CODE OF PRACTICE for Listed Seller of Poisons 列載毒藥銷售商執業守則 (2015)

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

This code of practice for Listed Seller of Poisons ("the Code") sets out the standards and obligations for the practice of the holders of the Listed Sellers of Poisons Licence (Licensees) in conducting retail sale of Part II poisons and other pharmaceutical products on the premises of Listed Sellers of Poisons ("the premises").

Compliance with the Code is one of the licensing criteria when issuing licences to Listed Sellers of Poisons (LSP). Non-compliance with the Code may result in removal or suspension for a period specified by the Pharmacy and Poisons Board ("the Board") from the list the name of LSP ("the List"); the Board may also issue a warning letter to the LSP or variate a condition imposed to the LSP.

DEFINITION

"food" includes drink, ice and articles and substances used as ingredients in the preparation of food.

"pharmaceutical product" and "medicine" mean 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

1. GENERAL RESPONSIBILITIES

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

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

b. Licensees must obtain prior approval of the Board to any change in their sole-proprietor, partnership, or directorship, otherwise the licensees may be removed from the List and the licence may be invalidated from the date of removal.

c. Licensees must ensure that no title, emblem or description displayed on the premises may carry any connotation that any staff member working on the premises is a registered pharmacist.

d. Licensees must cooperate with inspectors from the Department of Health in the carrying out of their duties under the Pharmacy and Poisons Ordinance, Cap. 138. They must provide any information relating to the licensing activities or persons working on the premises upon any reasonable request by the inspectors.

e. Licensees who intend to renew their licence must pay a prescribed fee on an annual basis for licence renewal.

2. PREMISES

a. The premises must comply with the prevailing legislative requirements and must be well-maintained so that it is suitable for conducting retail sale of Part II poisons or other pharmaceutical products.

b. Licensees must display the name of the LSP outside the premises in a conspicuous position. The LSP licence must be displayed in a conspicuous position of the retail area of the premises so that it is easily identified by the public and readily available for inspection.

c. In conducting retail sale of pharmaceutical products, licensees must not use any title, emblem, description or logo calculated to suggest that

- they are entitled to sell pharmaceutical products other than non-poison pharmaceutical products or a Part II poison;
- they are an authorized seller of poisons; and /or
- the premises are under the supervision of a registered pharmacist.

d. Licensees who sell pharmaceutical products on the premises must display to the public on the premises a prominent notice which specifies, in Chinese and English, that antibiotics prescribed by the Antibiotics Regulations, Cap. 137A may not be sold on the premises. A specimen of such notice is attached in the Appendix.

e. Licensees must maintain the premises in a clean and orderly manner. Adequate lighting, ventilation and air conditioning must be provided.

3. STORAGE AND STOCK

a. There must be a storeroom or designated facilities for storage of pharmaceutical products on the premises to allow orderly storage of pharmaceutical products.

b. Licensees must store pharmaceutical stocks under suitable storage conditions.

c. Pharmaceutical products must not be stored in close proximity to food and must be stored in the manufacturers' original packing.

d. All pharmaceutical products kept for sale on the premises must have batch numbers and expiry dates clearly shown on their outer packing.

e. Licensees must have procedures in place to eliminate the risk of supplying expired stock to the public. The expiry dates of the stocks must be checked regularly. All expired stocks must be removed from sales and display area for disposal or destruction in accordance with the guidance notes issued by the Environment Protection Department.

f. Licensees must proactively participate in the recall process for any substandard medicines upon receiving genuine information and recall notifications from manufacturers, wholesalers or the Department of Health. Licensees must remove all recalled pharmaceutical products immediately from their stock to prevent further distribution upon receipt of recall notifications.

4. SALE AND SUPPLY OF PHARMACEUTICAL PRODUCTS AND NON-MEDICINAL POISONS

a. Licensees may only conduct retail sale of Part II poisons on the premises specified on the licence.

b. Licensees must not possess or sell antibiotics, Part I poisons or dangerous drugs on the premises.

c. Licensees must not dispense any prescriptions for pharmaceutical products.

d. Licensees must ensure only registered pharmaceutical products from licensed traders are supplied and must exercise reasonable diligence to avoid supplying counterfeit/unregistered pharmaceutical products or products adulterated with unlabelled western medicines.

e. Licensees must ensure advertisements (e.g. pamphlets, signboards, etc) displayed on the premises which will likely promote use of medicine comply with the Undesirable Medical Advertisement Ordinance, Cap.231.

f. Licensees may only sell or supply pharmaceutical products in the original sealed containers supplied by the manufacturer.

g. Licensees must not sell non-medicinal poisons unless their container is labeled with:

- the name of the poison;
- in the case of a preparation of which one or more of the ingredients is a poison, particulars as to the proportion each poison bears to the total of the ingredients in the preparation;
- in both English and Chinese, the word “poison” or, in the case of a poison specified in the Fifth Schedule to the Pharmacy and Poisons Regulations, a statement specified therein as applicable to that poison; and
- in the case of a liquid other than a medicine in a container of a capacity of not more than 2 liters, the words "Not to be taken 忌食".

h. Licensees must not sell hair-dye preparations with phenylene diamines; toluene diamines; other alkylated-benzene diamines or their salts unless the containers of preparations are labeled in accordance with paragraph (g) and with the words "Caution. This preparation may cause serious inflammation of the skin in certain persons and should be used only in accordance with expert advice."
「注意：此藥可使某些人士皮膚嚴重發炎，須照專家指示使用。」.

5. PROCUREMENT

a. Licensees must ensure that all pharmaceutical products obtained must be registered in Hong Kong and conform to the relevant legal requirements. Licensees must not purchase any pharmaceutical products unless the quality, safety, efficacy and authenticity of the products can be verified. Licensees must exercise reasonable diligence to avoid obtaining counterfeit/unregistered pharmaceutical products or products adulterated with unlabelled western medicines.

b. All medicines received from suppliers must be checked against the sales invoices, purchase notes or delivery notes to ensure accuracy of the particulars, including the name, quantity, batch number and expiry date, of the medicines delivered.

c. Licensees must retain for inspection all sales invoices, purchase notes or delivery notes for two years from the date of issue or until the expiry of the pharmaceutical products concerned, whichever period is longer.

此列載毒藥銷售商執業守則(守則)，載述關於列載毒藥銷售商牌照持有人(持牌人)在其處所(處所)從事零售第II部毒藥及其他藥劑製品業務的標準及責任。

列載毒藥銷售商牌照的其中一項發牌因素，是必須遵從本守則的規定。若不遵從本守則的規定，藥劑業及毒藥管理局(管理局)可能會將持牌人的姓名或名稱從列載毒藥銷售商名單(名單)中除去、或在管理局指明的期間內，暫時吊銷其名列該名單內的資格；管理局亦可向該銷售商發出警告信，或更改對該銷售商而施加的某條件。

定義

“食物”包括飲品、冰及配製食物時用作配料的物品及物質。

“藥劑製品”及“藥物”指符合以下說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。

1. 一般責任

a. 持牌人須確保在其獲發牌處所內進行的所有程序及活動，均以符合相關法例的方式進行，當中包括但不限於：

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

b. 凡持牌人改變其獨資東主、合伙人或董事，必須先取得管理局的批准，否則持牌人的姓名或名稱可能會從名單中除去，而牌照亦可能自除名之日起變成無效。

c. 持牌人須確保處所展示的名銜、徽號或說明不帶有任何暗示，指在處所內工作的任何一名職員是註冊藥劑師。

d. 當衞生署督察履行其於《藥劑業及毒藥條例》(第138章)下的職責時，持牌人須予以合作。持牌人須按督察作出的任何合理要求，提供任何有關發牌工作或在處所內工作的人士的資料。

e. 擬續牌的持牌人須每年繳付訂明續牌費用。

2. 處所

a. 處所須符合現行的法例規定，並須妥善管理，務求適合從事零售第II部毒藥或其他藥劑製品業務。

b. 持牌人須在處所外的顯眼處展示列載毒藥銷售商的姓名或名稱。列載毒藥銷售商牌照須於處所內零售區的顯眼處展示，讓公眾易於識別，並隨時可供查閱。

c. 持牌人在從事藥劑製品的零售業務時，不得使用任何名銜、徽號、說明或標識以刻意暗示

- 他們有權銷售屬非毒藥的藥劑製品或第II部毒藥以外的藥劑製品；
- 他們是獲授權毒藥銷售商；及／或
- 處所由註冊藥劑師監督。

d. 在處所內有銷售藥劑製品的持牌人，須在處所向公眾展示顯眼的中英文通告，說明不得在該處所銷售《抗生素規例》(第137A章)訂明的抗生素。通告的樣本載於附件。

e. 持牌人須保持處所整潔，並提供足夠的照明、通風及空氣調節。

3. 貯存及存貨

a. 處所內須設有貯存房間或具備指定用作貯存藥劑製品之用的設施，以便有序地貯存藥劑製品。

b. 持牌人須按合適的貯存條件貯存藥劑製品存貨。

c. 藥劑製品不得存放在貼近食物的地方，並須保持原廠包裝。

d. 處所內所有供出售的藥劑製品的外包裝上，必須清楚顯示其批號和有效期。

e. 持牌人須制定程序，以排除向公眾供應已過期存貨的風險。持牌人須定期查核存貨的有效期。所有已過期的存貨，必須從銷售及展示區移走，並依照環境保護署發出的指引處置或銷毀。

f. 持牌人在收到製造商、批發商或衞生署發出的真確資訊及回收通知後，須主動參與回收任何不合標準藥物的程序。在收到回收通知後，持牌人必須立即從存貨中移走所有須回收的藥劑製品，以免該批製品再予分銷。

4. 出售及供應藥劑製品及非藥物類毒藥

a. 持牌人只可在牌照上指明的處所，從事零售第II部毒藥的業務。

b. 持牌人不得在處所管有或出售抗生素、第I部毒藥或危險藥物。

c. 持牌人不得配發任何藥劑製品的處方。

d. 持牌人須確保所供應的註冊藥劑製品均來自持牌的藥商，並須盡合理的努力，避免供應偽冒／未經註冊的藥劑製品或攙雜未標示西藥成分的製品。

e. 對於在處所內展示的廣告(如小冊子、廣告牌等)，如該等廣告有可能推廣藥物的使用，持牌人須確保它們符合《不良廣告(醫藥)條例》(第231章)的規定。

f. 持牌人只可出售或供應由製造商提供盛載於原裝密封容器的藥劑製品。

g. 持牌人不得出售非藥物類毒藥，但如其容器上的標籤載有下列資料則除外：

- 毒藥的名稱；
- (如製劑內有一種或多於一種成分是毒藥)每種毒藥在該製劑全部成分中所佔比例的詳情；
- 以中英文標明“毒藥”一詞，或如有關毒藥屬《藥劑業及毒藥規例》附表5指明的毒藥，則須附有該附表內指明適用於該毒藥的說明；以及
- 如屬非藥物類液體毒藥，並盛載於容量不超過2公升的容器，須標明“Not to be taken 忌食”的字句。

h. 持牌人不得出售含有苯二胺、甲苯二胺或其他烷化苯二胺或其鹽類的染髮製劑，除非有關製劑的容器已根據上文(g)段的規定加上標籤，並標明“Caution. This preparation may cause serious inflammation of the skin in certain persons and should be used only in accordance with expert advice.注意：此藥可使某些人士皮膚嚴重發炎，須照專家指示使用。”的字句。

5. 採購

a. 持牌人須確保取得的所有藥劑製品均已在香港註冊，並符合相關法例規定。除非藥劑製品的素質、安全程度、效能及真實性可予核實，否則持牌人不得購入該些藥劑製品。持牌人須盡合理的努力，避免所取藥劑製品為偽冒／未經註冊或攙雜了未經標示的西藥。

b. 所有從供應商取得的藥物，必須按藥物銷售發票、採購單據或送貨單據上的資料，包括交收藥物的名稱、數量、批次編號及有效期，進行核對，以確保資料正確無誤。

c. 持牌人須保存所有銷售發票、採購單據或送貨單據，以供查閱，保存期為由發出發票或單據的日期起計兩年，或直至有關藥劑製品的有效期屆滿為止(以為期較長者為準)。

NOTICE TO PUBLIC TO BE DISPLAYED ON THE PREMISES OF LICENSEES WHO SELL PHARMACEUTICAL PRODUCTS
在處所內有銷售藥劑製品的持牌人**在處所向公眾展示的通告**

顧客通告
NOTICE TO CUSTOMERS

根據《抗生素條例》(香港法例第137章)及《抗生素規例》(第137A章),此處所不得銷售該規例附表所指明的抗生素。

According to the Antibiotics Ordinance (Cap.137, Laws of Hong Kong) and the Antibiotics Regulations (Cap.137A), antibiotics specified in the Schedule to the Regulations may not be sold on these premises.

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