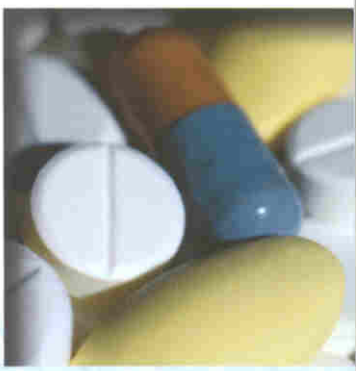
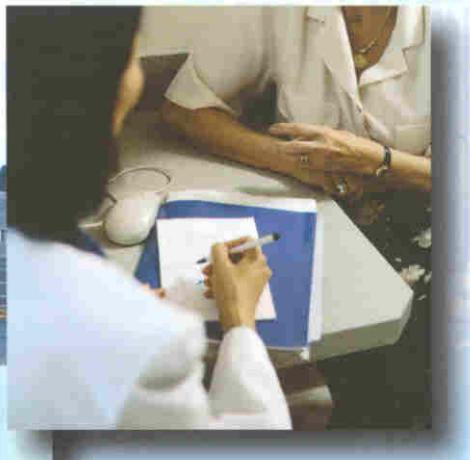
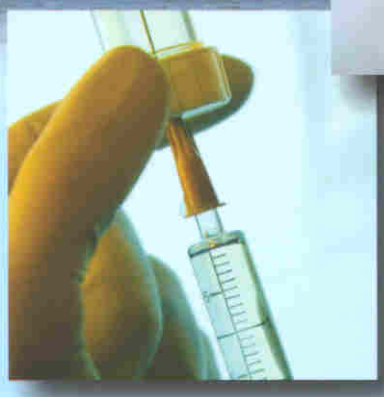
Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局







Annual Report 2004

二零零四年年報

Contents

主席獻辭

The Pharmacy and Poisons Board has gone through another busy year in the execution of its statutory functions under the Pharmacy and Poisons Ordinance (Cap. 138). I wish to take this opportunity to thank all members of the Board and the Board's executive committees for their steadfast and unfailing support.

In addition to performing its regular duties, the Board successfully carried out a review regarding the internship training arrangements and registration examination policies leading to registration of pharmacists in Hong Kong. The review report has also been circulated to relevant pharmacists' professional associations, pharmaceutical trade and industry for consultation. With an aim to maintaining the professional standard of the registered pharmacists to meet the ever-increasing demand of the community, the Board also embarked on developing a Continuing Professional Education programme for the registered pharmacists and a Code of Ethics for Pharmacists.

In the coming year, the Board and its committees will continue to work closely with the pharmacy profession and other health-care professions and interested parties and we expect to see the implementation of a number of new initiatives in developing the pharmacy profession.

Dr P.Y. LAM
Chairman
Pharmacy and Poisons Board
September 2005

在過去一年，藥劑業及毒藥管理局繼續執行《藥劑業及毒藥條例》(第138章)所賦予的法定職能。年內依舊繁重的工作得以順利進行，端賴管理局及其轄下各個執行委員會的全體成員努力不懈和鼎力支持，本人謹衷心致謝。

除履行一般職務之外，管理局已就藥劑師在香港註冊前的實習安排和考試政策完成有關檢討，並已將檢討報告交予相關的藥劑師專業組織和藥劑業界傳閱以徵詢意見。為了維持註冊藥劑師的專業水準以滿足市民與日俱增的需求，管理局亦已著手制定註冊藥劑師持續進修計劃及《藥劑師專業操守指引》。

展望來年，管理局及其轄下各個委員會將與藥劑業界、其他醫護專業和相關團體保持緊密合作，並會落實多項有助發展藥劑專業的新措施。

藥劑業及毒藥管理局主席
林秉恩醫生
二零零五年九月

Introduction

This annual report covers the calendar year 2004. Through this report, the Pharmacy and Poisons Board (the Board) aims to keep all registered pharmacists and interested parties in the pharmacy profession posted on the functions and work of the Board during the year. A brief summary of the work of the Pharmacy and Poisons Appeal Tribunal established under section 30 of the Pharmacy and Poisons Ordinance is also included.

In order to provide readers a quick reference, the description of the functions of the Board, its executive committees and the Appeal Tribunal has been simplified. Readers interested in more specific details of the statutory functions of these bodies should refer to the relevant provisions under the Pharmacy and Poisons Ordinance and its subsidiary legislation.

All inquiries with regard to this report or to the Pharmacy and Poisons Board in general can be addressed to: -

The Pharmacy and Poisons Board Secretariat
1/F, Shun Feng International Centre
182 Queen's Road East
Wanchai, Hong Kong

Facsimile : (852) 2527 2277
Telephone: (852) 2527 8418

這份年報載錄藥劑業及毒藥管理局(以下簡稱管理局)在二零零四年的工作。管理局希望透過這份年報，使所有註冊藥劑師以及藥劑業有關人士及團體了解管理局的職能及在這年內的工作；同時亦扼要介紹根據《藥劑業及毒藥條例》第30條成立的藥劑業及毒藥上訴審裁處的工作。

為使讀者可以更容易掌握有關內容，年報內對管理局及其轄下的執行委員會和上訴審裁處的職能的描述以精簡為旨。讀者如希望對這些組織的法定職能有更深入的認識，請查閱《藥劑業及毒藥條例》及其附屬法例的有關條文。

所有有關本年報或藥劑業及毒藥管理局的查詢，請聯絡：

香港灣仔皇后大道東 182 號
順豐國際中心一樓
藥劑業及毒藥管理局秘書處

圖文傳真： (852) 2527 2277
電　　話： (852) 2527 8418

Membership and Functions of the Board

管理局的成員及職能

Dr P.Y. LAM, JP (Chairman)
林秉恩醫生（主席）

Dr Ting Tai-lun, JP
丁大倫博士

Mr CHAN Wing-kin, Anthony
陳永健先生

Dr LEUNG Ting-hung, JP
梁挺雄醫生

Ms MAK Wai-yee, Corinna (Legal Adviser)
麥慧儀女士(法律顧問)

Professor CHO Chi-hin
曹之憲教授

Professor CHAN Yan-keung
陳恩強教授

Mr SIT Ka-keung, Perry
薛家強先生

Mr CHUA Sek-chon, Peter, JP
蔡錫聰先生

Mr LEUNG Kai-lok, Peter
梁佳樂先生

Dr WONG Shou-pang, Alexander
王壽鵬醫生

Membership and Functions of the Board

Members of the Board are appointed by the Chief Executive. Each term is for a period of not more than three years. Members may be re-appointed. They include: -

(a) the Director of Health (Chairman);
(b) the Government Chemist;
(c) the Chief Pharmacist of the Department of Health;

} ex officio Members

(d) a medical officer in the Department of Health;
(e) a legal adviser;
(f) a full-time teaching staff of pharmacology of the University of Hong Kong;
(g) a full-time teaching staff of pharmacology of the Chinese University of Hong Kong;
(h) three registered pharmacists (not being public officers) nominated by the Pharmaceutical Society of Hong Kong; and
(i) a registered medical practitioner (not being a public officer) nominated by the Hong Kong Medical Association.

The membership of the Board as at 31 December 2004 was as follows: -

(a) Dr P.Y. LAM, JP (Chairman)
(b) Dr TING Tai-lun, JP
(c) Mr CHAN Wing-kin, Anthony
(d) Dr LEUNG Ting-hung, JP
(e) Ms MAK Wai-yee, Corinna (Legal Adviser)
(f) Professor CHO Chi-hin
(g) Professor CHAN Yan-keung
(h) Mr SIT Ka-keung, Perry
Mr CHUA Sek-chon, Peter, JP
Mr LEUNG Kai-lok, Peter
(i) Dr WONG Shou-pang, Alexander

Mr AU Hing-yuen

管理局的成員由行政長官委任，每屆任期不多於三年，可以再獲委任。成員包括：

(a) 衞生署署長 (主席)；
(b) 政府化驗師；
(c) 衞生署總藥劑師；

} 當然成員

(d) 一名衞生署醫生；
(e) 一名法律顧問；
(f) 一名香港大學藥理學全職教員；
(g) 一名香港中文大學藥理學全職教員；
(h) 三名經香港藥學會提名的註冊藥劑師 (非公職人員)；及
(i) 一名經香港醫學會提名的註冊醫生(非公職人員)。

在二零零四年十二月三十一日，管理局的成員計有：

(a) 林秉恩醫生(主席)
(b) 丁大倫博士
(c) 陳永健先生
(d) 梁挺雄醫生
(e) 麥慧儀女士(法律顧問)
(f) 曹之憲教授
(g) 陳恩強教授
(h) 薛家強先生
蔡錫聰先生
梁佳樂先生
(i) 王壽鵬醫生

區慶源先生

管理局的成員及職能

The Board is established under section 3 of the Pharmacy and Poisons Ordinance to carry out the following functions in accordance with the provisions of the same Ordinance and its subsidiary legislation:-

(a) registration of pharmacists, including the prescription of training required for registration, the organization of registration examinations and the issue of certificates of registration and annual practising certificates, etc.;

(b) discipline of pharmacists, after inquiry into their conduct by Disciplinary Committees appointed for the purpose;

(c) licensing and regulatory control of retail traders (authorized sellers of poisons and listed sellers of poisons), including prescribing the conditions of sales, conducting inspections and test purchases and, for authorized sellers of poisons, inquiring into their conduct by Disciplinary Committees appointed for the purpose;

(d) licensing and regulatory control of wholesale dealers, importers, exporters and manufacturers of pharmaceutical products;

(e) regulatory control of the selling, purchasing, compounding and dispensing of pharmaceutical products; and

(f) registration, classification and reclassification of pharmaceutical products.

The Board is assisted by six executive committees. They meet regularly to consider and decide policies and actions in relation to the conduct of the above functions. The decisions of the Board and executive committees are carried out jointly by the Secretariat of the Board and the Pharmaceutical Service of the Department of Health.

管理局根據《藥劑業及毒藥條例》第3條成立，執行該條例及其附屬法例規定的下述職能：

(a) 處理藥劑師註冊事宜，包括訂明註冊所須的訓練、主辦註冊考試、簽發註冊證明書及周年執業證明書等；

(b) 委出紀律委員會，調查藥劑師的行為操守，並懲處被裁定行為不當的藥劑師；

(c) 規管及簽發零售商(獲授權毒藥銷售商及列載毒藥銷售商)牌照。有關工作包括訂明銷售條件、進行巡查及試買行動及委出紀律委員會調查獲授權毒藥銷售商的經營手法等；

(d) 規管及簽發藥劑製品批發商、進出口商、製造商牌照；

(e) 規管藥劑製品的銷售、購買、合成和配發事宜；以及

(f) 處理藥劑製品的註冊、分類和再分類事宜。

管理局轄下設有六個執行委員會。這些委員會定期舉行會議，就執行上述職能審議和制定政策及行動計劃。管理局及執行委員會的決定則由管理局秘書處及衞生署藥劑事務部執行。

Membership and Functions of the Executive Committees

To assist the Board in performing its functions, the following six executive committees are established under various provisions of the Pharmacy and Poisons Ordinance: -

管理局根據《藥劑業及毒藥條例》內相關的條文成立了下述六個執行委員會，協助管理局執行職能：

Professor CHAN Yan-keung (Chairman)
Dr TING Tai-lun, JP
Mr CHAN Wing-kin, Anthony
Dr LAI Kit-lim, Cindy
Mr CHUA Sek-chon, Peter, JP
Professor LEE Kwing-chin, Kenneth, JP
Mr CHENG Chung-kwong (Secretary)

陳恩強教授 (主席)
丁大倫博士
陳永健先生
黎潔廉醫生
蔡錫聰先生
李炯前教授
鄭中光先生 (秘書)

The Examination Committee is established under section 8(3) of the Pharmacy and Poisons Ordinance to: -

(a) advise the Board on matters regarding the registration of pharmacists and the training requirements and the examinations for registration;

(b) design and review the syllabuses of the registration examinations;

(c) appoint panels to assist in setting question papers and marking answer scripts for the registration examinations;

(d) oversee the setting and marking of examination papers;

(e) prepare and conduct the registration examinations;

(f) review the results of registration examinations and make recommendations regarding applicants' eligibility for registration to the Board for consideration;

(g) consider complaints and unusual circumstances arising from applications for registration or examinations, and make recommendations to the Board for consideration; and

(h) keep under review the standard of the registration examinations.

考試委員會根據《藥劑業及毒藥條例》第 8(3)條成立，負責：

(a) 就有關藥劑師註冊、註冊的訓練要求和考試的事宜向管理局提供意見；

(b) 制定及檢討註冊考試的範圍；

(c) 委聘小組設定註冊試題及評閱試卷；

(d) 監督試卷設定及評卷工作；

(e) 籌備及主辦註冊考試；

(f) 覆核註冊考試的成績，並向管理局就申請人的註冊資格提交建議；

(g) 調查註冊或考試申請的投訴及異常情況，並提交建議供管理局考慮；及

(h) 檢討註冊考試的水平。

管理局執行委員會的成員及職能

Mr CHAN Wing-kin, Anthony (Chairman)
Mr CHAU Wing-kit, Luke
Mr CHUA Sek-chon, Peter, JP
Mr LEUNG Kai-lok, Peter
Ms Linda WOO (Secretary)

The Pharmacy and Poisons (Listed Sellers of Poisons) Committee is established to consider and approve applications for listed sellers of poisons under regulation 24A of the Pharmacy and Poisons Regulations.

陳永健先生(主席)
周永傑先生
蔡錫聰先生
梁佳樂先生
吳婉宜女士(秘書)

藥劑業及毒藥(列載毒藥銷售商)委員會負責審批根據《藥劑業及毒藥規例》第24A條提出的列載毒藥銷售商牌照申請。

Mr CHAN Wing-kin, Anthony (Chairman)
Mr CHAU Wing-kit, Luke
Mr CHUA Sek-chon, Peter, JP
Mr LEUNG Kai-lok, Peter
Ms Linda WOO (Secretary)

In accordance with regulations 26 and 37A of the Pharmacy and Poisons Regulations, the Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee is established to: -

(a) consider and approve applications for wholesale poisons licences;

(b) revoke any wholesale poisons licence or suspend it for a specified period; and

(c) grant or refuse any application for registration as an importer or exporter of pharmaceutical products.

陳永健先生(主席)
周永傑先生
蔡錫聰先生
梁佳樂先生
吳婉宜女士(秘書)

藥劑業及毒藥(批發牌照及進出口商註冊)委員會根據《藥劑業及毒藥規例》第26條及第37A條，執行下列職能：

(a) 審批毒藥批發牌照的申請；

(b) 撤銷或在指定期間內暫時吊銷任何毒藥批發牌照；及

(c) 批准或拒絕藥劑製品進口商或出口商牌照申請。

Membership and Functions of the Executive Committees

Mr CHAN Wing-kin, Anthony (Chairman)
Mr CHAU Wing-kit, Luke
Mr CHUA Sek-chon, Peter, JP
Mr LEUNG Kai-lok, Peter
Ms Linda WOO (Secretary)

陳永健先生(主席)
周永傑先生
蔡錫聰先生
梁佳樂先生
吳婉宜女士(秘書)

The Pharmacy and Poisons (Manufacturers Licensing) Committee issues licences to manufacture pharmaceutical products; or revokes or suspends any of them for a specified period as it thinks fit in accordance with regulation 29 of the Pharmacy and Poisons Regulations.

藥劑業及毒藥(製造商牌照)委員會根據《藥劑業及毒藥規例》第29條所述的職能簽發藥劑製品製造牌照、或撤銷、或在委員會認為適當的期間內暫時吊銷該類牌照。

Mr CHAN Wing-kin, Anthony (Chairman)
Dr TING Tai-lun, JP
Dr KO Tak-him
Professor Brian TOMLINSON
Ms MA Yat-man, Vivian
Dr Lloyd KENDA
Mr MAK Yuk-lun (Secretary)

陳永健先生(主席)
丁大倫博士
高德謙醫生
Prof Brian TOMLINSON
馬逸敏女士
Dr Lloyd KENDA
麥煜綸先生(秘書)

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee carries out the following functions in accordance with Part VIII of the Pharmacy and Poisons Regulations: -

藥劑業及毒藥(藥劑製品及物質註冊：臨床試驗及藥物測試證明書)委員會執行下列根據《藥劑業及毒藥規例》第 VIII 部所述的職能：

管理局執行委員會的成員及職能

(a) issue registration certificates for pharmaceutical products or substances;

(b) deregister any pharmaceutical product or substance;

(c) consider applications for change of any registrable particulars of pharmaceutical products or substances; and

(d) consider applications for conducting clinical trials on human beings or medicinal tests on animals, and issue clinical trial certificates or medicinal test certificates.

(a) 簽發藥劑製品或物質註冊證明書；

(b) 撤銷藥劑製品或物質的註冊；

(c) 考慮有關更改藥劑製品或物質註冊詳情的申請；及

(d) 考慮有關對人類進行臨床試驗或對動物進行藥物測試的申請，以及簽發臨床試驗證明書或藥物測試證明書。

Professor CHO Chi-hin (Chairman)
Dr WONG Shou-pang, Alexander
Mr CHAN Wing-kin, Anthony
Dr TING Tai-lun, JP
Mr LEUNG Kai-lok, Peter
Mr SIT Ka-keung, Perry
Mr CHENG Chung-kwong (Secretary)

曹之憲教授(主席)
王壽鵬醫生
陳永健先生
丁大倫博士
梁佳樂先生
薛家強先生
鄭中光先生(秘書)

The Poisons Committee is set up under section 31 of the Pharmacy and Poisons Ordinance to advise the Board on the classification and distribution of poisons in Part I and Part II of the Poisons List and matters relating to the control of poisons and pharmaceutical products, including: -

(a) the classification of pharmaceutical products pending registration; and

(b) the review of the classification of pharmaceutical products regulated under the Poisons List Regulations and the Pharmacy and Poisons Regulations.

毒藥委員會根據《藥劑業及毒藥條例》第31條成立，就各種毒藥在毒藥表第I部及第II部中的分類及分配，以及有關管制毒藥及藥劑製品的事宜，向管理局提供意見。有關事宜包括：

(a) 有待註冊的藥劑製品的分類；及

(b) 檢討根據《藥劑業及毒藥規例》及《毒藥表規例》管制的藥劑製品的分類。

The Work of the Board and its Executive Committees

Any person intending to practise as a pharmacist in Hong Kong must first be registered with the Board. To be eligible for registration, an applicant must be able to meet with the qualification, examination and training requirements specified by the Board.

An applicant must satisfy either one of the following two criteria: -

(a) holds a pharmacy degree awarded by a recognized university in Hong Kong; or

(b) non-local applicants must have completed his/her tertiary education of not less than three full-time academic years, or equivalent, in pharmacy, and be registered or be professionally qualified to be registered as a pharmacist, normally in the country in which he/she has completed his/her studies in pharmacy.

An applicant who possesses the qualification (b) above must also pass the Board's registration examination in three subjects, namely Pharmacy Legislation in Hong Kong, Pharmacy Practice and Pharmacology.

The Examination Committee conducted two registration examinations in June and December 2004. A total of 40 applicants cumulatively passed all the three subjects in the year 2004.

The results of these two registration examinations are shown in . Figures for the years 2000 to 2003 are also included for comparison purpose.

擬於香港執業的藥劑師必須向管理局註冊。申請人必須具備管理局規定的資格、考試成績及實習履歷，方符合資格註冊。

申請人必須符合下述其中一項條件：

(a) 具備香港認可大學頒授的藥劑學士學位；或

(b) 在本港以外地區完成不少於三個完整學年或相等的藥劑學課程並已在其完成學業的地區註冊為藥劑師；或取得註冊為藥劑師的專業資格。

符合上述(b)項要求的申請人，必須通過由管理局舉辦的三個科目的註冊考試，包括香港藥劑法例、藥劑執業及藥理學。

考試委員會在二零零四年分別在六月及十二月舉辦了兩次註冊考試。同年共有40人累積取得全部三科合格的成績。

列出該兩次註冊考試的成績，以及二零零零年至二零零三年的有關數字，以供比較。

管理局及其執行委員會的工作

Applicants holding a pharmacy degree awarded by the Chinese University of Hong Kong, which is at present the only local university offering a Bachelor of Pharmacy programme, are required to undergo Board-approved training for one year before they can be registered as pharmacists.

Applicants holding a recognized pharmacy degree awarded elsewhere should have had an aggregate of relevant pre-registration training and post-registration experience of not less than one year. An applicant with less than one year's training and experience may be permitted to take the registration examinations but, upon passing all parts thereof, will be required to undergo an appropriate period of make-up training specified by the Board.

香港中文大學是香港目前唯一主辦藥劑學士學位課程的大學。持有香港中文大學藥劑學士學位的申請人，在獲准成為註冊藥劑師前，須接受管理局認可的實習訓練，為期一年。

持有其他地方頒發的認可藥劑學士學位的申請人，他的註冊前實習訓練及取得註冊後的工作經驗，合共不可少於一年。訓練及經驗合共少於一年的申請人亦可獲得批准參加註冊考試，惟通過全部考試後，須接受一段管理局認可的補償實習。

Upon registration the Secretary of the Board will issue to a registered pharmacist a certificate of registration.

The Secretary is also responsible for keeping a register of pharmacists in which particulars of all pharmacists registered in Hong Kong are entered. The register is open for inspection by the general public. A copy of the register is also published in the Gazette once every 12 months.

一經註冊，管理局秘書會向註冊藥劑師發出註冊證明書。

管理局秘書負責備存一份藥劑師名冊，詳列所有在香港註冊的藥劑師的個人資料，並公開予市民查閱。該名冊每十二個月在憲報刊登一次。

All practising pharmacists must obtain a practising certificate annually in accordance with section 10A of the Pharmacy and Poisons Ordinance. A total of 1,517 registered pharmacists were issued with practising certificates in the year 2004. Statistical data regarding registration of pharmacists and breakdown of fresh registration, removal from and restoration to the register of pharmacists for the years 2000 to 2004 are shown in

所有執業藥劑師必須根據《藥劑業及毒藥條例》第10A條的規定取得周年執業證明書。在二零零四年，共有1,517位註冊藥劑師獲發執業證明書。 列出二零零零年至二零零四年有關藥劑師註冊，以及新註冊、刪除註冊及重新註冊的分項數字的統計資料。

The Work of the Board and its Executive Committees

Inquiries into the conduct of registered pharmacists are made by Disciplinary Committees appointed under section 15 of the Pharmacy and Poisons Ordinance. A registered pharmacist found guilty of misconduct will be subject to disciplinary sanctions, ranging from censure to removal from the register of pharmacists for a specified period of time. A more detailed account of the set-up and work of Disciplinary Committees are given in pages 22 to 24 of this report.

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in the years 2000 to 2004 are shown in .

管理局根據《藥劑業及毒藥條例》第15條的規定，委出紀律委員會，調查註冊藥劑師的行為操守。被裁定行為不當的註冊藥劑師將接受紀律制裁，包括譴責或在指定的時期內從藥劑師名冊上除名。有關紀律委員會的組成及工作詳情，可參閱本年報第22至24頁。

詳列管理局在二零零零年至二零零四年對註冊藥劑師採取紀律行動的統計數字。

An authorized seller of poisons (ASP), commonly known as "pharmacy", "dispensary" or "drug store", is a business authorized to sell poisons included in Part I of the Poisons List, by or under the supervision of a registered pharmacist. Any person wishing to operate an ASP shall apply to the Board for registration of the premises where the retail sale of poisons is to be conducted. If the Board is satisfied that the requirements stipulated in section 13(4) of the Pharmacy and Poisons Ordinance are complied with, the application will be granted, subject to the payment of prescribed fee.

The name, the certificate of registration and a notice setting out the attending hours of the duty pharmacist are required to be displayed in a conspicuous location in the premises of the ASP. The ASP may also display a logo prescribed under section 13A.

獲授權毒藥銷售商一般稱為「藥房」("pharmacy","dispensary" 或 "drug store")，是獲授權銷售毒藥表內第I部毒藥的商號，惟銷售這些毒藥必須由註冊藥劑師監督或直接銷售。擬申請成為獲授權毒藥銷售商的商號，須向管理局申請將其進行毒藥零售業務的處所註冊。如管理局信納該申請符合《藥劑業及毒藥條例》第13(4)條所列的條件，便批准有關申請，在訂明費用繳付後生效。

獲授權毒藥銷售商須在其處所的當眼處展示其當值藥劑師的姓名、註冊證明書及工作時間的告示。銷售商亦可以展示根據條例第13(A)條訂明的標識。

管理局及其執行委員會的工作

The ASP must apply for renewal of registration annually. All records of an ASP will be taken into account when the Board assesses the application for renewal of registration of premises each year. If the ASP is not considered a fit and proper person to continue the retail business of poisons, the application will be rejected.

There were 441 ASPs registered in Hong Kong as at end of year 2004. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of an ASP in the years 2000 to 2004 are shown in .

The premises registered with the Board are subject to inspection by pharmacist inspectors of the Department of Health. Test purchases to check illegal activities involving controlled drugs or unregistered pharmaceutical products are conducted randomly and prosecutions are instituted against offenders.

Any act of alleged misconduct will be subject to inquiry by Disciplinary Committees appointed by the Board. If found guilty of misconduct, the ASP will be subject to disciplinary sanctions, ranging from written warning to disqualification from being an ASP for a specified period of time.

Twelve inquiries were held and twelve ASPs were found guilty of misconduct in the year 2004. Five of them were issued with written warnings whilst seven of them were disqualified from being an ASP for a period of time.

獲授權毒藥銷售商須每年向管理局申請註冊續期。管理局在審理獲授權毒藥銷售商的周年處所註冊續期申請時，會考慮有關銷售商的全部記錄。假如管理局認為該獲授權毒藥銷售商並不適宜繼續經營毒藥零售業務，管理局將拒絕其申請。

截至二零零四年年終，香港共有441名獲授權毒藥銷售商。

詳列二零零零年至二零零四年獲授權毒藥銷售商的總數、處所註冊申請及註冊續期申請的統計數字。

衞生署的藥劑師督察會巡查已經向管理局註冊的銷售商處所。署方亦會派員抽樣進行試買，偵查涉及受管制藥物的違法活動，並檢控違法者。

管理局會委出紀律委員會就任何不當行為展開研訊。銷售商如被裁定犯有不當行為，將會受到紀律制裁，由書面警告以至在指定期間被吊銷銷售商資格不等。

管理局在二零零四年舉行了十二次紀律研訊，共有十二名獲授權毒藥銷售商被裁定犯有不當行為。紀律委員會決定向其中五名獲授權毒藥銷售商發出書面警告，而另有七名獲授權毒藥銷售商被取消銷售商資格一段時間。

For minor infringement, the Board may decide not to initiate any disciplinary inquiry but direct the Chief Pharmacist of the Department of Health and the Secretary of the Board to interview and verbally caution the proprietor/director and duty pharmacist of the ASP concerned. A total of thirty-seven such interviews were held in the year 2004.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in the years 2000 to 2004 is shown in

.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in the years 2000 to 2004 are given in

.

A listed seller of poisons (LSP), commonly known as a medicine company, is a person approved to conduct the retail sale of poisons included in Part II of the Poisons List subject to the provision of the Pharmacy and Poisons Ordinance. Any person wishing to operate as an LSP shall apply for his name to be entered onto the list of LSPs kept by the Board. On behalf of the Board, the Pharmacy and Poisons (Listed Sellers of Poisons) Committee issues licences to LSPs.

There were 2,867 LSPs as at end of year 2004. The number of licensed LSPs in the years 2000 to 2004 is shown in . Statistical data regarding applications for LSP licences and renewal of such licences in these five years are shown in .

至於輕微的違法行為，管理局或會決定不展開紀律研訊，但會指示衞生署總藥劑師及管理局秘書，約見有關的獲授權毒藥銷售商的東主或董事及當值藥劑師，向他們發出口頭警告。管理局在二零零四年舉行了三十七次該類會面。

列出二零零零年至二零零四年由藥劑師督察對獲授權毒藥銷售商進行巡查及試買的數字。

詳列二零零零年至二零零四年管理局處理有關獲授權毒藥銷售商的紀律個案的統計數字。

列載毒藥銷售商一般稱為藥行，是根據《藥劑業及毒藥條例》的規定，獲准經營毒藥表內第II部毒藥零售業務的人士。擬成為列載毒藥銷售商的人士，可向管理局申請將其姓名載入管理局備存的列載毒藥銷售商名單內。藥劑業及毒藥(列載毒藥銷售商)委員會會代表管理局簽發牌照予列載毒藥銷售商。

截至二零零四年年終，香港共有2,867名列載毒藥銷售商。列出二零零零年至二零零四年列載毒藥銷售商的總數。 列出在上述五年申請發牌以及申請續牌的統計數字。

管理局及其執行委員會的工作

Like the ASPs, LSPs are also subject to inspection by pharmacist inspectors but unlike the ASPs, no disciplinary inquiries by Disciplinary Committees will be held to inquire into the conduct of an LSP. If an LSP is convicted of any offence under the Pharmacy and Poisons Ordinance, the Antibiotics Ordinance or the Dangerous Drugs Ordinance, his case will be submitted to the Board for consideration. His name will be removed from the list of LSPs if the Board considers him not a fit and proper person to continue the retail business of Part II poisons. For minor infringement, the Board may issue a written warning to the LSP concerned.

The number of inspections and test purchases conducted by pharmacist inspectors on LSPs in the years 2000 to 2004 is shown in . Statistical data regarding disciplinary cases handled by the Board in respect of LSPs in these five years are given in .

衞生署藥劑師督察同樣地會巡查列載毒藥銷售商的處所。但是，管理局不會因調查列載毒藥銷售商的經營手法而召開紀律研訊，這點與處理有關獲授權毒藥銷售商的紀律事宜的方法不同。假如有列載毒藥銷售商被裁定違反任何《藥劑業及毒藥條例》、《抗生素條例》或《危險藥物條例》的規定，有關個案將直接呈交管理局考慮。管理局假如認為涉案的列載毒藥銷售商並不適宜繼續經營第II部毒藥零售業務，便會把該列載毒藥銷售商的姓名從列載毒藥銷售商名單上刪除。至於輕微的違法行為，管理局可向有關的列載毒藥銷售商發出書面警告。

列出二零零零年至二零零四年由藥劑師督察對列載毒藥銷售商進行巡查以及試買的數字。詳列管理局在上述五年處理有關列載毒藥銷售商的紀律個案的統計數字。

Subject to the provisions of the Pharmacy and Poisons Regulations, any person other than an authorized seller of poisons or a licensed manufacturer wishing to sell or supply any poison or any substance/article containing poisons by way of wholesale dealing should apply to the Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee for an annual wholesale poisons licence.

除《藥劑業及毒藥規例》另有規定外，任何人如欲以批發經營方式銷售或供應任何毒藥或含有毒藥的物質或物品，均須向藥劑業及毒藥(批發牌照及進出口商註冊)委員會申請一年期毒藥批發牌照。

The Work of the Board and its Executive Committees

A licensed wholesale dealer must keep a record of all transactions involving poisons included in Part I of the Poisons List. Sales are restricted to authorized persons only.

There were 832 holders of a wholesale poisons licence as at end of year 2004. Statistical data for the years 2000 to 2004 are shown in

.

持牌的批發商須備存所有涉及毒藥表第 I 部所列毒藥的交易記錄，而銷售對象只限於獲授權人士。

截至二零零四年年終，香港共有832名毒藥批發牌照持有人。

列出二零零零年至二零零四年的統計數字。

Any person wishing to manufacture any pharmaceutical product shall apply to the Pharmacy and Poisons (Manufacturers Licensing) Committee for a licence annually.

Manufacturers are subject to the provisions of the Pharmacy and Poisons Regulations. They are required to label the container of each pharmaceutical product with the appropriate particulars, such as the active constituents or ingredients of the product, the quantitative particulars of these constituents or ingredients, and the name and address of the manufacturer. They are also required to take adequate steps to ensure that all personnel involved in the manufacturing or packing of pharmaceutical products do not contaminate or infect the products.

It is the duty of every manufacturer to test each batch of raw material intended to be used in the manufacture of pharmaceutical products as well as its finished form to ensure identity and purity, and identity and potency respectively. A system of control that will enable the rapid and complete recall of any product from sale to the public should be put in place.

A manufacturer should also ensure that the premises and the fittings and machinery in such premises meet an appropriate standard in respect of temperature, humidity, cleanliness and hygiene, and that a set of records regarding the manufacture of pharmaceutical products are properly kept.

任何人如欲製造任何藥劑製品，每年均須向藥劑業及毒藥(製造商牌照)委員會申請牌照。

製造商必須遵守《藥劑業及毒藥規例》的規定，他們須在每件藥劑製品的容器上加上適當的標籤，標明製品的成分或有效組分、該等成分或組分的數量詳情、製造商的名稱及地址等資料。他們並須採取足夠的步驟，確保所有從事製造或包裝藥劑製品的人員不會污染該等製品或使該等製品受到感染。

每名製造商必須測試擬用於製造藥劑製品的每一批原料及製成品，確保原料的本質及純度，以及製成品的本質及效力。製造商亦須設立一套管理制度，以便能向市場迅速地完全回收任何正在銷售的產品。

製造商同時須確保其廠房以及其裝置及機器符合溫度、濕度、清潔及衞生的標準，以及備存一套有關生產藥劑製品的記錄。

管理局及其執行委員會的工作

The manufacture of pharmaceutical products must be supervised by a registered pharmacist or persons with such other qualifications as approved by the Board.

There were 41 holders of a manufacturer's licence as at end of year 2004. Statistical data for the years 2000 to 2004 are given in .

製造藥劑製品必須在註冊藥劑師或具備管理局認可資格的人士監督下進行。

截至二零零四年年終，香港共有41名製造商牌照持有人。列出二零零零年至二零零四年的統計數字。

Under section 28A of the Pharmacy and Poisons Ordinance, any person other than a wholesale dealer wishing to carry out business as an importer and/or exporter of pharmaceutical products shall apply for registration with the Board annually. Applications will be considered by the Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee.

There were 257 holders of a registration certificate for importer and exporter of pharmaceutical products as at end of year 2004. Statistical figures for the years 2000 to 2004 are shown in .

根據《藥劑業及毒藥條例》第28A條的規定，除藥劑製品批發商外，任何人如欲以藥劑製品進出口商的身分經營業務，均須每年向管理局申請牌照。有關申請均由藥劑業及毒藥(批發牌照及進出口商註冊)委員會審理。

截至二零零四年年終，香港共有257名藥劑製品進出口商證明書持有人。　　列出二零零零年至二零零四年的統計數字。

In accordance with regulation 36 of the Pharmacy and Poisons Regulations, any person wishing to sell, offer for sale, distribute or possess any pharmaceutical product or substance, shall register the product or substance with the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee.

根據《藥劑業及毒藥規例》第36條的規定，任何人如欲銷售、要約出售、分銷或管有任何藥劑製品或物質，均須將有關製品或物質向藥劑業及毒藥(藥劑製品及物質註冊：臨床試驗及藥物測試證明書)委員會註冊。

In considering an application for registration of a pharmaceutical product, the Committee will take into account the safety, efficacy and quality of the subject product. In dealing with an application by an importer, the Committee may require the applicant to produce one or both of the following documents: -

(a) an undertaking to permit the Committee to inspect the manufacturing premises; and

(b) a declaration that the subject product is manufactured in accordance with the requirements imposed by or under the law of the country concerned.

A registration certificate will be issued on registration. The applicant will also be advised of the classification of the product.

There were 20,084 registered pharmaceutical products in Hong Kong as at end of year 2004. The number of registered pharmaceutical products as at end of years 2000 to 2004 is shown in .

On the advice of the Poisons Committee, the Board determines and regularly reviews the classification and distribution of pharmaceutical products in the Poisons List and regulates their control by posing further restrictions on their sales through the provision of the First and Third Schedules of the Pharmacy and Poisons Regulations. The classification of pharmaceutical products in the Poisons List and restrictions on sales under the two schedules are: -

在決定是否批准某一藥劑製品申請註冊時，委員會會考慮該藥品的安全程度、效能及素質。在處理進口商提交的申請時，委員會可能要求申請者出示下列其中一份或全部文件：

(a) 准許委員會視察其生產廠房的承諾書；及

(b) 承諾該產品是遵照有關國家的法律或根據法律施加的任何規定而製造的聲明書。

一經註冊，申請者會獲發註冊證明書，並獲告知產品的分類。

截至二零零四年年終，香港共有20,084種已註冊的藥劑製品。

列出截至二零零零年至二零零四年年終的註冊藥劑製品數字。

就毒藥委員會的建議，管理局會決定及定期檢討藥劑製品在毒藥表內的分類及分配，並透過《藥劑業及毒藥規例》附表 1 和附表 3 ，進一步規管藥劑製品的銷售。藥劑製品在毒藥表內的各種不同分類及在附表 1 和附表 3 內的銷售規管分述如下：

管理局及其執行委員會的工作

(a) Part I Poisons: Poisons included in Part I of the Poisons List (Poisons List Regulations, Cap. 138B)	They can be sold only by authorized sellers of poisons under the supervision of registered pharmacists.
(b) Part I First Schedule Poisons: Poisons included in Part I of the Poisons List and the First Schedule to the Pharmacy and Poisons Regulations (Cap. 138A)	They can be sold only by authorized sellers of poisons under the supervision of registered pharmacists and after entry in the Poisons book stating the particulars of the sale. They should also be stored in retail premises in a locked receptacle in a part of the premises to which customers do not have access.
(c) Part I Third Schedule Poisons: Poisons included in Part I of the Poisons List and the Third Schedule to the Pharmacy and Poisons Regulations (Cap. 138A)	They can be sold only by authorized sellers of poisons under the supervision of registered pharmacists with the authority of a prescription from a registered medical practitioner, registered dentist or registered veterinary surgeon.
(d) Part II Poisons: Poisons included in Part II of the Poisons List (Poisons List Regulations, Cap. 138B)	They can be sold by authorized sellers of poisons and listed sellers of poisons without the supervision of registered pharmacists.

Classification and distribution in the Poisons List and imposition of control through the two schedules are made through amendments to the Poisons List Regulations and the Pharmacy and Poisons Regulations. Amendments proposed by the Board and approved by the Legislative Council in the year 2004 included: -

(a) 第I部毒藥：《毒藥表規例》(第138章B)毒藥表第I部所列毒藥	在註冊藥劑師監督下，由獲授權毒藥銷售商銷售。
(b) 第I部附表1毒藥：同時列於毒藥表第I部及《藥劑業及毒藥規例》(第138章A)附表1的毒藥	在註冊藥劑師監督下，由獲授權毒藥銷售商銷售，並必須於出售前將銷售詳情記錄在毒藥冊中。該類毒藥必須存放在上鎖的盛器內，而盛器則須存放在處所內顧客不准進入的地方。
(c) 第I部附表3毒藥：同時列於毒藥表第I部及《藥劑業及毒藥規例》(第138章A)附表3的毒藥	須由註冊醫生、註冊牙醫或註冊獸醫處方授權，並在註冊藥劑師監督下，由獲授權毒藥銷售商銷售。
(d) 第II部毒藥：《毒藥表規例》(第138章B)毒藥表第II部所列毒藥	無須藥劑師監督，由獲授權毒藥銷售商或列載毒藥銷售商銷售。

管理局透過修訂《毒藥表規例》和《藥劑業及毒藥規例》，將藥劑製品在毒藥表內分類和分配，並透過兩個附表對藥劑製品施加規管。立法會在二零零四年批准管理局就藥劑製品分類對《毒藥表規例》和《藥劑業及毒藥規例》作出以下修訂：

(a) adding 10 new substances to Part I of the Poisons List Regulations and 10 to the First and Third Schedules to the Pharmacy and Poisons Regulations. Two lists of these substances are at respectively; and

(b) relaxing the control of 'Tromantadine; its salts; when contained in pharmaceutical products labelled for the treatment of cold sores only' by re-classifying them from Part I, First and Third Schedules poisons to Part I poisons.

Regulatory provisions in other related areas are contained in the Second and Fourth to Seventh Schedules to the Pharmacy and Poisons Regulations: -

(a) 在《毒藥表規例》第I部加入10種和在《藥劑業及毒藥規例》附表1及附表3加入10種新的物質。這些物質分別列載於
；及

(b) 放寬對"曲金剛胺；其鹽類；標明只作治療唇皰疹之用的藥劑製品所包含者"的管制，將其由《毒藥表規例》第I部和《藥劑業及毒藥規例》附表1及附表3毒藥重新分類為《毒藥表規例》第I部毒藥。

《藥劑業及毒藥規例》附表2及附表4至7詳列對下述其他方面的規管：

Second Schedule	providing for articles exempted from the provisions of the Pharmacy and Poisons Ordinance and the Pharmacy and Poisons Regulations.
Fourth Schedule	setting out the statement of particulars as to proportion of poisons in certain cases.
Fifth Schedule	prescribing the labelling requirements for certain poisons.
Sixth Schedule	listing out poisons exempted from labelling provisions when sold or supplied in certain circumstances.
Seventh Schedule	listing out poisons required to be specially labelled for transport.

附表2	列舉豁免受《藥劑業及毒藥條例》及《藥劑業及毒藥規例》條文規限的物品。
附表4	詳列在某些情況下有關毒藥比例的詳情說明。
附表5	說明對某些毒藥的標籤要求。
附表6	列出在某些情況下銷售或供應則無須加上標籤的毒藥。
附表7	列出為運輸而須特別加上標籤的毒藥。

紀律委員會的成員及職能

A Disciplinary Committee consists of the following persons: -

(a) a Chairman, who is the medical officer in the Department of Health appointed by the Chief Executive under section 3(2)(e) of the Ordinance as a member of the Board;

(b) two registered pharmacists (not being public officers) nominated by the Pharmaceutical Society of Hong Kong; and

(c) a legal adviser appointed by the Chief Executive.

As at 31 December 2004, the Chairman of the Disciplinary Committee was Dr LEUNG Ting-hung, JP, Deputy Director of the Department of Health. Registered pharmacists who had served as members in year 2004 included: -

Miss KWOK Hing-fun
Miss WONG Yuen-yin, Clara
Miss LAI Wing-han, Wingkie
Ms YAP Woan-tyng
Ms HO Yuk-fong, Cindy
Mr CHUNG Wing-ming, Billy
Mr LEUNG Kwong-hei
Mr WONG Kwong-cheung, Aaron
Mr SIN Ping-fai, Matthew
Mr TSANG Yuen-wo
Mr YAU Fuk-loi, Rico
Mr CHAN Chi-kit
Mr CHAN Cho-hung
Mr LAU Ho-kuen, Kenneth

紀律委員會的成員包括下列人士：

(a) 一名根據條例第3(2)(e)條由行政長官委任為管理局委員的衞生署醫生，並由其出任主席；

(b) 二名由香港藥學會提名的註冊藥劑師〔非公職人員〕；及

(c) 一名由行政長官委任的法律顧問。

衞生署副署長梁挺雄醫生是紀律委員會二零零四年十二月三十一日的主席。曾在二零零四年出任成員的註冊藥劑師包括：

郭興芬女士
黃婉妍女士
賴穎嫻女士
葉婉婷女士
何玉芳女士
鍾永明先生
梁廣熙先生
黃廣長先生
冼秉輝先生
曾遠和先生
邱福來先生
陳智傑先生
陳祖洪先生
劉浩權先生

Membership and Functions of the Disciplinary Committee

In accordance with section 15 of the Pharmacy and Poisons Ordinance, a Disciplinary Committee is appointed by the Board for the purpose of disciplinary inquiry of: -

(a) a complaint received by the Board regarding the conduct of a registered pharmacist or his employee, or an authorized seller of poisons (ASP) or its partner or employee; or

(b) any person or body, mentioned in (a) above, convicted of an offence under the Pharmacy and Poisons Ordinance, the Dangerous Drugs Ordinance or the Antibiotics Ordinance; or

(c) the conduct of any such person or body, which appears necessary or desirable to the Board, that should be inquired into.

In respect of a registered pharmacist, the Disciplinary Committee may, at the conclusion of an inquiry: -

(a) censure the registered pharmacist; or

(b) remove his name from the register of pharmacists for such period as the Disciplinary Committee directs.

As for an ASP, the Disciplinary Committee may at the conclusion of an inquiry direct that: -

(a) the ASP be disqualified, for such period as may be specified in the direction, from being an ASP; or

(b) any or all of the premises of that ASP be removed from the register of premises and be disqualified for a specified period; or

(c) a written warning be served on that ASP.

The Disciplinary Committee may, subject to any appeal, cause its decision in any inquiry to be published in the Gazette, with or without an account of the proceedings.

根據《藥劑業及毒藥條例》第15條，管理局委出紀律委員會就下列情況召開紀律研訊：

(a) 當管理局接到有關任何註冊藥劑師、其僱員、獲授權毒藥銷售商或其合夥人或僱員的行為操守的投訴；或

(b) 當上述(a)項所述的任何人士或團體被裁定觸犯《藥劑業及毒藥條例》、《危險藥物條例》或《抗生素條例》；或

(c) 當管理局覺得有需要或適宜就任何該等人士或團體的行為操守進行研訊。

如研訊對象是註冊藥劑師，紀律委員會可在研訊完結時：

(a) 譴責該名註冊藥劑師；或

(b) 在紀律委員會指示的期間內，將其姓名從藥劑師名冊中刪除。

至於獲授權毒藥銷售商，紀律委員會可在研訊完結時作出下列指示：

(a) 在某一指定的期間內，取消該團體作為獲授權毒藥銷售商的資格；或

(b) 從處所註冊記錄中刪除該團體的任何或全部處所的註冊登記，並在指定時間內，取消該等處所在註冊記錄冊內註冊的資格；或

(c) 向該獲授權毒藥銷售商發出書面警告。

如有關人士不提出上訴，紀律委員會便可安排將其指令在憲報刊登，並可刊登有關控罪的情由。

紀律委員會的成員及職能

An appeal against any direction of the Disciplinary Committee shall be made, within 28 days after receipt of notice of direction, to the Court of First Instance.

Statistical figures on the results of disciplinary inquiries into the conduct of registered pharmacists and ASPs are given in respectively. No appeal was made in 2004. Figures for the years 2000 to 2004 are shown in .

有關人士欲就紀律委員會作出的指令提出上訴，須於收到指示通知書的二十八日內，向原訟法庭提出。

分別詳載有關註冊藥劑師及獲授權毒藥銷售商的紀律研訊結果的統計數字。二零零四年並無接獲任何上訴。 詳列二零零零年至二零零四年的統計數字。

Membership and Functions of the Pharmacy and Poisons Appeal Tribunal

The Tribunal consists of the following members who are appointed by the Chief Executive in accordance with section 30 (2) of the Ordinance: -

(a) a legally qualified person who shall be the chairman of the Tribunal;

(b) a registered medical practitioner;

(c) a registered pharmacist;

(d) a person qualified in pharmacology;

(e) a person nominated by the Director of Health from a panel consisting of persons nominated by pharmacists' associations;

(f) a person nominated by the Director of Health from a panel consisting of persons nominated by pharmaceutical industry associations; and

(g) a person nominated by the Director of Health from a panel consisting of persons nominated by the retail pharmaceutical trade associations.

The membership of the Tribunal as at 31 December 2004 was as follows: -

審裁處包括下列根據條例第 30(2)條由行政長官委任的人士：

(a) 一名具備法律專業資格的人，並由其出任審裁處主席；

(b) 一名註冊醫生；

(c) 一名註冊藥劑師；

(d) 一名具備藥理學資格的人士；

(e) 一名由藥劑師組織提名組成的小組的成員，並為衞生署署長提名的人士；

(f) 一名由藥劑業組織提名組成的小組的成員，並為衞生署署長提名的人士；及

(g) 一名由藥劑零售業組織提名組成的小組的成員，並為衞生署署長提名的人士。

在二零零四年十二月三十一日，審裁處的成員如下：

Mr Alan HOO, S.C., JP	Chairman	胡漢清先生	主席
Dr YAM Yin-chun, Loretta	Member	任燕珍醫生	委員
Ms PONG Oi-lan, Scarlett	Member	龐愛蘭女士	委員
Dr CHEUNG Man-yung, Bernard	Member	張文勇醫生	委員
Ms YAP Woan-tyng	Panel Member	葉婉婷女士	小組委員
Mr TANG Wing-ming	Panel Member	鄧永明先生	小組委員
Ms CHAN Siu-yee, Sylvia	Panel Member	陳筱怡女士	小組委員
Mr CHONG Wing-kit, Donald	Panel Member	莊永傑先生	小組委員
Ms MA Yat-man, Vivian	Panel Member	馬逸敏女士	小組委員
Mr AW Yu-chun	Panel Member	柯宇春先生	小組委員
Dr CHAN Sung-kwong, Anthony	Panel Member	陳崇光牙醫	小組委員
Mr LEUNG Kwok-keung, Stephen	Panel Member	梁國強先生	小組委員
Mrs CHIN Hang-yin, Alice	Panel Member	陳阮幸賢女士	小組委員
Miss KAN Yu-yuk, Linda	Panel Member	簡如玉女士	小組委員
Dr CHENG Heung-kwan	Panel Member	鄭香郡博士	小組委員
Ms MO Sau-ping	Panel Member	巫秀萍女士	小組委員
Mr LAU Wing-keung	Panel Member	劉永強先生	小組委員
Mr NG Wing-yan	Panel Member	吳榮恩先生	小組委員
Mr LAU Oi-kwok	Panel Member	劉愛國先生	小組委員

藥劑業及毒藥上訴審裁處的成員及職能

The Pharmacy and Poisons Appeal Tribunal, established under section 30 of the Pharmacy and Poisons Ordinance, hears and determines the following matters: -

(a) any appeal against a decision of the Board in respect of application for registration of premises or application for renewal of registration of premises of an ASP;

(b) any appeal against a direction of the Board in respect of removal of the name of a listed seller of poisons (LSP) from the list of LSPs; and

(c) any appeal against a decision of a committee of the Board, excluding the Disciplinary Committee.

No appeal was heard in 2004. Breakdowns of the cases by nature and by result from 2000 to 2004 are shown in respectively.

藥劑業及毒藥上訴審裁處根據《藥劑業及毒藥條例》第30條成立，負責聆訊和裁定下列事宜：

(a) 就管理局對獲授權毒藥銷售商的處所註冊申請或處所註冊續期申請的決定而提出的上訴；

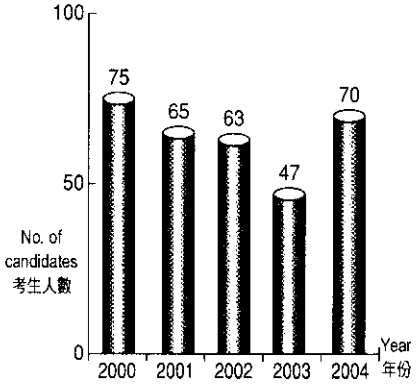
(b) 就管理局對從列載毒藥銷售商名單中刪除列載毒藥銷售商資格的決定而提出的上訴；及

(c) 就管理局屬下的委員會的決定提出的上訴，惟紀律委員會的決定除外。

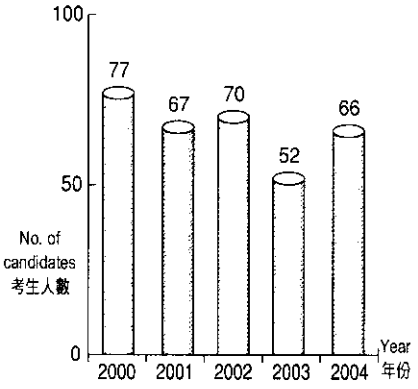
二零零四年並沒接獲任何上訴個案。分別列出在二零零零年至二零零四年有關個案的性質和結果的分項數字。

Statistical Tables and Charts

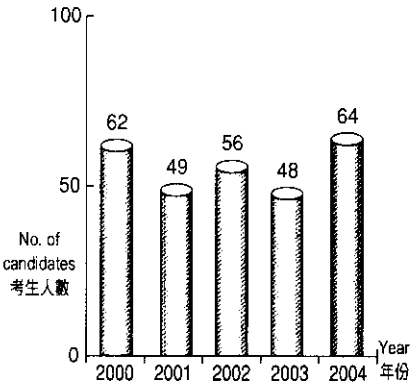
Year 年份	Pharmacy Legislation in Hong Kong 香港藥劑法例			Pharmacy Practice 藥劑執業			Pharmacology 藥理學		
	[illegible]	[illegible]	[illegible]	No. sat 參加人數	No. passed 合格人數	pass % 合格率	No. sat 參加人數	No. passed 合格人數	pass % 合格率
2000	75	33	44	77	39	50.6	62	45	72.6
2001	65	30	46.2	67	35	52.2	49	32	65.3
2002	63	33	52.4	70	33	47.1	56	33	58.9
2003	47	24	51.1	52	24	46.2	48	20	41.7
2004	70	39	55.7	66	42	63.6	64	44	68.8



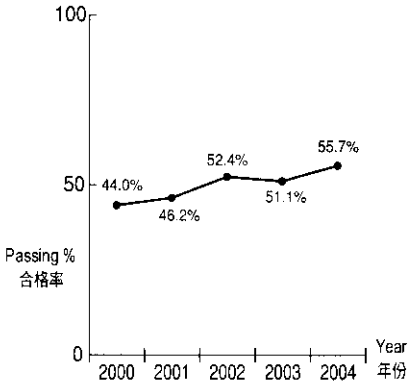
Pharmacy Legislation in Hong Kong
香港藥劑法例



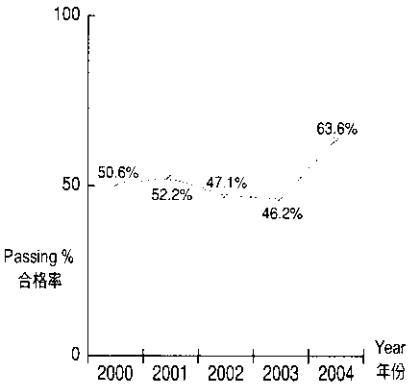
Pharmacy Practice
藥劑執業



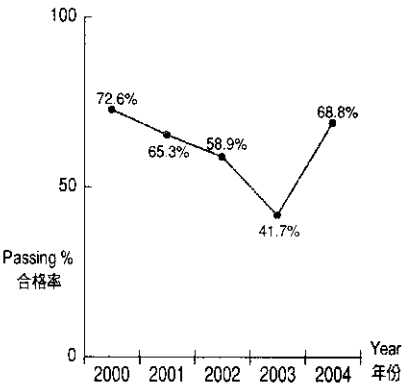
Pharmacology
藥理學



Pharmacy Legislation in Hong Kong
香港藥劑法例



Pharmacy Practice
藥劑執業



Pharmacology
藥理學

Table 表：2

No. of Registered Pharmacists in Hong Kong

No. of registered pharmacists as at end of year 截至年終的註冊藥劑師人數	1,315	1,362	1,414	1,457	1,517

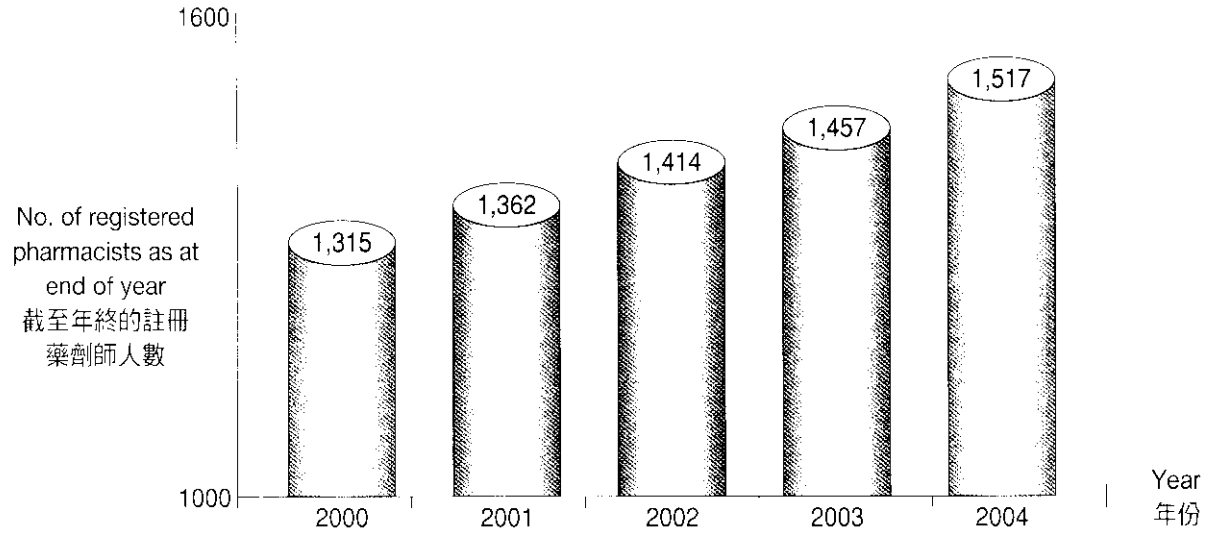


Table 表：3

Breakdown of Fresh Registration, Removal from and Restoration to the Register of Pharmacists
新註冊、刪除註冊及重新註冊的分項數字

Fresh registration (Overseas graduates) 新註冊〔海外畢業〕	24	43	25	21	34
Fresh registration (Local graduates) 新註冊〔本地畢業〕	29	24	32	27	28
Removal from the register* 刪除註冊*	17	24	10	10	8
Restoration to the register 重新註冊	6	4	5	5	6
Net increase 淨增長	42	47	52	43	60

* excluding orders by the Disciplinary Committee
* 不包括紀律委員會的指令

Table 表：4

Disciplinary Actions against Registered Pharmacists Taken by the Pharmacy and Poisons Board
藥劑業及毒藥管理局對註冊藥劑師採取的紀律行動

Disciplinary actions taken 採取的紀律行動	Number of cases 個案數目				
	2000	2001	2002	2003	2004
Formal disciplinary actions (i.e. Inquiry by Disciplinary Committee) 正式紀律行動 〔即由紀律委員會進行紀律研訊〕	1	0	4	1	2
Informal disciplinary actions (i.e. Verbal caution by representatives of the Board) 非正式紀律行動 〔即由管理局代表給予口頭警告〕	0	0	0	0	0
Total 總數	1	0	4	1	2

Table 表：5

Results of Disciplinary Inquiries into Registered Pharmacists
對註冊藥劑師進行紀律研訊的結果

Charge dismissed 指控不成立	1	0	0	0	0
Guilty of the charge 指控成立	0	0	4	1	2
Censure 譴責	0	0	3	1	1
Removed from the register for a period of time 由名冊除名一段時間	0	0	1	0	1

Statistical Tables and Charts

Table 表：6

Disciplinary Cases regarding Registered Pharmacists Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關註冊藥劑師的紀律個案

(1) Sale of Third Schedule poison without the authority of prescription 在沒有處方授權的情況下出售附表3毒藥	0	0	2	1	0
(2) Possession of Part I poison 管有第I部毒藥	0	0	0	0	1
(3) Possession of dangerous drug 管有危險藥物	0	0	0	0	1
(4) Misconduct in professional respect 專業上的失當行為	1	0	1	0	0
(5) Failing to store First Schedule poison in a receptacle locked with an adequate lock 沒有將附表1的毒藥存放在上鎖的盛器內	0	0	1	0	0
(6) Sale of Antibiotics without the authority of prescription 在沒有處方授權的情況下出售抗生素	0	0	0	0	1

Table 表：7

Number of Authorized Sellers of Poisons in Hong Kong
香港的獲授權毒藥銷售商數目

Year 年份	2000	2001	2002	2003	2004
No. of authorized sellers of poisons as at end of year 截至年終的獲授權毒藥銷售商數目	358	375	398	417	441

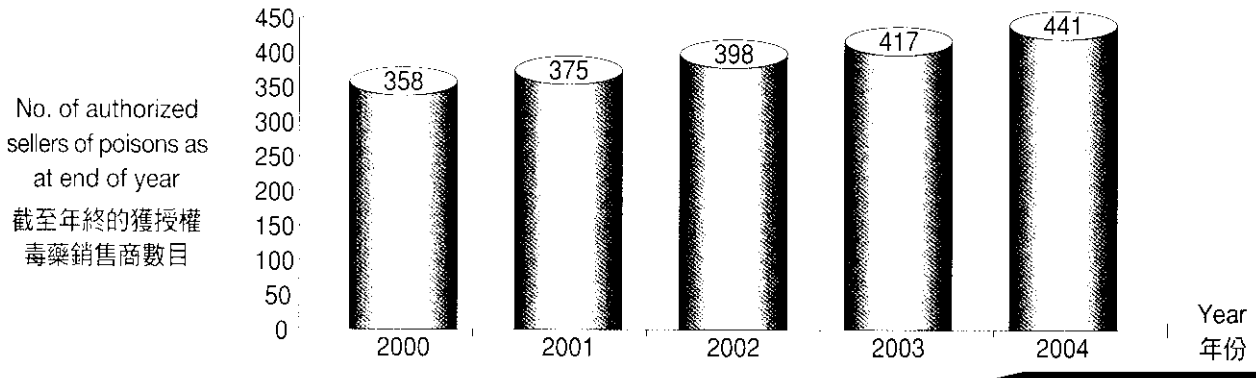


Table 表：8

Applications for Registration of Premises as Authorized Sellers of Poisons
獲授權毒藥銷售商的處所註冊申請

Year 年份	2000	2001	2002	2003	2004
No. of applications for registration of premises approved 接納處所註冊申請的數目	60	44	48	55	58
No. of applications for registration of premises rejected 拒絕處所註冊申請的數目	5	0	0	0	0
No. of applications for renewal of registration of premises rejected 拒絕處所註冊的續期申請數目	0	1	1	0	1

Table 表：9

Regulatory Control of Authorized Sellers of Poisons
獲授權毒藥銷售商的規管

Year 年份	2000	2001	2002	2003	2004
No. of inspections conducted 巡查數目	943	1205	1014	1020	1010
No. of test purchases conducted 試買數目	2916	3609	3212	2020	2368

Table 表：10

Disciplinary Actions against Authorized Sellers of Poisons Taken by the Pharmacy and Poisons Board
藥劑業及毒藥管理局就獲授權毒藥銷售商採取的紀律行動

Formal disciplinary actions (i.e. Inquiry by Disciplinary Committee) 正式紀律行動〔即由紀律委員會進行紀律研訊〕	7	7	18	4	12
Informal disciplinary actions (i. e. Verbal caution by representatives of the Board) 非正式紀律行動〔即由管理局代表給予口頭警告〕	15	10	23	4	37
The authorized seller of poisons ceased operation before action taken 該銷售商在管理局採取紀律行動前已經結業	0	1	2	0	1

Table 表：11

Results of Disciplinary Inquiries into Authorized Sellers of Poisons
對獲授權毒藥銷售商進行紀律研訊的結果

Findings of the Disciplinary Committee 紀律委員會的裁決	Number of cases 個案數目				
	2000	2001	2002	2003	2004
Charge dismissed 指控不成立	1	1	4	0	0
Guilty of the charge 指控成立	6	6	14	4	12
Sentence of the Disciplinary Committee 紀律委員會的判罰					
Issue of written warning 發出書面警告	2	2	8	4	5
Disqualified from being an authorized seller of poisons for a period of time 取消銷售商資格一段時間	4	4	6	0	7

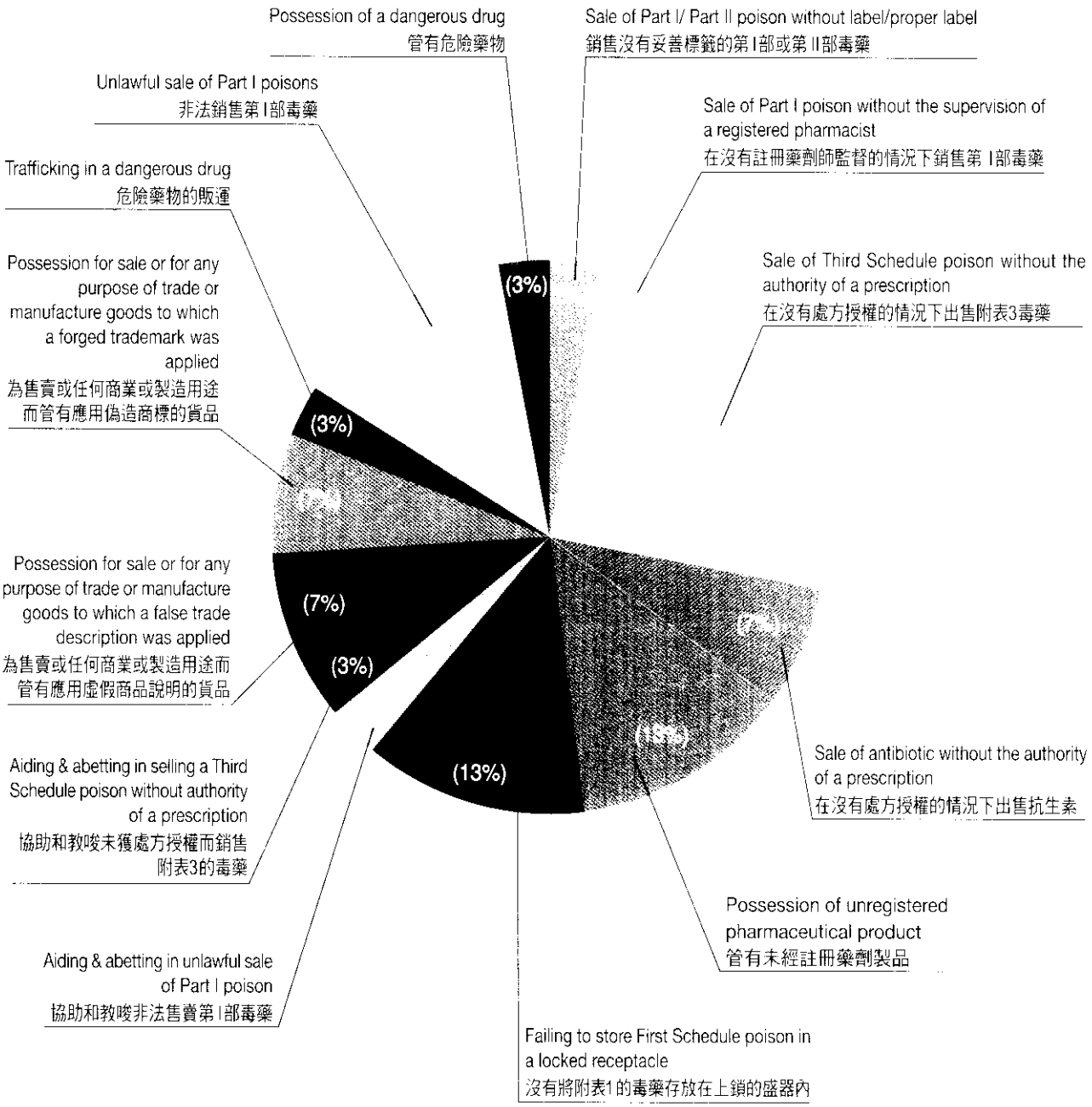
Table 表：12

Disciplinary Inquiries into Authorized Sellers of Poisons Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關獲授權毒藥銷售商的紀律研訊個案

Nature of offences 個案性質	Number of cases (percentage) 個案數目 (百份比)				
	2000	2001	2002	2003	2004
(1) Sale of Part I/Part II poison without label/proper label 銷售沒有妥善標籤的第I部或第II部毒藥	0 (0%)	0 (0%)	1 (2%)	0 (0%)	1 (3%)
(2) Sale of Part I poison without the supervision of a registered pharmacist 在沒有註冊藥劑師監督的情況下銷售第I部毒藥	7 (50%)	5 (41%)	20 (42%)	3 (30%)	2 (7%)
(3) Sale of Third Schedule poison without the authority of a prescription 在沒有處方授權的情況下出售附表3毒藥	5 (36%)	2 (17%)	11 (23%)	2 (20%)	5 (18%)
(4) Sale of antibiotic without the authority of a prescription 在沒有處方授權的情況下銷售抗生素	1 (7%)	2 (17%)	1 (2%)	0 (0%)	2 (7%)
(5) Sale of unregistered pharmaceutical product 銷售未經註冊藥劑製品	0 (0%)	0 (0%)	2 (4%)	0 (0%)	0 (0%)
(6) Possession of Part I poison 管有第I部毒藥	0 (0%)	0 (0%)	1 (2%)	1 (10%)	0 (0%)
(7) Possession of antibiotic 管有抗生素	0 (0%)	0 (0%)	1 (2%)	0 (0%)	0 (0%)
(8) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	0 (0%)	2 (17%)	6 (13%)	1 (10%)	4 (13%)
(9) Failing to keep proper record in the Poisons Book 沒有將交易記錄妥善備存在毒藥簿冊內	0 (0%)	0 (0%)	2 (4%)	1 (10%)	0 (0%)
(10) Failing to store First Schedule poison in a locked receptacle 沒有將附表1的毒藥存放在上鎖的盛器內	1 (7%)	1 (8%)	3 (6%)	2 (20%)	4 (13%)

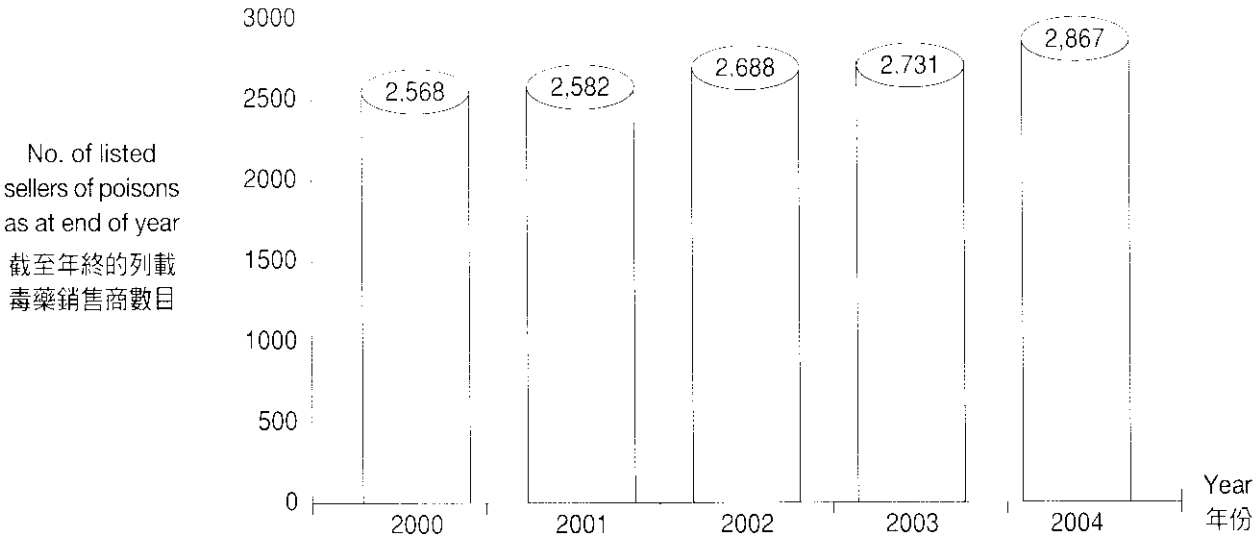
統計圖表

Nature of offences 罪行性質	Number of cases (percentage) 個案數目 (百分比)				
	2000	2001	2002	2003	2004
(11) Aiding & abetting in unlawful sale of Part I Poison 協助和教唆非法售賣第I部毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
(12) Aiding & abetting in selling a Third Schedule poison without authority of a prescription 協助和教唆未獲處方授權而銷售附表3的毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
(13) Possession for sale or for any purpose of trade or manufacture goods to which a false trade description was applied 為售賣或任何商業或製造用途而管有應用虛假商品說明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (7%)
(14) Possession for sale or for any purpose of trade or manufacture goods to which a forged trademark was applied 為售賣或任何商業或製造用途而管有應用偽造商標的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (7%)
(15) Trafficking in a dangerous drug 危險藥物的販運	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
(16) Unlawful sale of Part I poisons 非法銷售第I部毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (13%)
(17) Possession of a dangerous drug 管有危險藥物	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)


Possession of a dangerous drug
管有危險藥物
Sale of Part I/ Part II poison without label/proper label
銷售沒有妥善標籤的第I部或第II部毒藥
Unlawful sale of Part I poisons
非法銷售第I部毒藥
Sale of Part I poison without the supervision of a registered pharmacist
在沒有註冊藥劑師監督的情況下銷售第 I部毒藥
Trafficking in a dangerous drug
危險藥物的販運
Possession for sale or for any purpose of trade or manufacture goods to which a forged trademark was applied
為售賣或任何商業或製造用途而管有應用偽造商標的貨品
Sale of Third Schedule poison without the authority of a prescription
在沒有處方授權的情況下出售附表3毒藥
(3%)
(3%)
(7%)
(3%)
(13%)
Possession for sale or for any purpose of trade or manufacture goods to which a false trade description was applied
為售賣或任何商業或製造用途而管有應用虛假商品說明的貨品
Aiding & abetting in selling a Third Schedule poison without authority of a prescription
協助和教唆未獲處方授權而銷售附表3的毒藥
Sale of antibiotic without the authority of a prescription
在沒有處方授權的情況下出售抗生素
Possession of unregistered pharmaceutical product
管有未經註冊藥劑製品
Aiding & abetting in unlawful sale of Part I poison
協助和教唆非法售賣第I部毒藥
Failing to store First Schedule poison in a locked receptacle
沒有將附表1的毒藥存放在上鎖的盛器內

統計圖表

No. of listed sellers of poisons as at end of year 截至年終的列載毒藥銷售商數目	2,568	2,582	2,688	2,731	2,867



No. of applications approved 接納列載毒藥銷售商的牌照申請數目	321	339	357	282	409
No. of applications rejected 拒絕列載毒藥銷售商的牌照申請數目	5	1	1	0	1
No. of renewal application rejected 拒絕列載毒藥銷售商的續牌申請數目	0	0	0	0	0

Statistical Tables and Charts

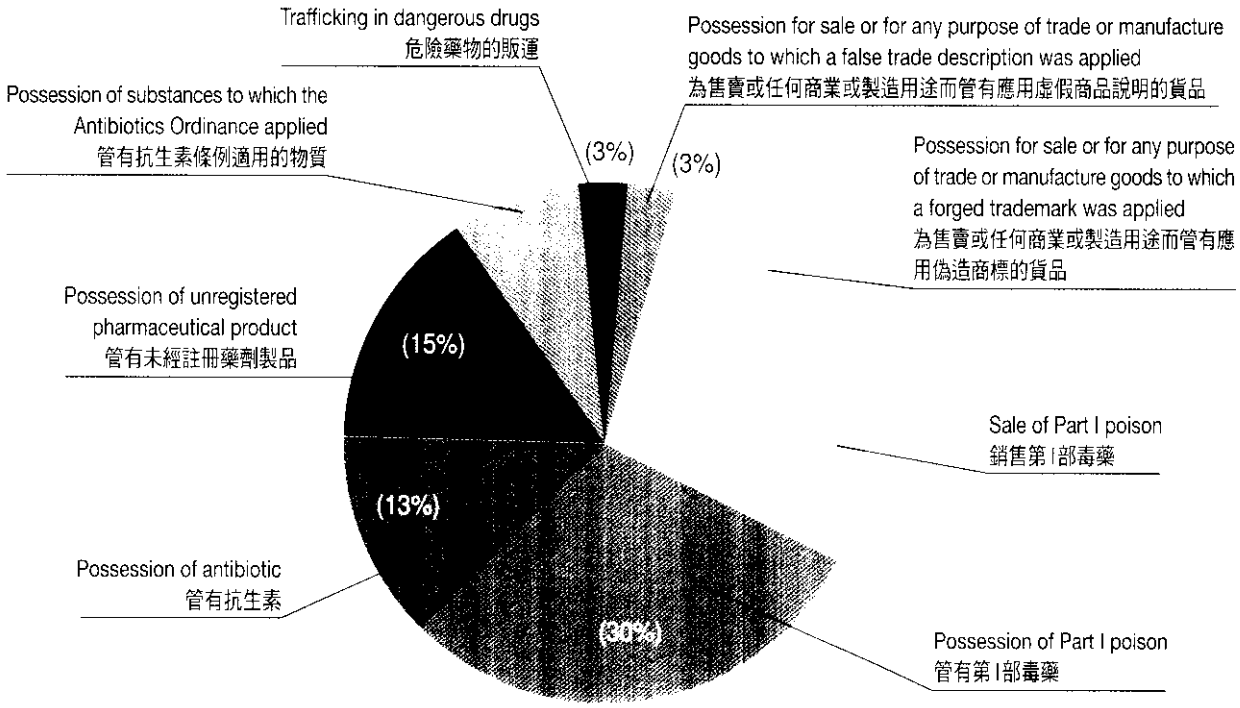
No. of inspections conducted 巡查數目	5,587	5,431	5,466	5,465	5,443
No. of test purchases conducted 試買數目	7,125	6,178	6,140	1,260	1,459

[illegible]	[illegible]				
	2010	2011	2012	2013	2014
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名冊除名	5	2	7	6	11
Issue of written warning 發出書面警告	7	8	4	5	5
The listed seller of poisons ceased operation before action taken 該銷售商在管理局採取紀律行動前已經結業	0	0	2	3	0
[illegible]	12	10	13	14	16

統計圖表

(1)	Sale of Part I poison 銷售第I部毒藥	2 (6%)	9 (28%)	4 (12%)	6 (19%)	7 (18%)
(2)	Sale of Third Schedule poison 銷售附表3毒藥	0 (0%)	1 (3%)	0 (0%)	2 (6%)	0 (0%)
(3)	Sale of antibiotic 銷售抗生素	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)
(4)	Sale of unregistered pharmaceutical product 銷售未經註冊藥劑製品	0 (0%)	1 (3%)	2 (6%)	0 (0%)	0 (0%)
(5)	Possession of Part I poison 管有第I部毒藥	14 (45%)	11 (35%)	13 (40%)	10 (31%)	12 (30%)
(6)	Possession of antibiotic 管有抗生素	11 (36%)	7 (22%)	6 (18%)	9 (28%)	5 (13%)
(7)	Possession of dangerous drug 管有危險藥物	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)
(8)	Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	4 (13%)	3 (9%)	5 (15%)	4 (13%)	6 (15%)
(9)	Aiding and abetting a person in selling substance to which the Antibiotics Ordinance applies 協助和教唆他人銷售《抗生素條例》適用的物質	0 (0%)	0 (0%)	1 (3%)	0 (0%)	0 (0%)
(10)	Practising Chinese medicine without registration 未經註冊作中醫執業	0 (0%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
(11)	Possession of substances to which the Antibiotics Ordinance applied 管有抗生素條例適用的物質	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (8%)

Nature of offences 個案性質	Number of cases (percentage) 個案數目 (百份比)				
	2000	2001	2002	2003	2004
(12) Trafficking in dangerous drugs 危險藥物的販運	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
(13) Possession for sale or for any purpose of trade or manufacture goods to which a false trade description was applied 為售賣或任何商業或製造用途而管有應用虛假商品說明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)
(14) Possession for sale or for any purpose of trade or manufacture goods to which a forged trademark was applied 為售賣或任何商業或製造用途而管有應用偽造商標的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	4 (10%)



Statistical Tables and Charts

Table 表：18

Issue of Wholesale Poisons Licences
毒藥批發牌照的簽發

No. of holders of wholesale poisons licences as at end of year 截至年終的毒藥批發牌照持有人的數目	897	866	862	848	832
No. of wholesale poisons licences revoked/ suspended 撤銷或吊銷毒藥批發牌照的數目	1	0	0	0	0

Table 表：19

Issue of Manufacturer's Licences for Pharmaceutical Products
藥劑製品製造商牌照的簽發

	2000	2001	2002	2003	2004
No. of holders of manufacturer's licences as at end of year 截至年終的製造商牌照持有人的數目	45	43	42	39	41
No. of manufacturer's licences revoked/ suspended 撤銷或吊銷製造商牌照的數目	0	1	0	1	0

Table 表：20

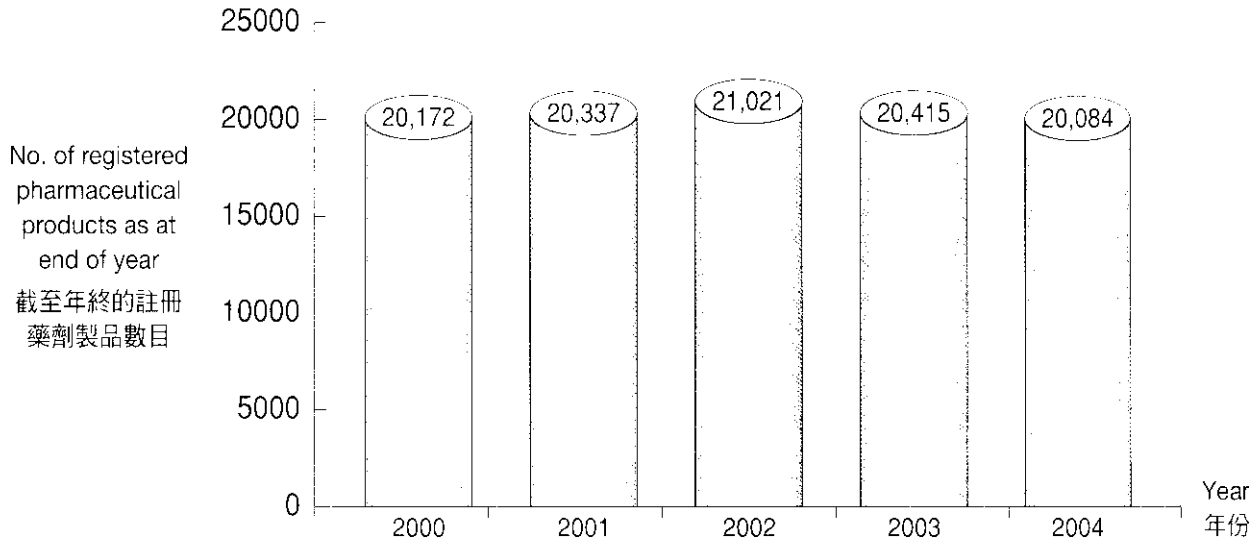
Registration of Importers & Exporters of Pharmaceutical Products
藥劑製品進出口商的註冊

No. of holders of registration certificates for importer and exporter of pharmaceutical products as at end of year 截至年終的進出口商證明書持有人的數目	332	302	262	256	257
No. of applications for registration certificates for importer and exporter of pharmaceutical products rejected 拒絕進出口商證明書申請的數目	0	0	0	0	0

Table

Registration of Pharmaceutical Products
藥劑製品的註冊

	2000	2001	2002	2003	2004
No. of registered pharmaceutical products as at end of year 截至年終的註冊藥劑製品數目	20,172	20,337	21,021	20,415	20,084



Table

New Substances Added to Part I of the Poisons List Regulations in 2004
二零零四年在毒藥表規例第1部加入的新物質

1. Teriparatide; its salts	特立帕肽；其鹽類
2. Aprepitant; its salts	阿瑞匹坦；其鹽類
3. Marbofloxacin; its salts	馬波沙星；其鹽類
4. Articaine; its salts	阿替卡因；其鹽類
5. Atazanavir; its salts	阿扎那韋；其鹽類
6. Efalizumab	依法珠單抗
7. Pemirolast; its salts	吡嘧司特；其鹽類
8. Eplerenone	依普利酮
9. Olmesartan; its salts; its esters; their salts	奧美沙坦；其鹽類；其酯類；它們的鹽類
10. Pregabalin; its salts	普瑞巴林；其鹽類

Table 表：23

New Substances Added to First and Third Schedules to the Pharmacy and Poisons Regulations in 2004
二零零四年在藥劑業及毒藥規例附表1和3加入的新物質

1. Teriparatide; its salts	特立帕肽；其鹽類
2. Aprepitant; its salts	阿瑞匹坦；其鹽類
3. Marbofloxacin; its salts	馬波沙星；其鹽類
4. Articaine; its salts	阿替卡因；其鹽類
5. Atazanavir; its salts	阿扎那韋；其鹽類
6. Efalizumab	依法珠單抗
7. Pemirolast; its salts	吡嘧司特；其鹽類
8. Eplerenone	依普利酮
9. Olmesartan; its salts; its esters; their salts	奧美沙坦；其鹽類；其酯類；它們的鹽類
10. Pregabalin; its salts	普瑞巴林；其鹽類

Table 表：24

Results of Appeals to the Court of First Instance
向原訟法庭上訴的結果

Dismissed 駁回	0	0	0	0	0
Allowed 得直	0	0	0	0	0
Appeal withdrawn by the appellant 上訴人撤回上訴	0	0	0	0	0

Table 表：25

Appeal Cases Handled by the Pharmacy and Poisons Appeal Tribunal
藥劑業及毒藥上訴審裁處處理的上訴個案

Nature of appeals 上訴性質	Number of cases 個案數目				
	2000	2001	2002	2003	2004
Application for renewal of registration of premises of an authorized seller of poisons 申請續期為獲授權毒藥銷售商	2	0	0	0	0
Removal of name from the list of listed sellers of poisons 從列載毒藥銷售商名冊除名	3	1	0	1	0
Application for a listed seller of poisons licence 申請列載毒藥銷售商牌照	0	0	1	0	0
Revocation of wholesale poisons licence 撤銷毒藥批發商牌照	1	0	0	0	0
Suspension of manufacturer's licence for a specified period of time 在指定期間內吊銷製造商牌照	0	1	0	0	0
Application for registration of a pharmaceutical product 申請將藥劑製品註冊	0	0	1	0	0
De-registration of a pharmaceutical product 撤銷藥劑製品的註冊	0	0	1	0	0
Application for a manufacturer's licence for pharmaceutical products 申請藥劑製品製造商牌照	0	0	1	0	0
Total 總數	6	2	4	1	0

統計圖表

Dismissed 駁回	5	1	2	0	0
Partly allowed 部份得直	0	0	1	0	0
Allowed 得直	0	0	1	1	0
Appeal withdrawn by the appellant 上訴人撤回上訴	1	1	0	0	0

政府物流服務署印
(採用環保油墨及取材自可再生林木的紙張印製)

2322164　10/2005