或供應的總數量；以及

i. 毒藥或藥劑製品交易後的餘量。

每種第1部毒藥或藥劑製品須有獨立的紀錄，而每項交易須在有關交易進行後72小時內予以記錄。

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

根據《藥劑業及毒藥規例》備存的銷售或供應紀錄，須有購買人所簽署的文件支持。如屬進口或出口交易，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1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 Electronic record may only be used if it can be readily retrieved and printed out for inspection.

4.4 可使用電子紀錄，但有關紀錄必須能隨時檢索和列印，以供查閱。

4.5 A WDL holder shall retain the supporting records and documents for each transaction of Part 1 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.

4.5 批發商牌照持有人須保留支持每項第1部毒藥或藥劑製品交易的紀錄和文件，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 A WDL holder shall state the batch number of the Part 1 poisons or pharmaceutical products supplied in the invoice for the transaction.

4.6 批發商牌照持有人須於發票內註明所供應第1部毒藥或藥劑製品的批次號碼。

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.

4.7 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紀錄及文件，均須保存於記錄有關交易的處所內 –

a. 為期兩年，由在該等簿冊或紀錄記入最後的記項的日期起計；或

b. 就證明書或文件而言，由交易日期起計為期兩年。

4.8 For an ATP, all books, records and documents required to be kept or retained ("specified documents") in respect of the product must be preserved by the WDL holder for a period of 30 years after the expiry date of the product. If a WDL holder ceases to operate as a WDL holder before the period aforementioned expires, the specified documents must be transferred to the Board within 14 days after the cessation.

4.8 就先進療法製品而言，就該製品而備存或保留的所有簿冊、紀錄及文件(「指明文件」)，須由批發商牌照持有人保存，保存期為該製品的使用期限後的30年。如批發商牌照持有人在前提述的期間屆滿之前停止以批發商牌照持有人的身分營運，則須在停止營運後的14日內，將指明文件移交給管理局。

4.9 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.

4.9 就任何本守則提及的其他紀錄和文件，批發商牌照持有人須由有關紀錄或文件完成日期起計，備存或保留至少兩年。

4.10 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.

4.10 須定期覆檢紀錄和文件。如發現紀錄和文件不當及/或不足情況，須查明原因，而所採取的任何糾正和預防措施，須記錄在案 。

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

4.11 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 : 呈報產品投訴、產品回收、產品改變和藥品不良反應

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 not initiated by the DH, a WDL holder shall report the recall to 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, the manufacturer, wholesaler, importer or registration certificate holder of the concerned pharmaceutical products.

5.1 批發商牌照持有人須仔細調查及記錄有關有潛在問題的藥劑製品的任何投訴和資料。如因投訴或產品問題導致回收，而該回收行動並非由衞生署指示下開展，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"執行衞生署指示或同意的回收行動。有關指引載於以下網站連結：

http://www.drugoffice.gov.hk/eps/do/tc/doc/guidelines_forms/Pharmaceutical_Products_Recall_Guidelines_tc.pdf

藥劑製品的回收行動可由衞生署、或有關藥劑製品的製造商、批發商、進口商或其註冊證明書持有人開展。

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 for any significant changes or conditions which may affect the safety, efficacy or quality of the pharmaceutical products. Any notification of such changes or conditions received from the manufacturer shall be promptly reported to the DH.

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

https://www.drugoffice.gov.hk

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，則須就可能影響該產品的安全、療效及質素的任何重要改變或狀況，與海外製造商緊密聯系。批發商牌照持有人從製造商收到任何有關此等改變或狀況的通知，均須立即向衞生署呈報。

5.3 當批發商牌照持有人得悉其供應的產品有藥品不良反應，須進行調查及記錄，並按照"藥劑業界指引-呈報藥品不良反應的要求"，向衞生署藥物辦公室呈報。有關指引載於以下網站：

https://www.drugoffice.gov.hk

# Section 6 : Specific Requirement for Handling Advanced Therapy Products
# 第 6 節 : 處理先進療法製品的特定要求

6.1 Apart from the record keeping requirements as provided under Section 4, a WDL holder handling advanced therapy products (ATPs) must ensure the specific requirements stipulated in this section are met.

## Traceability

6.2 A WDL holder should ensure a system that enables the bidirectional tracking of cells/tissues contained in ATPs from the point of donation, through manufacturing, to the delivery of the finished product to the use by a medical practitioner or dentist is in place.

## Product Labelling

6.3 Notwithstanding other labelling requirements applicable to pharmaceutical products, a WDL holder shall ensure that the ATPs they supply should be labelled with:

a. a product code and a unique donation identifier assigned in accordance with Appendix D; and

b. For ATPs for autologous use only, the product should be labelled with a unique recipient identifier assigned in accordance with Appendix E, and the English words "For autologous use only" or the Chinese characters "只供自體使用".

6.1 除第4節提出對記錄備存的要求外，處理先進療法製品的批發商牌照持有人必須確保符合本節中規定的特定要求。

## 追溯性

6.2 批發商牌照持有人須確保有一套系統能夠從捐贈點，經製造，至交予醫生或牙醫使用，雙向追踪先進療法製品中包含的細胞或組織。

## 製品的標籤

6.3 儘管有其他適用於藥劑製品的標籤要求，批發商牌照持有人須確保其供應的先進療法製品上標明：

a. 按照附錄D而編配的製品代碼及獨特捐贈標識符;及

b. 就只供自體使用的先進療法製品而言，該製品必須標明按照附錄E而編配的獨特受贈者標識符，以及"For autologous use only"的英文字句或"只供自體使用"的中文字樣 。

# Glossary
# 辭彙

**“advanced therapy product”**

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.

**“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。

**“Adverse Drug Reaction (ADR)”**

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

**“藥品不良反應”**

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，從而預期該些產品都是均質。

**“The Board”**

The Pharmacy and Poisons Board.

藥劑業及毒藥管理局

**“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.

**“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 。

**“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.

**“本守則”**

批發商牌照持有人執業守則。

**“Committee”**

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

**“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。

**“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"**

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.

**"dangerous drugs"**

The drugs and substances specified in Part I of the First Schedule of the Dangerous Drugs Ordinance (Cap.134).

**"DH"**

The Department of Health

**"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.

**"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

**"容器"**

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。

**"危險藥物"**

《危險藥物條例》(第134章)附表1第I部指明的任何藥物或物質。

衞生署

**"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。

**"使用期限"**

就任何藥劑製品而言，指符合以下說明的日期：由製造商按該產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，而假設該產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產品。

**"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.

**"gene therapy product"**

(a) means a product —
  (i) that contains an active substance containing or consisting of a recombinant nucleic acid that may be used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and
  (ii) the therapeutic, prophylactic or diagnostic effect of which relates directly to —
    (A) the recombinant nucleic acid sequence it contains; or
    (B) the product of genetic expression of that sequence; but

(b) does not include a vaccine against an infectious disease.

**"institution"**

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

**"Listed Seller of Poisons"**

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

**"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。

**"基因療法製品"**

(a) 指符合以下說明的製品 –
  (i) 含有一種有效物質，該物質含有重組核酸或由重組核酸組成，而該核酸可應用或施用於人類，以期調節、修補、置換、加入或刪除基因序列；及
  (ii) 其治療、預防或診斷功效，直接關乎 –
    (A) 該製品包含的重組核酸序列；或
    (B) 該序列的基因表達產物；但

(b) 不包括抗傳染病的疫苗。

**"機構"**

與《藥劑業及毒藥條例》(第138章)給予該詞的涵義相同。

**"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).

**"The Ordinance"**

The Pharmacy and Poisons Ordinance (Cap.138).

**"pharmaceutical product"**

(a) means a substance or combination of substances that —
  (i) is presented as having properties for treating or preventing disease in human beings or animals; or
  (ii) may be used in or administered to human beings or animals with a view to —
    (A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
    (B) making a medical diagnosis; and

(b) includes an advanced therapy product.

**"Part 1 poison"**

A substance which is specified in Part 1 of the Poisons List (Cap.138A Schedule 10).

**"Part 2 poison"**

A substance which is specified in Part 2 of the Poisons List (Cap.138A Schedule 10).

**"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。

**"本條例"**

《藥劑業及毒藥條例》(第138章)。

**"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) 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。

**"第1部毒藥"**

在毒藥表(第138A章附表10)第1部內指明的物質。

**"第2部毒藥"**

在毒藥表(第138A章附表10)第2部內指明的物質。

**"poison"**

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

**"procure"**

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

**"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.

**"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.

**"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.

**"registered"**

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

**"毒藥"**

在毒藥表(第138A章附表10)內指明的物質 。

**"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。

**"產品回收"**

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

**"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。

**"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 。

**"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"**

Finished product sent back to a holder of Wholesale Dealer Licence.

**"somatic cell therapy product"**

A product that —

(a) contains or consists of any of the following cells or tissues —
  (i) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;
  (ii) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(b) is presented as having properties for, or may be used in or administered to human beings with a view to —
  (i) treating, preventing or diagnosing a disease; or
  (ii) restoring, correcting or modifying physiological functions, through the pharmacological, immunological or metabolic action of those cells or tissues.

**"specification"**

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.

**"退回的藥劑製品"**

送回批發商牌照持有人的製成品。

**"體細胞療法製品"**

指符合以下說明的製品 –

(a) 含有符合任何以下說明的細胞或組織，或由符合任何以下說明的細胞或組織組成 –
  (i) 該等細胞或組織經實質處理，以致其與擬作的臨牀用途相關的生物特質、生理功能或結構特性，已有所變更；
  (ii) 該等細胞或組織，並非擬在其受贈者及捐贈者的體內，用於相同的基本功能；及

(b) 對該製品的表述或其狀況顯示，該製品具有的特性，使其可產生以下作用，或該製品可應用或施用於人類，以期產生以下作用 –
  (i) 透過該等細胞或組織的藥理、免疫或新陳代謝作用，治療、預防或診斷疾病；或
  (ii) 透過該等細胞或組織的藥理、免疫或新陳代謝作用，恢復、矯正或改變生理機能。

**"規格"**

製造過程中所使用或獲取的產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"**

The storing of pharmaceutical products up to the point of use.

**"tissue engineered product"**

(a) means a product that —
  (i) contains or consists of any of the following cells or tissues —
    (A) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered;
    (B) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and
  (ii) is presented as having properties for, or may be used in or administered to human beings with a view to, regenerating, repairing or replacing a human tissue; but

(b) does not include a product that —
  (i) contains or consists of exclusively non-viable human or animal cells or tissues; and
  (ii) does not act principally by pharmacological, immunological or metabolic action.

**"WDL"**

The Wholesale Dealer Licence

**"貯存"**

貯存藥劑製品 直至使用為止的過程。

**"組織工程製品"**

(a) 指符合以下說明的製品 -
  (i) 含有符合任何以下說明的細胞或組織，或由符合任何以下說明的細胞或組織組成 -
    (A) 該等細胞或組織經實質處理，以致其與擬作的再生、修補或置換相關的生物特質、生理功能或結構特性，已有所變更；
    (B) 該等細胞或組織，並非擬在其受贈者及捐贈者的體內，用於相同的基本功能；及
  (ii) 對該製品的表述或其狀況顯示，該製品具有的特性，使其可用於再生、修補或置換人體組織，或該製品可應用或施用於人類，以期再生、修補或置換人體組織；但

(b) 不包括符合以下說明的製品 -
  (i) 純粹含有非活性人類或動物細胞或組織，或純粹由非活性人類或動物細胞或組織組成；及
  (ii) 並非主要透過藥理、免疫或新陳代謝作用而發揮作用。

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
唑吡咀
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

[regulation 28(4)]
[第28(4)條]

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 1 OF THE POISONS LIST OR ANY PHARMACEUTICAL PRODUCTS
TO BE KEPT BY LICENSED WHOLESALE DEALERS OR LICENSED MANUFACTURERS
持牌批發商或持牌製造商須備存的涉及毒藥表第1部毒藥或任何藥劑製品的交易紀錄格式

| Name of Poison/ Pharmaceutical Product<br>毒藥/藥劑製品名稱 | | | | Pack Size<br>包裝大小 | | Unit of Quantity<br>數量單位 |
|---|---|---|---|---|---|---|
| Date of Transaction<br>交易日期 | Nature of Transaction<br>交易性質 | Supplier or to whom supplied<br>供應人或獲供應的人 | Invoice Number<br>發票號碼 | Batch Number<br>批次編號 | Total Quantity<br>總數量 | Balance after Transaction<br>交易後的餘量 |
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# Appendix C
# 附錄 C

[regulation 28(4)]
[第28(4)條]

PHARMACY AND POISONS ORDINANCE
藥劑業及毒藥條例

(Chapter 138)
(第138章)

FORM OF RECORDS OF TRANSACTIONS INVOLVING ADVANCED THERAPY PRODUCTS TO BE KEPT BY LICENSED WHOLESALE DEALERS OR LICENSED MANUFACTURERS
持牌批發商或持牌製造商須備存的涉及先進療法製品的交易紀錄格式

| Name of Advanced Therapy Product<br>先進療法製品名稱 | | | | Pack Size<br>包裝大小 | | Unit of Quantity<br>數量單位 | |
|---|---|---|---|---|---|---|---|
| Date of Transaction<br>交易日期 | Nature of Transaction<br>交易性質 | Supplier or to whom supplied<br>供應人或獲供應的人 | Name and Address of Registered Medical Practitioner or Registered Dentist (if supplied for use by them)<br>註冊醫生或註冊牙醫的姓名及地址（如供應予他們使用） | Invoice Number<br>發票號碼 | Batch Number<br>批次編號 | Total Quantity<br>總數量 | Balance after Transaction<br>交易後的餘量 |
| | | | | | | | |
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# Appendix D : Product Code and Unique Donation Identifier for Advanced Therapy Products
# 附錄 D : 先進療法製品的製品代碼及獨特捐贈標識符

D.1 According to regulation 31(1)(g)(i) of the Pharmacy and Poisons Regulations, Cap. 138A (PPR), a licensed manufacturer shall label the container of the advanced therapy product (ATP) with the Product Code and the Unique Donation Identifier (UDI) assigned in accordance with the codes of practice issued by the Board. This appendix sets out the requirements for assignment of the product code and the UDI.

D.2 Product Code is a set of coding sequence for identification of cell and tissue types that an ATP contains or consists of. UDI is a unique sequence attributed to the specific donation of the cells or tissues for unique identification.

D.3 ISBT 128 (Information Standard for Blood and Transplant) standard by the International Council for Commonality in Blood Banking Automation (ICCBBA) and Single European Code (SEC) in the European Union (EU) are two widely accepted coding systems for human cells and tissues. Both systems include two components – coding for identification of the cell and tissue type and coding for the identification of the donation – which could be used to facilitate traceability of the cells and tissues from donation to products, and vice versa.

D.1 根據《藥劑業及毒藥規例》（第138A章）（《規例》）第31(1)(g) (i)條，持牌製造商須在盛載先進療法製品的容器上，加上標籤，標明按照管理局發出的執業守則而編配的製品代碼和獨特捐贈標識符。本附錄列出有關編配製品代碼和獨特捐贈標識符的要求。

D.2 製品代碼是一組編碼序列，用於標識先進療法製品中含有或組成的細胞和組織類型。獨特捐贈標識符是一組獨特序列，用作獨特標識細胞或組織的特定捐贈。

D.3 國際血庫自動化委員會(「ICCBBA」)的ISBT128(血液和移植資料標準)標準和歐洲聯盟(「歐盟」)的歐洲單一代碼(「SEC」)是兩個獲廣泛接受的人類細胞和組織編碼系統。這兩個系統都包含兩個組成部分 — 用以標識細胞和組織類型的編碼和用以標識捐贈的編碼 — 這些編碼可便於追溯細胞和組織從捐贈到製品整個過程，反之亦然。

D.4 Either one of the systems mentioned in section D.3 could be used in labelling ATPs containing or consisting of human cells or tissues to meet the requirements of Product Code and UDI required under regulation 31(1)(g)(i) of the PPR.

D.5 If the ATPs containing or consisting of human cells or tissues are not labelled in accordance with one of the systems mentioned in section D.3, Product Code and UDI could be assigned in accordance with section D.7 to D.12 and section D.13 to D.15 respectively.

D.6 Since both internationally recognized systems are applicable to human cells and tissues only, for ATPs that do not contain or consist of any human cells or tissues, the product should be labelled with the following particulars in order to meet the Product Code and UDI requirement under regulation 31(1)(g)(i) of the PPR –

- product name;
- international non-proprietary name (INN), if any; and
- for ATPs containing or consisting of animal cells or tissues, information reflecting the animal species, the country of origins and the types of cells or tissues that they contain or consist of.

D.4 任何一個於D.3提及的系統均可用於標明含有人類細胞或組織或由其組成的先進療法製品，以符合《規例》第31(1)(g) (i)條對於製品代碼和獨特捐贈標識符的要求。

D.5 若未有按照D.3提及的其中一個系統標明含有人類細胞或組織或由其組成的先進療法製品，則可按照D.7至D.12及D.13至D.15分別為製品編配製品代碼和獨特捐贈標識符。

D.6 由於這兩個國際認可系統僅適用於人類細胞和組織，因此對於不含任何人類細胞或組織或由其組成的先進療法製品，應標明以下詳情以符合《規例》第31(1)(g)(i)條的要求 –

- 製品名稱；
- 國際非專利藥品名稱(INN)(如有)；及
- 對於含有動物細胞或組織或由其組成的先進療法製品，可反映動物物種、原產國和所含有或組成的細胞或組織類型的資料。

## Product Code

D.7 If neither ISBT 128 standard nor SEC is adopted for labelling the ATPs containing or consisting of human cells and tissues, a set of coding sequence should be assigned according to section D.8 to D.12 and labelled on the product as the Product Code.

D.8 The Product Code consists of two parts – the Product Coding System Identifier and the Product Number. The structure and the format of the Product Code are as follows:

| Product Code | |
|---|---|
| Product Coding System Identifier | Product Number |
| 1 character (alphabetic) | 7 characters (alphanumeric) |

D.9 Currently there are three product coding systems available globally which are widely used for describing human cells and tissues. They are the ISBT 128 standard product code by the ICCBBA, the Eurocode and the EU Tissue and Cell Product Compendium (EUTC). One of the three coding systems should be adopted for assigning the Product Code for ATPs supplied in Hong Kong.

## 製品代碼

D.7 若未有採用ISBT標準或SEC標明含有人類細胞和組織或由其組成的先進療法製品，則應根據D.8至D.12為該製品編配一組編碼序列並標明在該製品作為製品代碼。

D.8 製品代碼由兩部分組成 — 製品編碼系統標識符和製品編號。製品代碼的結構和格式如下：

| 製品代碼 | |
|---|---|
| 製品編碼系統標識符 | 製品編號 |
| 1 個字符(字母) | 7 個字符(字母數字) |

D.9 目前全球有三個製品編碼系統獲廣泛用作描述人類細胞和組織，分別是ICCBBA 的 ISBT 128 標準製品代碼、歐洲編碼 (Eurocode) 和歐盟組織和細胞製品綱要 (EU Tissue and Cell Product Compendium，「EUTC」)。應從以上三個編碼系統中選擇一個用作編配在香港供應的先進療法製品的製品代碼。

D.10 Product Coding System Identifier is a 1-alphabetic character indicating the coding system adopted for labelling ATPs supplied in Hong Kong of which “A” is assigned to the ISBT 128 standard product code, “B” is assigned to the Eurocode and “E” is assigned to the EUTC.

D.10 製品編碼系統標識符由一個字母字符組成，表明在香港供應的先進療法製品標籤上所採用的編碼系統，其中「A」代表採用了 ISBT 128 標準的製品代碼系統，「B」代表採用了歐洲編碼系統，「E」代表採用了EUTC系統。

D.11 Product Number is 7-alphanumeric characters revealing the type of cells or tissues that an ATP contains or consists of. The most appropriate product number must be chosen from the adopted coding system to describe the type of cells or tissues that an ATP contains or consists of. If the product number is less than 7 characters, it should be padded with leading zeros.

D.11 製品編號由7個字母數字字符組成，表明先進療法製品所含有或組成的細胞或組織類型。必須從所採用的編碼系統中選擇最合適的製品編號，以描述先進療法製品中所含有或組成的細胞或組織類型。如製品編號少於7個字符，則應在編號前加上零字補足。

D.12 Subject to consideration and approval by the respective committees of the Board, the requirement of product code may be deemed to have fulfilled if an ATP, that is not labelled with the product code assigned according to section D.4 or section D.8 to D.11, is labelled with sufficient information that specifically identifies the types of cells or tissues that the ATP contains or consists of.

D.12 若先進療法製品未有標明按照D.4或D.8至D.11編配的製品代碼，但標明了足夠的資料以明確標識製品所含有或組成的細胞或組織類型，則經管理局相應委員會考慮及批准，可視為已符合製品代碼的要求。

## Unique Donation Identifier (UDI)

D.13 If neither ISBT 128 standard nor SEC is adopted for labelling the ATPs containing or consisting of human cells and tissues, a set of coding sequence should be assigned according to section D.14 to D.15 and labelled on the product as UDI.

D.14 For human cells or tissues obtained from a tissue establishment in the EU and already assigned with a SEC or donation identification sequence of a SEC (SEC-DI), the SEC-DI part of that SEC could be adopted as the UDI of the ATPs manufactured from them.

D.15 For human cells or tissues without any assigned SEC (or SEC-DI), for example, those obtained from a non-European country or collected locally, the ISBT 128 standard should be adopted. The Donation Identification Number (DIN) part of the ISBT 128 standard of those cells and tissues should be labelled on the ATPs manufactured from them as a UDI. If the human cells or tissues obtained has already been assigned with a DIN of the ISBT 128 standard, this DIN could be used and labelled on the ATPs manufactured from them as a UDI. For human cells or tissues without any assigned DIN of the ISBT 128 standard, licensed manufacturers should assign a DIN or SEC-DI to the cells and tissues obtained according to ISBT 128 standard or SEC-DI (if applicable) respectively.

## 獨特捐贈標識符

D.13 若未有採用ISBT 128標準或SEC標明含有人類細胞和組織或由其組成的先進療法製品，則應按照D.14至D.15編配一組編碼序列並將其標明在製品上作為獨特捐贈標識符。

D.14 對於從歐盟組織機構獲得並已編配有SEC或SEC的捐贈標識序列「SEC-DI」的人類細胞或組織，可採用SEC的SEC-DI部分為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。

D.15 對於沒有編配任何 SEC (或SEC-DI) 的人類細胞或組織，例如從非歐洲國家獲得或在本地收集的細胞或組織，應採用 ISBT 128 標準進行編碼。ISBT 128 標準的捐贈標識碼「DIN」部分可標明為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。若所獲得的人類細胞或組織已編配有 ISBT 128標準的DIN，該DIN可標明為由該等細胞或組織製造的先進療法製品的獨特捐贈標識符。對於未編配任何ISBT 128 標準的 DIN 的人體細胞或組織，持牌製造商應按照ISBT 128標準或SEC-DI (如適用) 為所獲得的細胞或組織編配一個DIN或SEC-DI。

# Appendix E : Unique Recipient Identifier for Advanced Therapy Products for Autologous Use
# 附錄 E : 供自體使用的先進療法製品的獨特受贈者標識符

E.1 According to regulation 31(1)(g)(ii) of the PPR, an ATP for autologous use should be labelled with a Unique Recipient Identifier (URI) assigned in accordance with the codes of practice issued by the Board. This appendix sets out the requirements for assignment of the URI.

E.2 The URI is a combination of recipient information sufficient for healthcare professionals to verify the identity of the intended recipient of the product. The URI should consist of at least two sets of information including the recipient's surname followed by initials of the first name plus either –

- Month and year of birth; or
- Any other numeric or alphanumeric number/sequence that is referring to the recipient (e.g. Part of recipient's hospital number/medical record number).

E.3 A WDL holder should ensure that healthcare professionals who use the ATPs fully understand how to interpret and use the recipient information contained in the URI to verify the identity of the recipient.

E.4 In addition, a WDL holder should comply with the requirements in the Personal Data (Privacy) Ordinance, Cap. 486 (PDPO) when handling personal data.

E.1 根據《規例》第31(1)(g)(ii)條，供自體使用的先進療法製品須以標籤標明按照管理局發出的執業守則而編配的獨特受贈者標識符。本附錄列出有關編配獨特受贈者標識符的要求。

E.2 獨特受贈者標識符是為專業醫護人員提供的受贈者資料組合，使其能核實製品的預期受贈者的身分。獨特受贈者標識符應至少由兩組資料組成，包括受贈者的姓氏後跟名字的首字母及以下其中一項資料 –

- 出生年月；或
- 代表受贈者的任何其他數字或字母數字編號 / 序列(例如受贈者的醫院編號 / 病歷編號其中一部分)。

E.3 批發商牌照持有人應確保使用先進療法製品的專業醫護人員完全了解如何詮釋和使用獨特受贈者標識符中包含的受贈者資料以核實受贈者身分。

E.4 此外，批發商牌照持有人須遵守《個人資料(私隱)條例》(第486章)的要求處理個人資料。


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