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INTRODUCTION

The Code of Practice for Holder of Wholesale Poisons Licence (the Code) is published for the purpose of explaining the roles and responsibilities of the holders of Wholesale Poisons Licence (WPL) and setting out the minimum standards that a WPL holder has to meet in distribution of pharmaceutical products. Distribution includes the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, and movement from the premises of a WPL holder to other premises of pharmaceutical products.

WPL holders shall comply with the Pharmacy and Poisons 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:

a. Dangerous Drugs Ordinance (Cap. 134);
b. Antibiotics Ordinance (Cap. 137);
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).

Compliance with the Code is one of the licensing conditions for issuing a WPL. Breach of the Code may lead to revocation or suspension of the WPL for a period as the Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee (the Committee) thinks fit.

The Code does not apply to the trade in non-medicinal poisons, for example, chemical reagents, hair-dyes, industrial chemicals e.g. cyanide, arsenic, sulphuric acid, etc.
SECTION 1: GENERAL RESPONSIBILITIES OF HOLDER OF WHOLESALE POISONS LICENCE

1.1 No person shall, by way of wholesale dealing, sell or supply at or from any premises any substance or article consisting of or containing any poison unless he is the holder of a WPL issued by the Committee in respect of those premises. The Committee may issue a WPL on payment of the fee prescribed in the Pharmacy and Poisons Regulations (“PPR”).

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

1.3 A WPL holder shall nominate a responsible person to be in charge of poisons, and may nominate a deputy to act during his temporary absence. A WPL holder shall obtain approval from the Committee prior to any change in the person in charge of poisons or his deputy and the Committee shall not approve the change unless it considers the person nominated fit and proper.

1.4 A WPL 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.

1.5 A WPL holder shall not sell or deal in any listed psychotropic substances (Appendix A) unless under the supervision of a registered pharmacist.

1.6 A WPL holder shall ensure that all activities relating to pharmaceutical products are conducted in a manner that complies with applicable legislation and the Code.
SECTION 2: STORAGE FACILITY

2.1 A WPL holder shall provide for 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 WPL holder should ensure that the storage facility is commensurate with or suitable for the amount and the nature of the pharmaceutical products handled.

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

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

2.4 No person shall store any poison except in a container impervious to the poison 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 should be stored subject to appropriate additional safety and security measures.

2.6 Storage area should have adequate lighting and ventilation.

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

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

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

2.10 Measures should be taken to prevent contamination of pharmaceutical products and mixing up of different products. There should 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 should be appropriately identified.
2.11 Storage facility should be maintained at a temperature and humidity within the range specified in the storage instructions of the pharmaceutical products kept. A WPL holder should 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 should 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, should be kept. The equipment should be calibrated at defined interval for the required operating range and the calibration records should be maintained.

2.12 Cold room or refrigerator for the storing of temperature-sensitive pharmaceutical products should be installed with an alarm or alert system to alert staff of any temperature excursions. The alarm system should be tested periodically and testing records should be kept. Backup power should be available to maintain the storage conditions of the pharmaceutical product in the event of power failure. Any backup generators used should 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 should be put in place.

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

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

2.15 Procedures for temperature and humidity monitoring, cleaning, and pest control should be audited. The audit records should be reviewed regularly. In the event of irregularities and/or deficiencies, the causes of irregularities and/or deficiencies should be investigated and any corrective and preventive actions taken should be documented.
SECTION 3: OPERATIONS

Procurement, Import and Export of Pharmaceutical Products

3.1 A WPL holder should exercise due diligence to ensure that pharmaceutical products are procured from reputable or licensed wholesalers or manufacturers.

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

3.3 A WPL holder should report to the Department of Health (DH) the actual import and export shipment of pharmaceutical products within 14 days of the shipment arrived or departed.

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

Receipt and Storage of Pharmaceutical Products

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

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

3.7 A WPL holder should make available within a reasonable time
frame batch sample of imported drugs from overseas manufacturer to facilitate DH’s investigation into drug incident, if any, when required.

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

Supply of Pharmaceutical Products

3.9 No person holding a WPL shall sell or supply any poisons except to:

a. another WPL holder;
b. an authorized seller of poisons;
c. a registered pharmacist;
d. a registered medical practitioner, a registered dentist or a registered veterinary surgeon;
e. persons who require the poison for the purpose of their trade or business;
f. a Government department or public officer requiring the article for the purposes of public service;
g. a person or an establishment concerned with education or scientific research, if the article is required for the purposes of such education or research;
h. an institution;
i. purchasers outside Hong Kong; or
j. a Listed Seller of Poisons (provided that only Part II poisons may be sold or supplied).

3.10 A WPL holder should obtain an order in writing issued by the purchaser before the completion of a sale of Part I poisons, dangerous drugs or antibiotics.

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.
3.12 Pharmaceutical products with broken seals, damaged packaging, suspected tampering or contamination, or which have been stored in undesirable storage condition should not be supplied and should be properly segregated. The cause of any such defect should be investigated and corrective and preventive measures should be taken and documented.

3.13 Pharmaceutical products should not be supplied after their expiry date or so close to their expiry date that the pharmaceutical products will likely expire by the time of consumption.

3.14 A system shall be in place to ensure that 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.

**Transportation**

3.15 No person shall consign any poison for transport unless it is sufficiently stoutly packed to avoid leakage arising from the ordinary risks of handling and transport.

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

a. ensure their identification;

b. not cause 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 WPL holder should make arrangement with their transportation agents to ensure safe and secure delivery of pharmaceutical products, especially where the products delivered are dangerous drugs or psychotropic substances.
Handling of Returned Pharmaceutical Products

3.18 All returned pharmaceutical products should be segregated from saleable stock.

3.19 Pharmaceutical products returned from the market should be destroyed unless the WPL holder has no doubt about their quality. Reissue or reuse of pharmaceutical products returned should be considered only after a risk assessment has been carried out. The risk assessment should be provided in a written procedure and 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 should be approved by the person in charge of poisons and recorded.

Destruction of Pharmaceutical Products

3.21 Pharmaceutical products intended to be destroyed should be handled in accordance with relevant legislation and guidelines, if any, issued by the Environmental Protection Department. WPL holders should notify DH in advance of the destruction and where the destruction is of dangerous drugs, the destruction should be witnessed by pharmacist of DH. Record of destruction of pharmaceutical products should be kept.

Regular Checking and Review of Operation

3.22 All operation procedures related to the handling and control of pharmaceutical products should be reviewed regularly and documented. Relevant operation records should also be reviewed regularly. In the event of irregularities and/or deficiencies, the causes of irregularities and/or deficiencies should be investigated and corrective and preventive measures should be taken and documented.
SECTION 4: DOCUMENTATION

4.1 A WPL holder shall provide all documentation related to the licensed activities for inspection when required by DH.

4.2 A WPL holder shall keep record of all transactions of pharmaceutical products and the records should contain the following particulars:

   a. the name of the pharmaceutical products;
   b. the unit of quantity;
   c. the date of the transaction;
   d. the nature of the transaction;
   e. the name of supplier or the person to whom the pharmaceutical product is supplied;
   f. the invoice number;
   g. the quantity received or supplied; and
   h. the balance of the pharmaceutical product kept after transaction.

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

Where the pharmaceutical products are Part I poisons, the records of transactions shall be made in the form prescribed in the Eighth Schedule of PPR (Form 2) unless the Committee approves another system of recording.

Records of sales or supplies maintained under PPR shall be supported by documents signed by the purchaser. In the case of an export transaction a WPL holder shall retain all shipping and other documents supporting the transaction.

4.3 A WPL holder shall collect the signed receipts of sales or supply of Part I poisons 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.
4.5 A WPL holder shall retain the supporting records and documents for each transaction of 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 WPL holder should state the batch number of the pharmaceutical product it supplied in the invoice.

4.7 All books or other form of records and documents required to be kept or retained by a WPL 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.

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

4.9 Records and documents should be reviewed regularly. In the event of irregularities and/or deficiencies, the causes of irregularities and/or deficiencies should be investigated and any corrective and preventive actions taken should be documented.
SECTION 5: REPORTING OF PRODUCT COMPLAINTS, PRODUCT RECALLS AND ADVERSE DRUG REACTIONS

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


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

5.2 A WPL holder should investigate and report Adverse Drug Reactions (ADR) to the Pharmacovigilance Unit of DH once made aware of an ADR in accordance with the “ADR Reporting Guidelines” published at the following website link:

GLOSSARY

“Adverse Drug Reaction” (ADR)
A reaction to drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

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

“authorized seller of poisons”
This has the same meaning assigned to it under the Pharmacy and Poisons Ordinance (Cap.138).

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

“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.

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

“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.

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

“distribution of pharmaceutical products”
Include the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement from the premises of a WPL holder to other premises of pharmaceutical products, with the exception of dispensing or providing pharmaceutical products directly to a patient or his or her agent.

“expiry date”
The date indicated on the individual container (usually on the label) of a pharmaceutical product up to and including the date on which the product is expected to remain within the product specifications, if stored under appropriate condition. It is established for each batch by counting the period of time representing the shelf-life of the pharmaceutical product from the date of manufacture.

“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.

“institution”
This includes hospital, maternity home or clinic as defined 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).

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

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

“Part I poison”
A substance which is specified in Part I of the Poisons List (Cap.138B).

“Part II poison”
A substance which is specified in Part II of the Poisons List (Cap.138B).

“poison”
A substance which is specified in the Poisons List (Cap.138B).

“procure”
Obtain, acquire, purchase or buy 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).
Ordinance (Cap.138).

“returned pharmaceutical product”
Finished product sent back to a holder of Wholesale Poisons Licence.

“shelf-life”
The period of time during which a pharmaceutical product, if stored under appropriate condition, is expected to comply with the product specifications. It is derived from a number of stability studies on the product and is used to establish the expiry date of a particular batch of a pharmaceutical product.

“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.

“storage”
The storing of pharmaceutical products up to the point of use.
APPENDIX A

List of poisons which are psychotropic substances and which must be handled by registered pharmacists
Effective: 1 January 2004

1. Allobarbital
2. Amineptine
3. Amobarbital
4. Buprenorphine
5. Butalbital
6. Butobarbital
7. Cyclobarbital
8. Ethchlorvynol
9. Ethinamate
10. Fencamfamin
11. Glutethimide
12. Lefetamine
13. Mazindol
14. Meprobamate
15. Methylphenobarbital
16. Methyprylon
17. Pemoline
18. Pentazocine
19. Pentobarbital
20. Phenobarbital
21. Pipradrol
22. Pyrovalerone
23. Secbutabarbital
24. Vinylbital
25. Zolpidem
26. any salt or preparation of any of the above