Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

Annual Report 2003

二零零三年年報

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Message from the Chairman

主席獻辭

Thanks for the invaluable contributions and unfailing support of Members, the Pharmacy and Poisons Board performed its statutory functions smoothly in year 2003.

With an aim to maintaining the professional standard of the registered pharmacists to meet the aspirations of the public, the Board has embarked on a review regarding the internship training arrangements and registration examination policies leading to registration of pharmacists in Hong Kong. The review is now in full swing. The results, once available, will be carefully considered by the Board, and relevant parties will be consulted.

Year 2003 was a most challenging year for the people of Hong Kong, in particular for the healthcare professions. With the concerted efforts of all sectors of the community, we have overcome the attack of Severe Acute Respiratory Syndrome. The Board and its committees will continue to work together with all interested parties and healthcare professions to meet the challenge ahead and the ever-increasing demand of the public for quality health care.

Dr P.Y. LAM
Chairman
Pharmacy and Poisons Board
May 2004

藥劑業及毒藥管理局在二零零三年順利履行其法定職能，這個成果端賴各位委員努力耕耘，不斷支持，本人謹致衷心謝意。

為了維持註冊藥劑師的專業水準以切合市民的期望，本局已就藥劑師在香港註冊前的實習安排和考試政策展開檢討，現正全力進行有關工作。一有結果，本局便會詳加考慮，並會徵詢相關各方的意見。

在二零零三年，香港市民經歷了前所未有的挑戰，醫護專業人士更是首當其衝。然而，憑着社會各界齊心協力，我們終於克服重重困難，度過嚴重急性呼吸系統綜合症的疫潮。本局及全體委員將繼續與相關團體和醫護專業界別攜手合作，迎接未來的挑戰，以滿足市民對優質醫護服務與日俱增的殷切需求。

藥劑業及毒藥管理局主席
林秉恩醫生
二零零四年五月

Introduction

引　言

This annual report covers the calendar year 2003. 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)在二零零三年的工作。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
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林秉恩醫生（主席）


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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


Dr LAU Sze-ngar, Grace
劉思雅博士


Mr CHUA Sek-chon, Peter, JP
蔡錫聰先生


Mr LEUNG Kai-lok, Peter
梁佳樂先生


Dr CHOI Kin
蔡堅醫生

Membership and Functions of the Board

管理局的成員及職能

1 Membership

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 2003 was as follows: -

(a) Dr P.Y. LAM, JP (Chairman)
(b) Dr D.G. CLARKE, 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) Dr LAU Sze-ngar, Grace
Mr CHUA Sek-chon, Peter, JP
Mr LEUNG Kai-lok, Peter
(i) Dr CHOI Kin

Secretary

Mr CHIU Hon-kwan, Raymond

1 成員

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）。

在二零零三年十二月三十一日，管理局的成員計有：

(a) 林秉恩醫生（主席）
(b) 郭大偉博士
(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) 劉思雅博士
蔡錫聰先生
梁佳樂先生
(i) 蔡堅醫生

秘書

招漢鈞先生

2 Functions

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.

2 職能

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

管理局執行委員會的成員及職能

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

1 Examination Committee

(i) Membership as at 31 December 2003

Professor CHAN Yan-keung (Chairman)

Dr D.G. CLARKE, 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)

(ii) Functions

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.

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：

1 考試委員會

(i) 截至二零零三年十二月三十一日的成員名單

陳恩強教授 (主席)

郭大偉博士

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)

(ii) 職能

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。

Membership and Functions of the Executive Committees

管理局執行委員會的成員及職能

2 Pharmacy and Poisons (Listed Sellers of Poisons) Committee

(i) Membership as at 31 December 2003

Mr CHAN Wing-kin, Anthony (Chairman)

Mr CHAU Wing-kit, Luke

Mr SIT Ka-keung, Perry

Ms Linda WOO (Secretary)

(ii) Functions

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.

3 Pharmacy and Poisons (Wholesale Licences and Registration of Importers & Exporters) Committee

(i) Membership as at 31 December 2003

Mr CHAN Wing-kin, Anthony (Chairman)

Mr CHAU Wing-kit, Luke

Mr SIT Ka-keung, Perry

Ms Linda WOO (Secretary)

(ii) Functions

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.

2 藥劑業及毒藥（列載毒藥銷售商）委員會

(i) 截至二零零三年十二月三十一日的成員名單

陳永健先生（主席）

周永傑先生

薛家強先生

吳婉宜女士（秘書）

(ii) 職能

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。

3 藥劑業及毒藥 （批發牌照及進出口商註冊）委員會

(i) 截至二零零三年十二月三十一日的成員名單

陳永健先生（主席）

周永傑先生

薛家強先生

吳婉宜女士（秘書）

(ii) 職能

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

管理局執行委員會的成員及職能

4 Pharmacy and Poisons (Manufacturers Licensing) Committee

(i) Membership as at 31 December 2003

Mr CHAN Wing-kin, Anthony (Chairman)

Mr CHAU Wing-kit, Luke

Mr SIT Ka-keung, Perry

Ms Linda WOO (Secretary)

(ii) Functions

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.

5 Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee

(i) Membership as at 31 December 2003

Mr CHAN Wing-kin, Anthony (Chairman)

Dr D.G. CLARKE, JP

Dr KO Tak-him

Professor C.R. KUMANA

Mr LING Ho-ming, Michael

Dr Lloyd KENDA

Mr MAK Yuk-lun (Secretary)

(ii) Functions

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: -

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

4 藥劑業及毒藥(製造商牌照)委員會

(i) 截至二零零三年十二月三十一日的成員名單

陳永健先生（主席）

周永傑先生

薛家強先生

吳婉宜女士（秘書）

(ii) 職能

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。

5 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

(i) 截至二零零三年十二月三十一日的成員名單

陳永健先生(主席)

郭大偉博士

高德謙醫生

顧崇仁教授

凌浩明先生

Dr Lloyd KENDA

麥煜綸先生(秘書)

(ii) 職能

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：

(a) 簽發藥劑製品或物質註冊證明書；

(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.

6 Poisons Committee

(i) Membership as at 31 December 2003

Professor CHO Chi-hin (Chairman)

Dr CHOI Kin

Mr CHAN Wing-kin, Anthony

Dr D.G. CLARKE, JP

Dr LAU Sze-ngar, Grace

Mr CHUA Sek-chon, Peter, JP

Mr CHENG Chung-kwong (Secretary)

(ii) Functions

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.

(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。

6 毒藥委員會

(i) 截至二零零三年十二月三十一日的成員名單

曹之憲教授（主席）

蔡堅醫生

陳永健先生

郭大偉博士

劉思雅博士

蔡錫聰先生

鄭中光先生（秘書）

(ii) 職能

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

管理局及其執行委員會的工作

1 Registration of Pharmacists

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.

(i) Qualification

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) must be registered or professionally qualified to be registered as a pharmacist, normally in the country in which he/she has completed his/her studies in pharmacy.

(ii) Examination

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 2003. A total of 24 applicants cumulatively passed all the three subjects in the year 2003.

The results of these two registration examinations are shown in Table 1. Figures for the years 1999 to 2002 are also included for comparison purpose.

(iii) Training

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.

1 藥劑師的註冊

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。

(i) 資格

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) 本身經已在外地註冊為藥劑師；或於完成藥劑學課程後取得可在外地〈通常為當地〉註冊為藥劑師的專業資格。

(ii) 考試

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。

考試委員會在二零零三年分別在六月及十二月舉辦了兩次註冊考試。同年共有 24 人累積取得全部三科合格的成績。

表 1 列出該兩次註冊考試的成績，以及一九九九年至二零零二年的有關數字，以供比較。

(iii) 實習

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。

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.

(iv) Registration

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.

(v) Practising Certificates

All practising pharmacists must obtain a practising certificate annually in accordance with section 10A of the Pharmacy and Poisons Ordinance. A total of 1,457 registered pharmacists were issued with practising certificates in the year 2003. Statistical data regarding registration of pharmacists and breakdown of fresh registration, removal from and restoration to the register of pharmacists for the years 1999 to 2003 are shown in Tables 2 and 3.

(vi) Discipline of Pharmacists

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 23 to 24 of this report.

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。

(iv) 註冊

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。

(v) 執業證明書

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。在二零零三年，共有1,457位註冊藥劑師獲發執業證明書。表2及3列出一九九九年至二零零三年有關藥劑師註冊，以及新註冊、刪除註冊及重新註冊的分項數字的統計資料。

(vi) 藥劑師的紀律事宜

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23至24頁。

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in the years 1999 to 2003 are shown in Tables 4, 5 and 6.

2 Licensing and Regulatory Control of Retail Traders (Including Authorized Sellers of Poisons and Listed Sellers of Poisons)

(i) Authorized Sellers of Poisons: Licensing

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.

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 417 ASPs registered in Hong Kong as at end of year 2003. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of an ASP in the years 1999 to 2003 are shown in Tables 7 and 8.

表4、5及6詳列管理局在一九九九年至二零零三年對註冊藥劑師採取紀律行動的統計數字。

2 零售商（包括獲授權毒藥銷售商及列載毒藥銷售商）的發牌及規管工作

(i) 獲授權毒藥銷售商：發牌工作

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。

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。

截至二零零三年年終，香港共有417名獲授權毒藥銷售商。表7及8詳列一九九九年至二零零三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。

(ii) Authorized Sellers of Poisons: Discipline

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.

Four inquiries were held and four ASPs were found guilty of misconduct in the year 2003. All of them were issued with written warnings.

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 four such interviews were held in the year 2003.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in the years 1999 to 2003 is shown in Table 9.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in the years 1999 to 2003 are given in Tables 10, 11, 12 and 12A.

(iii) Listed Sellers of Poisons: Licensing

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.

(ii) 獲授權毒藥銷售商：紀律事宜

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。

管理局在二零零三年舉行了四次紀律研訊，共有四名獲授權毒藥銷售商被裁定犯有不當行為。紀律委員會決定向這四名獲授權毒藥銷售商發出書面警告。

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。管理局在二零零三年舉行了四次該類會面。

表9列出一九九九年至二零零三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。

表10、11、12及12A詳列一九九九年至二零零三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。

(iii) 列載毒藥銷售商：發牌工作

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。

There were 2,731 LSPs as at end of year 2003. The number of licensed LSPs in the years 1999 to 2003 is shown in Table 13. Statistical data regarding applications for LSP licences and renewal of such licences in these five years are shown in Table 14.

(iv) Listed Sellers of Poisons: Discipline

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 1999 to 2003 is shown in Table 15. Statistical data regarding disciplinary cases handled by the Board in respect of LSPs in these five years are given in Tables 16, 17 and 17A.

截至二零零三年年終，香港共有2,731名列載毒藥銷售商。表 13 列出一九九九年至二零零三年列載毒藥銷售商的總數。表 14 列出在上述五年申請發牌以及申請續牌的統計數字。

(iv) 列載毒藥銷售商：紀律事宜

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。

表 15 列出一九九九年至二零零三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。表 16、17 及 17A 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。

3 Licensing and Regulatory Control of Wholesale Dealers, Manufacturers, Importers and Exporters of Pharmaceutical Products

(i) Wholesale Dealers of Pharmaceutical Products

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.

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 848 holders of a wholesale poisons licence as at end of year 2003. Statistical data for the years 1999 to 2003 are shown in Table 18.

(ii) Manufacturers of Pharmaceutical Products

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.

3 藥劑製品批發商、製造商、進出口商的發牌及規管工作

(i) 藥劑製品批發商

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。

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。

截至二零零三年年終，香港共有848名毒藥批發牌照持有人。表18列出一九九九年至二零零三年的統計數字。

(ii) 藥劑製品製造商

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。

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.

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 39 holders of a manufacturer's licence as at end of year 2003. Statistical data for the years 1999 to 2003 are given in Table 19.

(iii) Good Manufacturing Practices (GMP)

With a view to improving the standard of local pharmaceutical manufacturing in order to achieve the internationally accepted Good Manufacturing Practices (GMP) standard, the Board issued a "Hong Kong Good Manufacturing Practices Guidelines for Pharmaceutical Products" and an implementation programme for GMP compliance in 1995. These guidelines are used as a basis for the inspection and licensing of manufacturing facilities by the Board.

The completion of GMP for local manufacturers of pharmaceutical products is phased as follows: -

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。

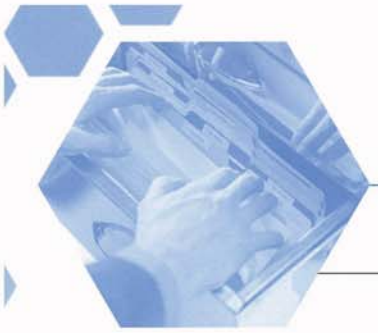
製造藥劑製品必須在註冊藥劑師或具備管理局認可資格的人士監督下進行。

截至二零零三年年終，香港共有39名製造商牌照持有人。表 19 列出一九九九年至二零零三年的統計數字。

(iii) 藥品生產質量管理規範

為使本地藥劑製品製造商的產品質量水平提升至國際認可的「藥品生產質量管理規範」水平，管理局於一九九五年制定了一份「香港藥劑製品生產質量管理規範指引」及有關的執行計劃。這些指引亦會是管理局用作巡查及發牌予製造商的準則。

針對本地藥劑製品製造商而進行的生產質量管理規範的計劃分下列各階段完成：



Phase	Details of the Programme
1	(a) A general appreciation of the principles of quality assurance of GMP and validation of all processes and procedures; (b) documentation of procedures for handling complaints and drug recalls; (c) implementation of arrangements relating to contract production and analysis; and (d) implementation of self-inspection and quality audits.
2	(a) Implementation of the principles and practices relating to quality control, and all documentation requirements; (b) implementation of requirements as to personnel and handling of materials; and (c) implementation of requirements as to the manufacture of active pharmaceutical ingredients.
3	(a) Compliance with the requirements as to design, construction, maintenance, sanitation, production, quality control and cleaning, etc.; (b) implementation of the principles and practices relating to production; and (c) implementation of the requirements as to the manufacture of sterile pharmaceutical products.

Taking into account the feedback from the local manufacturing industry after satisfactory completion of Phase 1 and part of Phase 2, the Board decided in February 1999 to revise the time table for the completion of the programme as follows: -

Phase	Details of the programme	Revised target completion date
2	Documentation requirements Handling of materials	31 December 1999
2	Execution and operation of quality control	31 December 2000
3	All items included under Phase 3	31 December 2002

階段	計劃詳情
1	(a) 就生產質量管理規範的品質保證原則作一概括的理解，並檢測確定所有過程及程序的準確性； (b) 擬備文件，訂明處理投訴及回收藥物的程序； (c) 實施有關外判生產及分析程序的安排；及 (d) 實施自我檢察及質素審計。
2	(a) 落實有關品質控制的原則及守則的要求，並實行所有擬備文件的規定； (b) 落實關於人事及物料處理的規定；及 (c) 落實關於製造藥劑原材料的規定。
3	(a) 實施關於設計、建造、維修、衞生、生產、品質控制及清潔等規定； (b) 實施有關生產的原則及守則的要求；及 (c) 實施有關製造無菌藥劑製品的規定。

第1和部份第2階段如期完成。管理局其後在考慮業內的意見後，在一九九九年二月決定把完成餘下計劃的時間表修訂如下：

階段	計劃詳情	修訂目標完成日期
2	擬備文件的規定 物料處理	一九九九年十二月三十一日
2	執行和實施品質控制	二零零零年十二月三十一日
3	第三階段的所有項目	二零零二年十二月三十一日

Phase 2 was completed on schedule. However, some manufacturers had written to the Board in November 2002 requesting for further extension of the Phase 3 implementation deadline by 12 months. On the other hand, some manufacturers had also written to express the view that the stipulated target completion date should be upheld. Having considered the views of different sectors of the industry and based on the interests of Hong Kong, the Board maintained that all manufacturers should adhere to the original deadline of 31 December 2002. All interested parties and manufacturers were apprised of the Board's decision accordingly. Phase 3 was subsequently completed on schedule.

(iv) Importers and Exporters of Pharmaceutical Products

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 256 holders of a registration certificate for importer and exporter of pharmaceutical products as at end of year 2003. Statistical figures for the years 1999 to 2003 are shown in Table 20.

第2階段依期完成。惟部份製造商在二零零二年十一月去信管理局，要求將推行第3階段的最後期限延遲十二個月。另一方面，另一部份的製造商則去信管理局表示原定的限期應維持不變。管理局經考慮業內不同的意見及香港的利益因素後，決定所有製造商必須遵守二零零二年十二月三十一日的最後限期。管理局已將該項決定通知所有有關團體及製造商。第3階段最後依期完成。

(iv) 藥劑製品進出口商

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。

截止二零零三年年終，香港共有256名藥劑製品進出口商證明書持有人。表20列出一九九九年至二零零三年的統計數字。

4 Registration and Classification of Pharmaceutical Products

(i) Registration of Pharmaceutical Products

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.

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 20,415 registered pharmaceutical products in Hong Kong as at end of year 2003. The number of registered pharmaceutical products as at end of years 1999 to 2003 is shown in Table 21.

(ii) Classification of Pharmaceutical Products

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: -

4 藥劑製品的註冊及分類

(i) 藥劑製品的註冊

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。

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。

截至二零零三年年終，香港共有20,415種已註冊的藥劑製品。表21列出截至一九九九年至二零零三年年終的註冊藥劑製品數字。

(ii) 藥劑製品的分類

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：

Classification	Restriction(s) on sale
(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 2003 included: -

(a) adding 26 new substances to Part I of the Poisons List Regulations and 25 to the First and Third Schedules to the Pharmacy and Poisons Regulations. Two lists of these substances are at Tables 22 and 23 respectively; and

分類	銷售的限制
(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。立法會在二零零三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) 在《毒藥表規例》第 I 部加入 26 種和在《藥劑業及毒藥規例》附表 1 及附表 3 加入 25 種新的物質。這些物質分別列載於表 22 和 23；及

(b) tightening the control of 39 pharmaceutical products by re-classifying them from non-poisons to Part I, First and Third Schedules poisons. List of these pharmaceutical products is at Table 24.

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

Schedule	Provisions
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.

(b) 加強對 39 種藥劑製品的管制，將其由非毒藥重新分類為《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。這些物質列載於表 24 。

《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：

附表	內容
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。

Membership and Functions of the Disciplinary Committee

紀律委員會的成員及職能

1 Membership

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 2003, 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 2003 included: -

Ms KWOK Hing-fun

Mr LAU Ho-kuen, Kenneth

Mr SIT Ka-keung, Perry

Mr TANG Wing-ming

Mr WONG Kwong-cheung, Aaron

Mr YAU Fuk-loi, Rico

2 Functions

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 poison (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.

1 成員

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二零零三年十二月三十一日的主席。曾在二零零三年出任成員的註冊藥劑師包括：

郭興芬女士

劉浩權先生

薛家強先生

鄧永明先生

黃廣長先生

邱福來先生

2 職能

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。

Membership and Functions of the Disciplinary Committee

紀律委員會的成員及職能

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.

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 Tables 5 and 11 respectively. No appeal was made in 2003. Figures for the years 1999 to 2002 are shown in Table 25 for comparison purpose.

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。

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。

表 5 及 11 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。二零零三年並無接獲任何上訴。表 25 詳列一九九九年至二零零二年的統計數字以供比較。

Membership and Functions of the Pharmacy and Poisons Appeal Tribunal

藥劑業及毒藥上訴審裁處的成員及職能

1 Membership

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 2003 was as follows: -

Name	Membership
Mr CHAN King-sang, Edward, SC	Chairman
Dr YAM Yin-chun, Loretta	Member
Ms PONG Oi-lan, Scarlett	Member
Dr CHEUNG Man-yung, Bernard	Member
Ms YAP Woan-tyng	Panel Member
Mr TANG Wing-ming	Panel Member
Ms CHAN Siu-yee, Sylvia	Panel Member
Mr CHONG Wing-kit, Donald	Panel Member
Ms MA Yat-man, Vivian	Panel Member
Mr AW Yu-chun	Panel Member
Dr CHAN Sung-kwong, Anthony	Panel Member
Mr LEUNG Kwok-keung, Stephen	Panel Member
Mrs CHIN Hang-yin, Alice	Panel Member
Miss KAN Yu-yuk, Linda	Panel Member
Dr CHENG Heung-kwan	Panel Member
Ms MO Sau-ping	Panel Member
Mr LAU Wing-keung	Panel Member
Mr NG Wing-yan	Panel Member
Mr LAU Oi-kwok	Panel Member

1 成員

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。

在二零零三年十二月三十一日，審裁處的成員如下：

姓名	成員
陳景生先生	主席
任燕珍醫生	委員
龐愛蘭女士	委員
張文勇醫生	委員
葉婉婷女士	小組委員
鄧永明先生	小組委員
陳筱怡女士	小組委員
莊永傑先生	小組委員
馬逸敏女士	小組委員
柯宇春先生	小組委員
陳崇光牙醫	小組委員
梁國強先生	小組委員
陳阮幸賢女士	小組委員
簡如玉女士	小組委員
鄭香郡博士	小組委員
巫秀萍女士	小組委員
劉永強先生	小組委員
吳榮恩先生	小組委員
劉愛國先生	小組委員

Membership and Functions of the Pharmacy and Poisons Appeal Tribunal

藥劑業及毒藥上訴審裁處的成員及職能

2 Functions

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.

One appeal was heard in 2003. Breakdowns of the cases by nature and by result from 1999 to 2003 are shown in Tables 26 and 27 respectively.

2 職能

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。

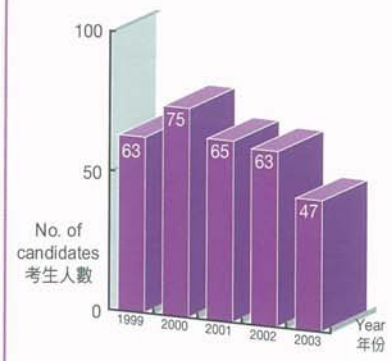
二零零三年有一宗個案。表26和27分別列出在一九九九年至二零零三年有關個案的性質和結果的分項數字。

Table 表：1

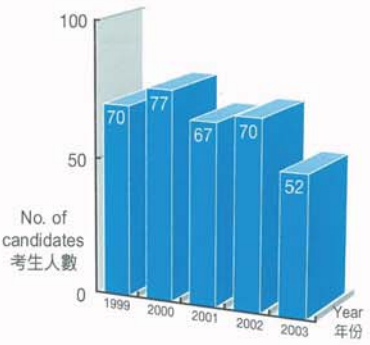
Results of the Registration Examinations 註冊考試成績

Year 年份	Pharmacy Legislation in Hong Kong 香港藥劑法例			Pharmacy Practice 藥劑執業			Pharmacology 藥理學		
	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	No. sat 參加人數	No. passed 合格人數	pass % 合格率
1999	63	33	52.4	70	26	37.1	65	45	69.2
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

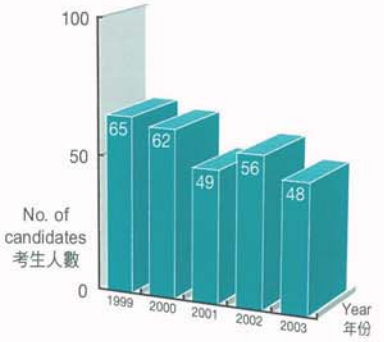
Number of Candidates Sitting Each Examination Subject 每科考試的考生人數



Pharmacy Legislation in Hong Kong
香港藥劑法例

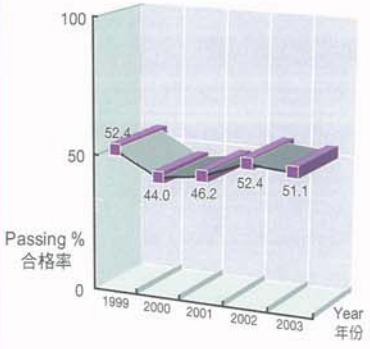


Pharmacy Practice
藥劑執業

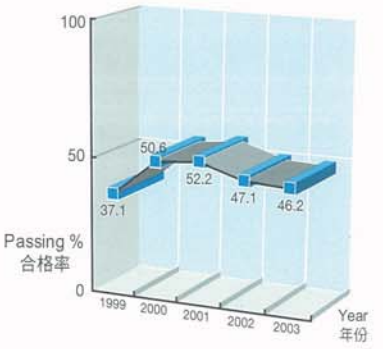


Pharmacology
藥理學

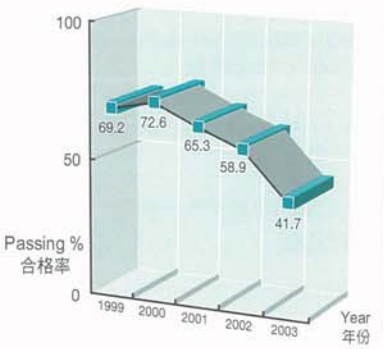
Passing Percentage in Each Examination Subject 每科考試的合格率



Pharmacy Legislation in Hong Kong
香港藥劑法例



Pharmacy Practice
藥劑執業



Pharmacology
藥理學

Table 表：2

Number of Registered Pharmacists in Hong Kong 香港註冊藥劑師人數					
Year 年份	1999	2000	2001	2002	2003
No. of registered pharmacists as at end of year 截至年終的註冊藥劑師人數	1,273	1,315	1,362	1,414	1,457

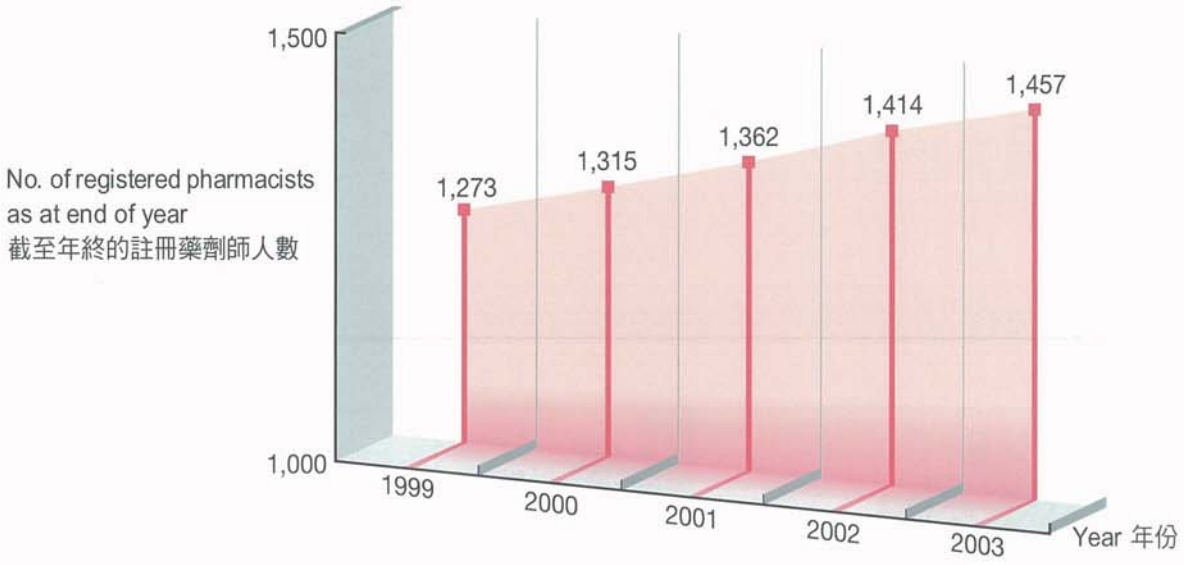


Table 表：3

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					
Year 年份	1999	2000	2001	2002	2003
Fresh registration (Overseas graduates) 新註冊〔海外畢業〕	46	24	43	25	27
Fresh registration (Local graduates) 新註冊〔本地畢業〕	30	29	24	32	21
Removal from the register* 刪除註冊*	17	17	24	10	10
Restoration to the register 重新註冊	2	6	4	5	5
Net increase 淨增長	61	42	47	52	43

*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				
	1999	2000	2001	2002	2003
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〕	4	1	0	4	1
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	4	1	0	4	1

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

Findings of the Disciplinary Committee 紀律委員會的裁決	Number of cases 個案數目				
	1999	2000	2001	2002	2003
Charge dismissed 指控不成立	0	1	0	0	0
Guilty of the charge 指控成立	4	0	0	4	1
Sentence of the Disciplinary Committee 紀律委員會的判決					
Censure 譴責	2	0	0	3	1
Removed from the register for a period of time 由名冊除名一段時間	2	0	0	1	0

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

Nature of offences 個案性質	Number of cases 個案數字				
	1999	2000	2001	2002	2003
(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	3	0	0	2	1
(2) Possession of Part I poison 管有第I部毒藥	1	0	0	0	0
(3) Possession of dangerous drug 管有危險藥物	1	0	0	0	0
(4) Misconduct in professional respect 專業上的失當行為	0	1	0	1	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	0	1	0

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	1999	2000	2001	2002	2003
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	328	358	375	398	417

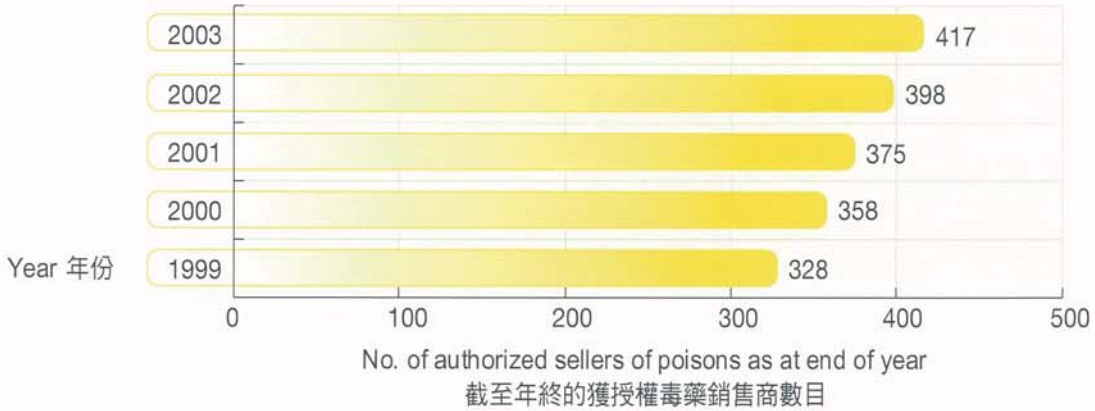


Table 表：8

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

Year 年份	1999	2000	2001	2002	2003
No. of applications for registration of premises approved 接納處所註冊申請的數目	50	60	44	48	55
No. of applications for registration of premises rejected 拒絕處所註冊申請的數目	0	5	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	0	1	1	0

Table 表：9

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

Year 年份	1999	2000	2001	2002	2003
No. of inspections conducted 巡查數目	1,024	943	1,205	1,014	1,020
No. of test purchases conducted 試買數目	3,065	2,916	3,609	3,212	2,020

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對獲授權毒藥銷售商採取的紀律行動

Disciplinary actions taken 紀律行動	Number of cases 個案數字				
	1999	2000	2001	2002	2003
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〕	17	7	7	18	4
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〕	12	15	10	23	4
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	0	1	2	0
Total 總數	29	22	18	43	8

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				
	1999	2000	2001	2002	2003
Charge dismissed 指控不成立	3	1	1	4	0
Guilty of the charge 指控成立	14	6	6	14	4
Sentence of the Disciplinary Committee 紀律委員會的判罰					
Issue of written warning 發出書面警告	5	2	2	8	4
Disqualified from being an authorized seller of poisons for a period of time 取消銷售商資格一段時間	9	4	4	6	0

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)				
	1999	2000	2001	2002	2003
(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%)	0 (0%)	1 (2%)	0 (0%)
(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	10 (32%)	7 (50%)	5 (41%)	20 (42%)	3 (30%)
(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	6 (20%)	5 (36%)	2 (17%)	11 (23%)	2 (20%)
(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 (3%)	1 (7%)	2 (17%)	1 (2%)	0 (0%)
(5) Sale of unregistered pharmaceutical product 銷售未經註冊藥劑製品	1 (3%)	0 (0%)	0 (0%)	2 (4%)	0 (0%)
(6) Possession of Part I poison 管有第I部毒藥	1 (3%)	0 (0%)	0 (0%)	1 (2%)	1 (10%)
(7) Possession of antibiotic 管有抗生素	0 (0%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)
(8) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	2 (7%)	0 (0%)	2 (17%)	6 (13%)	1 (10%)
(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%)	0 (0%)	2 (4%)	1 (10%)
(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	9 (29%)	1 (7%)	1 (8%)	3 (6%)	2 (20%)
(11) Failing to keep a proper record of dangerous drug 沒有妥善備存危險藥物記錄	1 (3%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 表：12A

Disciplinary Inquiries into Authorized Sellers of Poisons in 2003
2003年有關獲授權毒藥銷售商的紀律研訊個案

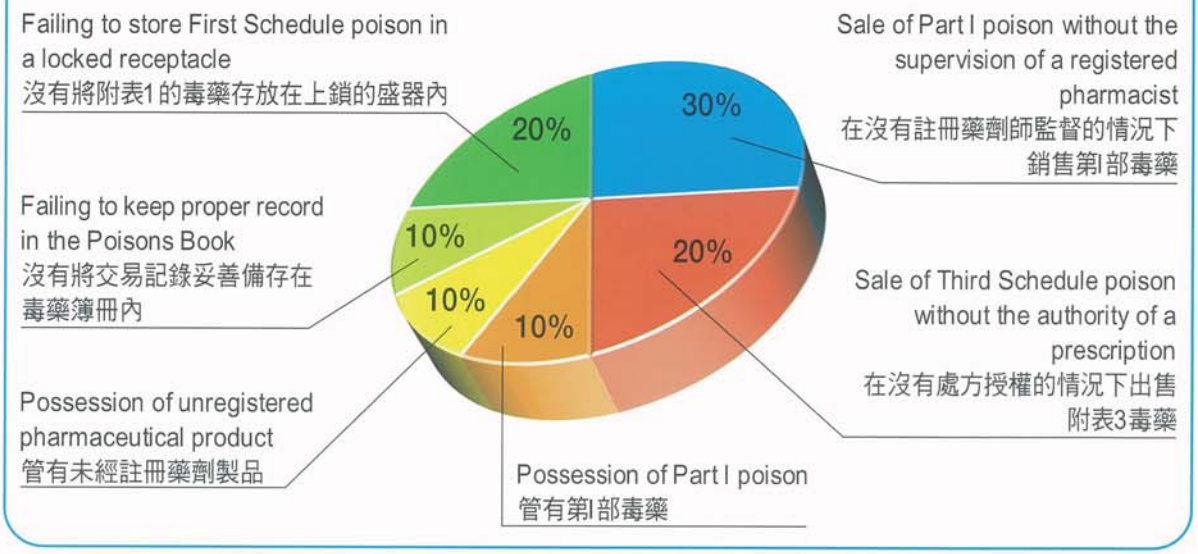


Table 表：13

Number of Listed Sellers of Poisons in Hong Kong
香港列載毒藥銷售商的數目

Year 年份	1999	2000	2001	2002	2003
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	2,510	2,568	2,582	2,688	2,731

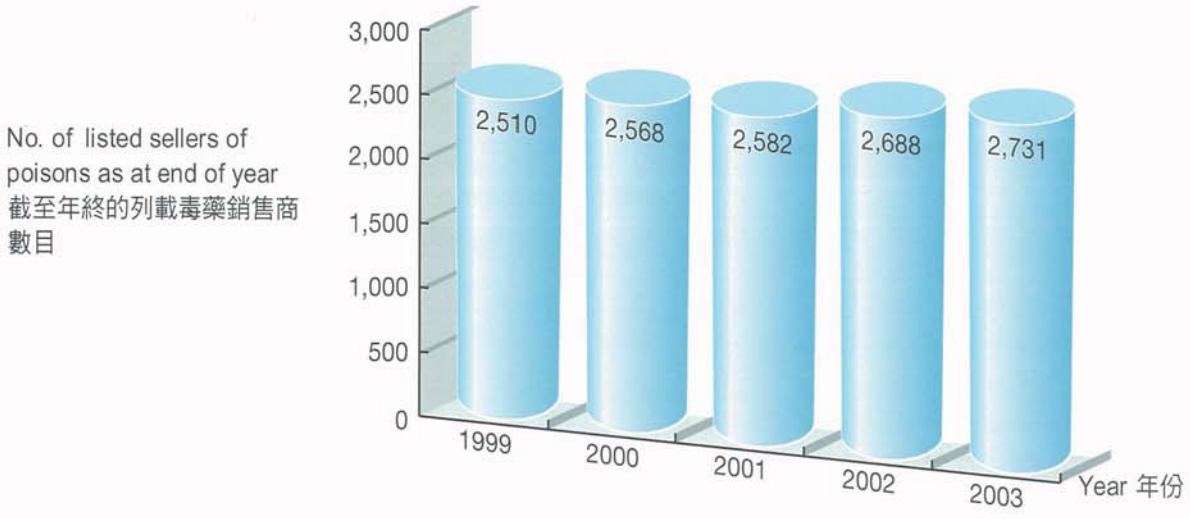


Table 表：14

Applications for Licensing as Listed Sellers of Poisons
申請列載毒藥銷售商牌照

Year 年份	1999	2000	2001	2002	2003
No. of applications approved 接納列載毒藥銷售商的牌照申請數目	764	321	339	357	282
No. of applications rejected 拒絕列載毒藥銷售商的牌照申請數目	4	5	1	1	0
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

Table 表：15

Regulatory Control of Listed Sellers of Poisons
列載毒藥銷售商的規管

Year 年份	1999	2000	2001	2002	2003
No. of inspections conducted 巡查數目	5,894	5,587	5,431	5,466	5,465
No. of test purchases conducted 試買數目	6,045	7,125	6,178	6,140	1,260

Table 表：16

Disciplinary Actions against Listed Sellers of Poisons Taken by the Pharmacy and Poisons Board
藥劑業及毒藥管理局對列載毒藥銷售商採取的紀律行動

Disciplinary actions taken 紀律行動	Number of cases 個案數目				
	1999	2000	2001	2002	2003
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名冊除名	2	5	2	7	6
Issue of written warning 發出書面警告	9	7	8	4	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	0	2	3
總數Total	11	12	10	13	14

Table 表：17

Disciplinary Cases regarding Listed Sellers of Poisons Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關列載毒藥銷售商的紀律個案

Nature of offences 個案性質	Number of cases (percentage) 個案數目 (百份比)				
	1999	2000	2001	2002	2003
(1) Sale of Part I poison 銷售第I部毒藥	3 (10%)	2 (6%)	9 (28%)	4 (12%)	6 (19%)
(2) Sale of Third Schedule poison 銷售附表3毒藥	0 (0%)	0 (0%)	1 (3%)	0 (0%)	2 (6%)
(3) Sale of antibiotic 銷售抗生素	0 (0%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
(4) Sale of unregistered pharmaceutical product 銷售未經註冊藥劑製品	0 (0%)	0 (0%)	1 (3%)	2 (6%)	0 (0%)
(5) Possession of Part I poison 管有第I部毒藥	11 (38%)	14 (45%)	11 (35%)	13 (40%)	10 (31%)
(6) Possession of antibiotic 管有抗生素	12 (41%)	11 (36%)	7 (22%)	6 (18%)	9 (28%)
(7) Possession of dangerous drug 管有危險藥物	1 (4%)	0 (0%)	0 (0%)	1 (3%)	0 (0%)
(8) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	2 (7%)	4 (13%)	3 (9%)	5 (15%)	4 (13%)
(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%)	0 (0%)	1 (3%)	0 (0%)
(10) Practising Chinese medicine without registration 未經註冊作中醫執業	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3%)

Table 表：17A

Disciplinary Cases regarding Listed Sellers of Poisons in 2003
2003年有關列載毒藥銷售商的紀律個案

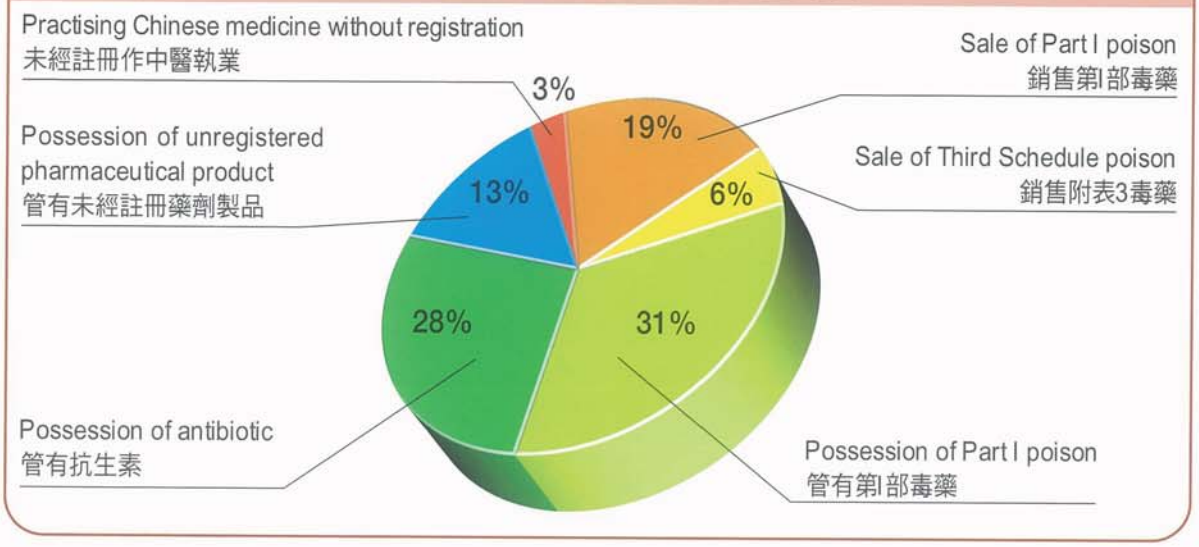


Table 表：18

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

Year 年份	1999	2000	2001	2002	2003
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	944	897	866	862	848
No. of wholesale poisons licences revoked/suspended 撤銷或吊銷毒藥批發牌照的數目	0	1	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

Year 年份	1999	2000	2001	2002	2003
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	48	45	43	42	39
No. of manufacturer's licences revoked/suspended 撤銷或吊銷製造商牌照的數目	0	0	1	0	1*

* pending the result of the appeal lodged with the Pharmacy and Poisons Appeal Tribunal

Table 表：20

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

Year 年份	1999	2000	2001	2002	2003
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	355	332	302	262	256
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 表：21

Registration of Pharmaceutical Products
藥劑製品的註冊

Year 年份	1999	2000	2001	2002	2003
No. of registered pharmaceutical products as at end of year 截至年終的註冊藥劑製品數目	20,521	20,172	20,337	21,021	20,415

No. of registered pharmaceutical products as at end of year
截至年終的註冊藥劑製品數目

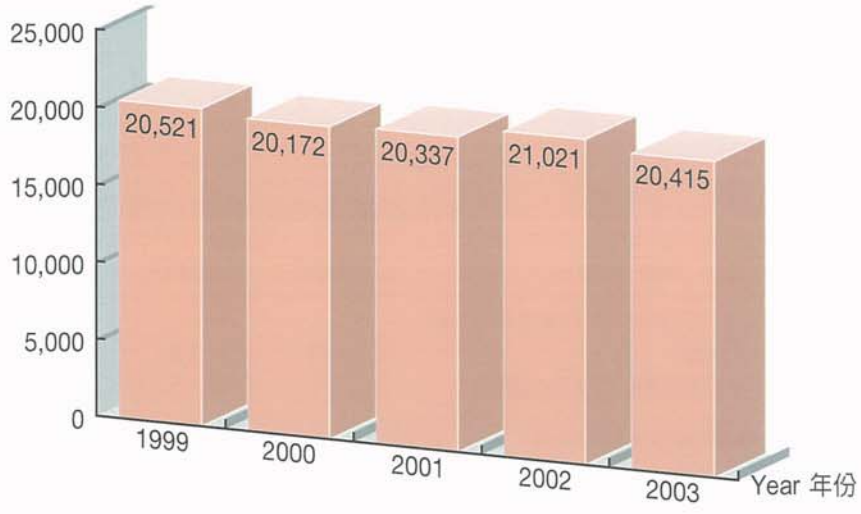


Table 表：22

New Substances Added to Part I of the Poisons List Regulations in 2003
二零零三年在毒藥表規例第1部加入的新物質

1. Drotrecogin alfa	Drotrecogin alfa
2. Tegaserod; its salts	替加色羅；其鹽類
3. Thymosin alpha 1	胸腺肽a1
4. Bimatoprost	Bimatoprost
5. Adefovir; its salts	阿德福韋；其鹽類
6. Etoricoxib; its salts	依托考昔；其鹽類
7. Ezetimibe	依折麥布
8. Pimecrolimus	Pimecrolimus
9. Sevelamer; its salts	Sevelamer；其鹽類
10. Tadalafil; its salts	Tadalafil；其鹽類
11. Tianeptine; its salts; its esters; their salts	噻萘普汀；其鹽類；其酯類；它們的鹽類
12. Valganciclovir; its salts	Valganciclovir；其鹽類
13. Voriconazole; its salts	Voriconazole；其鹽類
14. Adalimumab	阿達木單抗
15. Anagrelide; its salts	Anagrelide；其鹽類
16. Bosentan; its salts	波生坦；其鹽類
17. Darbepoetin alfa	Darbepoetin alfa
18. Dutasteride	度他雄胺
19. Ferucarbotran; its salts	鐵羧葡胺；其鹽類
20. Gadobutrol; its salts	釓布醇；其鹽類
21. Gefitinib; its salts	吉非替尼；其鹽類
22. Levodropropizine; its salts	左旋羥丙哌嗪；其鹽類
23. Memantine; its salts	美金鋼；其鹽類
24. Rosuvastatin; its salts	瑞舒伐他汀；其鹽類
25. Vardenafil; its salts	伐地那非；其鹽類
26. Sulphur Hexafluoride	六氟化硫

Table 表：23

New Substances Added to First and Third Schedules to the Pharmacy and Poisons Regulations in 2003
二零零三年在藥劑業及毒藥規例附表1和3加入的新物質

1. Drotrecogin alfa	Drotrecogin alfa
2. Tegaserod; its salts	替加色羅；其鹽類
3. Thymosin alpha 1	胸腺肽a1
4. Bimatoprost	Bimatoprost
5. Adefovir; its salts	阿德福韋；其鹽類
6. Etoricoxib; its salts	依托考昔；其鹽類
7. Ezetimibe	依折麥布
8. Pimecrolimus	Pimecrolimus
9. Sevelamer; its salts	Sevelamer；其鹽類
10. Tadalafil; its salts	Tadalafil；其鹽類
11. Tianeptine; its salts; its esters; their salts	噻萘普汀；其鹽類；其酯類；它們的鹽類
12. Valganciclovir; its salts	Valganciclovir；其鹽類
13. Voriconazole; its salts	Voriconazole；其鹽類
14. Adalimumab	阿達木單抗
15. Anagrelide; its salts	Anagrelide；其鹽類
16. Bosentan; its salts	波生坦；其鹽類
17. Darbepoetin alfa	Darbepoetin alfa
18. Dutasteride	度他雄胺
19. Ferucarbotran; its salts	鐵羧葡胺；其鹽類
20. Gadobutrol; its salts	釓布醇；其鹽類
21. Gefitinib; its salts	吉非替尼；其鹽類
22. Memantine; its salts	美金鋼；其鹽類
23. Rosuvastatin; its salts	瑞舒伐他汀；其鹽類
24. Vardenafil; its salts	伐地那非；其鹽類
25. Sulphur Hexafluoride	六氟化硫

Table 表：24

Pharmaceutical Products Re-classified as Part I, First and Third Schedules Poisons in 2003
二零零三年重新分類為第 I 部附表1及附表3毒藥的藥劑製品

1. Acetazolamide; its salts	乙酰唑胺；其鹽類
2. Antilymphocyte Immunoglobulins	Antilymphocyte Immunoglobulins
3. Chorionic Gonadotrophin	絨促性素
4. Clofazimine; its salts	氯法齊明；其鹽類
5. Desferrioxamine; its salts	去鐵胺；其鹽類
6. Dimefline; its salts	二甲弗林；其鹽類
7. Etamivan; its salts	香草二乙胺；其鹽類
8. Ethosuximide; its salts	乙琥胺；其鹽類
9. Etilefrine; its salts	依替福林；其鹽類
10. Flavoxate; its salts	黃酮哌酯；其鹽類
11. Folinic acid; its salts	亞葉酸；其鹽類
12. Glucagon; its salts	高血糖素；其鹽類
13. Gonadorelin; its salts	戈那瑞林；其鹽類
14. Inosine pranobex	Inosine pranobex
15. Metyrapone; its salts	美替拉酮；其鹽類
16. Midodrine; its salts	米多君；其鹽類
17. Moroxydine; its salts	嗎啉胍；其鹽類
18. Ribavirin; its salts	利巴韋林；其鹽類
19. Vidarabine; its salts	阿糖腺苷；其鹽類
20. Benzbromarone	苯溴馬隆
21. Mesalazine; its salts	美沙拉秦；其鹽類
22. Nadroparin; its salts	那屈肝素；其鹽類
23. Naftidrofuryl; its salts	萘呋胺；其鹽類
24. Nalidixic acid	萘啶酸
25. Nicergoline	尼麥角林
26. Pantethine; its salts	泛硫乙胺；其鹽類
27. Pipemidic acid	吡哌酸
28. Pralidoxime; its salts	解磷定；其鹽類
29. Pridinol; its salts	普立地諾；其鹽類
30. Protirelin; its salts	普羅瑞林；其鹽類
31. Pyricarbate (Pyridinolcarbamate)	吡卡酯
32. Sermorelin; its salts	舍莫瑞林；其鹽類
33. Somatostatin	生長抑素
34. Streptokinase	鏈激酶
35. Tranexamic acid	氨甲環酸
36. Trifluridine; its salts	曲氟尿苷；其鹽類
37. Trimethoprim	甲氧苄啶
38. Tromantadine; its salts	曲金剛胺；其鹽類
39. Urokinase	尿激酶

Table 表：25

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

Findings of the Court of First Instance 原訟法庭的判決	Number of cases 個案數目				
	1999	2000	2001	2002	2003
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	1	0	0	0	0
Total 總數	1	0	0	0	0

Table 表：26

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				
	1999	2000	2001	2002	2003
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	0	2	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	0	3	1	0	1
Application for a listed seller of poisons licence 申請列載毒藥銷售商牌照	0	0	0	1	0
Revocation of wholesale poisons licence 撤銷毒藥批發商牌照	0	1	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	0	1	0	0
Application for registration of a pharmaceutical product 申請將藥劑製品註冊	0	0	0	1	0
De-registration of a pharmaceutical product 撤銷藥劑製品的註冊	0	0	0	1	0
Application for a manufacturer's licence for pharmaceutical products 申請藥劑製品製造商牌照	0	0	0	1	0
Total 總數	0	6	2	4	1

Table 表：27

Results of Appeals to the Pharmacy and Poisons Appeal Tribunal
向藥劑業及毒藥上訴審裁處上訴的結果

Findings of the Pharmacy and Poisons Appeal Tribunal 藥劑業及毒藥上訴審裁處的判決	Number of cases 個案數目				
	1999	2000	2001	2002	2003
Dismissed 駁回	0	5	1	2	0
Partly allowed 部份得直	0	0	0	1	0
Allowed 得直	0	0	0	1	1
Appeal withdrawn by the appellant 上訴人撤回上訴	0	1	1	0	0
Total 總數	0	6	2	4	1