Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

Annual Report

2016

年報

Contents
目錄

Message from the Chairman
主席獻辭

In year 2016, the Pharmacy and Poisons Board ("the Board") continued to execute its statutory functions under the Pharmacy and Poisons Ordinance (Cap. 138, Laws of Hong Kong) smoothly and effectively.

On 1 January 2016, the Board officially became the 47th Participating Authority of the Pharmaceutical Inspection Co-operation Scheme ("PIC/S"). This was an important milestone for the Board as well as the pharmaceutical industry in Hong Kong. Being recognized by international drug regulatory authorities around the globe, our Good Manufacturing Practice ("GMP") Inspectorate under the Drug Office of the Department of Health, the executive arm of the Board, maintains close communication with other drug regulatory authorities, especially when events of defective or substandard products arise. This facilitates Hong Kong to take rapid actions in dealing with problematic medicines so as to protect the public health.

As a member of the PIC/S, the Board hosted the PIC/S Expert Circle Meeting on Blood, Tissues, Cells & Advanced Therapies Medicinal Products in October 2016. The event gathered manufacturers of cell & tissue-based products and more than 50 overseas GMP experts in the field of blood and cell & tissue-based products in Hong Kong to share their experience in the regulation of blood establishments and manufacturers. Our GMP inspectors also learned a lot from these experts and became more prepared for future regulatory needs.

In order to uphold the quality of registered medicines in Hong Kong so that they were on a par with the international standards, the Board decided that with effect from 1 January 2016, all new applications for registration with the Board must include evidence that the manufacturers had complied with the PIC/S GMP standards.

To address the patent right protection of innovator drugs, the Board decided that with effect from 1 March 2016, all registration certificates of pharmaceutical products should include a registration condition to the effect that any infringement on patent might lead to suspension for sale or de-registration of the product concerned. Accordingly, the registration guideline of pharmaceutical products has been updated to remind applicants to comply with the relevant legal requirements on patent right.

二零一六年，藥劑業及毒藥管理局(「管理局」)竭誠盡心，繼續悉力履行香港法例第138章《藥劑業及毒藥條例》所訂明的法定職能，成效卓著，工作順利。

二零一六年一月一日，管理局正式成為國際醫藥品稽查協約組織(「協約組織」)第四十七個成員機關。此事不論對管理局還是對本港藥劑業界來說，均是重要里程碑。管理局生產質量管理規範稽查組隸屬協助本局處理行政工作的衞生署藥物辦公室，獲世界各地的藥物監管機構認可，今後當與其他藥監機構保持緊密聯繫，尤其在發現有問題或不合標準的產品時，更會充分溝通。此舉有助本港迅速處理有問題的藥物，加強保障市民健康。

作為協約組織的成員機關之一，管理局於二零一六年十月主辦了協約組織轄下血液、組織、細胞及先進療法藥品專家組會議。數家製造細胞和組織產品的機構，以及海外逾50名血液及細胞和組織產品方面的生產質量管理規範專家齊集本港出席會議，分享規管血液處理機構及先進療法藥品製造商的經驗。管理局的生產質量管理規範巡查員從中獲益不淺，為日後可能須推行的規管措施作出更好準備。

為了確保本港註冊藥物保持優良品質並符合國際標準，管理局決定由二零一六年一月一日起，所有向管理局新提交的藥劑製品註冊申請均須附有證明，可顯示相關製造商符合協約組織的生產質量管理規範標準。

此外，管理局亦決定由二零一六年三月一日起，所有藥劑製品的註冊證明書均須附加註冊條件，訂明侵犯專利的藥劑製品可被暫時禁售，或撤銷註冊，以保障原廠藥物的專利權。就此，藥劑製品的註冊指引已更新，以提醒申請人遵守與專利權有關的法律規定。

In recent years, the expiration of patents and/or data protection for many originators' biological products had ushered in an era of products that were designed to be similar to the registered originator biological products. These products were regarded as "biosimilar" products. In line with the international practice and scientific consensus, the Board considered that information to demonstrate similarity in safety, quality and efficacy was essential for the registration of biosimilar products. Based on the World Health Organization's guidelines on the evaluation of biosimilar products, registration requirements of some competent authorities, and comments received from the stakeholders after consultation, the Board has promulgated a set of guidelines for the registration of biosimilar products with effect from 1 January 2016.

Besides, following the implementation of the Phase 1 registration requirement for bioavailability and bioequivalence ("BABE") studies covering 29 antiepileptic drugs in 2010, the Board decided to further enhance the quality of generic medicines and implemented the Phase 2 registration requirement for BABE studies covering 38 critical dose drugs or narrow therapeutic range drugs for all new applications for registration of pharmaceutical products with effect from 1 August 2016.

Subsequent to the commencement of the Pharmacy and Poisons (Amendment) Ordinance 2015 ("PPAO"), all provisions under the PPAO have been implemented including the new labeling requirements (i.e. "Prescription Drug"for prescription-only medicines, or "Drug under Supervised Sales"for pharmacy-only medicines) which came into effect on 5 August 2016.

The assistance and support of the Board and its committees are crucial to the smooth discharge of the Board's functions. I would like to take this opportunity to thank all members for their steadfast and unfailing contributions and commitment. We shall strive our best to meet the ever-increasing demand and aspirations of the community for better health protection and quality healthcare services.

Dr Constance CHAN
Chairman
Pharmacy and Poisons Board

近年，不少原廠生物製劑的專利及／或資料保護期相繼屆滿，各種與該類已註冊藥品相似的產品遂應運而生，這些產品稱為「生物相似」製劑。按照國際慣例和科學共識，管理局認為生物相似製劑必須具備可證明其安全、品質及成效與原廠產品相似的資料，方可獲註冊。管理局參考世界衞生組織有關評估生物相似製劑的指引和若干主管當局的註冊規定，以及諮詢相關各方的意見後，就生物相似製劑的註冊事宜公布了指引，由二零一六年一月一日起生效。

此外，管理局於二零一零年推行有關生物等效性測試報告的第一階段措施，規定29款抗癲癇藥物須具備該等報告方可註冊。本局其後決定由二零一六年八月一日起推行第二階段措施，即就38款關鍵劑量藥物或治療劑量界限狹窄的藥物而言，所有新提交的藥劑製品註冊申請均須附有生物等效性測試報告，以進一步提升仿製藥物的質素。

隨着《2015年藥劑業及毒藥(修訂)條例》正式生效，該條例的所有條文已於二零一六年八月五日實施，當中包括新的標籤規定，即處方藥物須標明「處方藥物」字句，而藥房專售藥物則須標明「監督售賣藥物」字句。

管理局得以順利執行各項職能，實有賴管理局及轄下各委員會的成員鼎力協助。他們克盡厥職，努力不懈，對管理局貢獻良多，本人謹此衷心致謝。管理局今後定會竭盡所能，確保市民獲得更佳的健康保障和優質的醫療服務，以應他們日增的需求。

藥劑業及毒藥管理局主席
陳漢儀醫生

Introduction
引言

This annual report covers the calendar year 2016. 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 ("the 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 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 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
E-mail address : ppb@dh.gov.hk
Website: www.ppbhk.org.hk

這份年報載錄藥劑業及毒藥管理局(「管理局」)在二零一六年的工作。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(「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
電郵地址：ppb@dh.gov.hk
網址　　：www.ppbhk.org.hk

Membership and Functions of the Board
管理局的成員及職能

Dr Constance CHAN, JP (Chairman)
陳漢儀醫生(主席)

Dr Della SIN, JP
單慧媚博士

Ms Linda WOO
吳婉宜女士

Dr Cindy LAI, JP
黎潔廉醫生

Mr WONG Wai-hung, Geoffrey
(Legal Adviser)
黃惠鴻先生(法律顧問)

Dr LEUNG Pak-heng, George
梁栢行博士

Professor LEE Wing-yan, Vivian
李詠恩教授

Ms CHIANG Sau-chu
蔣秀珠女士

Mr KWONG Yiu-sum, Benjamin
鄺耀深先生

Mr WONG Ka-kin, Andy
黃家健先生

Dr SO Yui-chi
蘇睿智醫生

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. The current membership is as follows:

(a) the Director of Health (Chairman);
(b) the Government Chemist;
(c) the Assistant Director of Health in the Drug Office 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 2016 was as follows:

(a) Dr Constance CHAN, JP (Chairman)
(b) Dr Della SIN, JP
(c) Ms Linda WOO
(d) Dr Cindy LAI, JP
(e) Mr WONG Wai-hung, Geoffrey (Legal Adviser)
(f) Dr LEUNG Pak-heng, George
(g) Professor LEE Wing-yan, Vivian
(h) Ms CHIANG Sau-chu
Mr KWONG Yiu-sum, Benjamin
Mr WONG Ka-kin, Andy
(i) Dr SO Yui-chi

Secretary
Ms Lisa LAI

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。現任成員包括：

(a) 衞生署署長（主席）；
(b) 政府化驗師；
(c) 衞生署藥物辦公室的衞生署助理署長；

（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）。

在二零一六年十二月三十一日，管理局的成員計有：

(a) 陳漢儀醫生(主席)
(b) 單慧媚博士
(c) 吳婉宜女士
(d) 黎潔廉醫生
(e) 黃惠鴻先生(法律顧問)
(f) 梁栢行博士
(g) 李詠恩教授
(h) 蔣秀珠女士
鄺耀深先生
黃家健先生
(i) 蘇睿智醫生

秘書
賴玉雲女士

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;

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

(c) licensing and regulatory control of retail traders of pharmaceutical products (authorized sellers of poisons and listed sellers of poisons), conducting inspections and test purchases and initiating prosecution of offences 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 and classification of pharmaceutical products.

The Board is assisted by seven 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 its committees are carried out jointly by the Secretariat of the Board and the Drug Office 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、簽發註冊證明書及週年執業證明書等；

(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) 規管及簽發藥劑製品零售商(獲授權毒藥銷售商及列載毒藥銷售商)牌照。有關工作包括進行巡查及試買行動、提出檢控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、進出口商和製造商牌照；

(e) 規管藥劑製品的銷售、購買、合成和配發事宜；及

(f) 處理藥劑製品的註冊和分類事宜。

管理局轄下設有七個委員會。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。管理局及委員會的決定則由管理局秘書處及衞生署藥物辦公室執行。

Membership and Functions of the Committees
管理局委員會的成員及職能

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

(1) Examination Committee

(i) Membership as at 31 December 2016

Dr LEUNG Pak-heng, George (Chairman)

Dr Della SIN, JP

Ms Linda WOO

Dr NG Ping-sum, Sammy

Dr LEE Chui-ping

Mr Frank CHAN

Professor LEE Wing-yan, Vivian

Dr WONG Siu-ming, Raymond

Ms Alice TANG (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) draw up 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七個委員會，協助管理局執行職能：

(1) 考試委員會

(i) 截至二零一六年十二月三十一日的成員名單

梁栢行博士（主席）

單慧媚博士

吳婉宜女士

吳秉琛醫生

李翠萍博士

陳凌峯先生

李詠恩教授

王紹明醫生

鄧淑雯女士（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。

(2) Pharmacy and Poisons (Listed Sellers of Poisons) Committee

(i) Membership as at 31 December 2016

Ms Linda WOO (Chairman)
Ms CHAN, Shirley Sze-ki
Mr CHAN Wing-kai
Mr FONG Wing-kai, Guy
Mr HUI Siu-chor, Samuel
Mr TAM Hung-pun
Ms TANG Mui-fun
Mr Vincent CHOW (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) Committee

(i) Membership as at 31 December 2016

Ms Linda WOO (Chairman)
Mr CHENG Kit-man
Mr CHIU Kwok-leung, Philip
Mr LAU Oi-kwok
Mr LIU Hing-yuen, Bobbie
Mr Andrew WONG
Mr Grant NG (Secretary)

(2) 藥劑業及毒藥(列載毒藥銷售商)委員會

(i) 截至二零一六年十二月三十一日的成員名單

吳婉宜女士(主席)
陳思琦女士
陳永佳先生
方永佳先生
許肇礎先生
譚鴻彬先生
鄧梅芬女士
周偉仁先生(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)委員會

(i) 截至二零一六年十二月三十一日的成員名單

吳婉宜女士(主席)
鄭結文先生
趙國亮先生
劉愛國先生
廖興源先生
黃志賢先生
吳偉傑先生(秘書)

(ii) Functions

In accordance with regulation 26 of the Pharmacy and Poisons Regulations, the Pharmacy and Poisons (Wholesale Licences) Committee is established to:

(a) consider and approve applications for wholesale dealer licence, subject to any conditions it thinks fit to impose; and

(b) revoke a wholesale dealer licence, suspend a wholesale dealer licence for a specified period, issue warning letter(s) to the licensed wholesale dealer or vary a condition of the wholesale dealer licence in the circumstances specified in regulation 26 of the Pharmacy and Poisons Regulations.

(4) Pharmacy and Poisons (Manufacturers Licensing) Committee

(i) Membership as at 31 December 2016

Ms Linda WOO (Chairman)

Ms Sabrina CHAN

Dr Celine CHENG

Dr LAU Ying-kei, Henry

Professor LEE Wai-yip, Thomas

Mr TSUI Kai-hung, William

Dr WONG Sai-yin, Samson

Dr WONG Yiu-chung

Dr Ken YEUNG

Mr Vincent CHIANG (Secretary)

(ii) Functions

The Pharmacy and Poisons (Manufacturers Licensing) Committee is established to carry out the following functions in accordance with the Pharmacy and Poisons Regulations:

(a) consider and approve applications for licence to manufacture pharmaceutical products, subject to any conditions it thinks fit to impose;

(ii) 職能

藥劑業及毒藥(批發牌照)委員會根據《藥劑業及毒藥規例》第26條，執行下列職能：

(a)在委員會認為適宜施加的條件的規限下，審議及批准批發商牌照的申請；及

(b)在《藥劑業及毒藥規例》第26條指明的情況下，撤銷批發商牌照、在訂明期間內暫時吊銷批發商牌照、向有關持牌批發商發出警告信或更改施加於批發商牌照的牌照條件。

(4) 藥劑業及毒藥（製造商牌照）委員會

(i) 截至二零一六年十二月三十一日的成員名單

吳婉宜女士(主席)

陳素娟女士

鄭香郡博士

劉應機博士

李偉業教授

徐啓雄先生

黃世賢博士

黃耀松博士

楊樹英博士

姜志成先生(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》，執行下列職能:

(a)在委員會認為適宜施加的條件的規限下，審議及批准藥劑製品製造牌照的申請;

(b) revoke a licence to manufacture pharmaceutical products, suspend a licence to manufacture pharmaceutical products for a specified period, issue warning letter(s) to the licensed manufacturer or vary a condition of the licence to manufacture pharmaceutical products in the circumstances specified in regulation 29 of the Pharmacy and Poisons Regulations;

(c) consider and approve applications for registration as authorized person or renewal of registration as authorized person, subject to any conditions it thinks fit to impose; and

(d) cancel the registration as authorized person, suspend the registration as authorized person for a specified period, issue warning letter(s) to the registered authorized person or vary a condition of the registration as authorized person in the circumstances specified in regulation 30F of the Pharmacy and Poisons Regulations.

(b)在《藥劑業及毒藥規例》第29條指明的情況下，撤銷藥劑製品製造牌照或在指明期間內暫時吊銷藥劑製品製造牌照、向有關持牌製造商發出警告信或更改施加於藥劑製品製造牌照的牌照條件;

(c)在委員會認為適宜施加的條件的規限下，審議及批准註冊為獲授權人的註冊申請或續期申請;及

(d)在《藥劑業及毒藥規例》第30F條指明的情況下，取消獲授權人的註冊或在指明的期間內暫時吊銷獲授權人的註冊、向有關已註冊為獲授權人發出警告信或更改註冊為獲授權人所施加的註冊條件。

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

(i) Membership as at 31 December 2016

Ms Linda WOO (Chairman)
Dr CHANG Chee-siu
Dr CHEUNG Siu-ming, Henry
Professor CHIM Chor-sang
Dr HO King-man
Dr KWAN Wing-hong
Ms Teresa NGAN
Professor TO Kin-wah, Kenneth
Dr TO Kwong-yuk
Mr Clive CHAN (Secretary)

(5) 藥劑業及毒藥（藥劑製品及物質註冊：臨牀試驗及藥物測試證明書）委員會

(i) 截至二零一六年十二月三十一日的成員名單

吳婉宜女士(主席)
張茲劭醫生
張兆明獸醫
詹楚生教授
何景文醫生
關永康醫生
顏文珊女士
杜健華教授
杜光旭博士
陳鴻健先生(秘書)

(ii) Functions

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee is established to carry out the following functions in accordance with the Pharmacy and Poisons Regulations:

(a) consider new or renewal applications for registration of pharmaceutical products or substances, and issue registration certificates subject to any conditions it thinks fit to impose;

(b) deregister a pharmaceutical product or substance, suspend the registration of a pharmaceutical product or substance for a specified period, issue warning letter(s) to the holder of a registration certificate or vary a condition of the registration of pharmaceutical products or substances;

(c) consider applications for approval to change any of the registrable particulars of a pharmaceutical product or substance;

(d) consider applications for conducting a clinical trial on human beings or a medicinal test on animals, and issue a clinical trial certificate or medicinal test certificate, subject to any conditions it thinks fit to impose; and

(e) cancel a clinical trial certificate or medicinal test certificate, suspend a clinical trial certificate or medicinal test certificate for a specified period, issue warning letter(s) to the holder of the certificate or vary a condition of the certificate.

(ii) 職能

藥劑業及毒藥(藥劑製品及物質註冊：臨牀試驗及藥物測試證明書)委員會根據《藥劑業及毒藥規例》，執行下列職能：

(a)在委員會認為適宜施加的條件的規限下，審議藥劑製品或物質的新註冊申請或續期註冊申請以及簽發註冊證明書；

(b)撤銷藥劑製品或物質的註冊、在指明期間內暫時吊銷藥劑製品或物質的註冊、向有關註冊證明書持有人發出警告信或更改施加於藥劑製品或物質的註冊條件；

(c)審議有關更改藥劑製品或物質註冊詳情的申請;

(d)在委員會認為適宜施加的條件的規限下，審議有關對人類進行臨牀試驗或對動物進行藥物測試的申請以及簽發臨牀試驗證明書或藥物測試證明書；及

(e)取消臨牀試驗證明書或藥物測試證明書、在指明期間內暫時吊銷臨牀試驗證明書或藥物測試證明書、向有關證明書的持有人發出警告信或更改施加於證明書的條件。

(6) Poisons Committee

(i) Membership as at 31 December 2016

Dr Della SIN, JP (Chairman)

Ms CHIANG Sau-chu

Mr KWONG Yiu-sum, Benjamin

Dr LEUNG Pak-heng, George

Dr SO Yui-chi

Ms Linda WOO

Ms Alice TANG (Secretary)

(6) 毒藥委員會

(i) 截至二零一六年十二月三十一日的成員名單

單慧媚博士(主席)

蔣秀珠女士

鄺耀深先生

梁栢行博士

蘇睿智醫生

吳婉宜女士

鄧淑雯女士(秘書)

(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 1 and Part 2 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 Pharmacy and Poisons Regulations.

(7) Pharmacy Internship Training Committee

(i) Membership as at 31 December 2016

Professor LEE Wing-yan, Vivian (Chairman)

Mr Frank CHAN

Ms Victoria CHAN

Dr Celine CHENG

Mr Antonio KWONG, MH

Dr LEUNG Pak-heng, George

Mr Winham LOK

Dr NG Chor-shan, Sian

Dr NG Ping-sum, Sammy

Professor TO Kin-wah, Kenneth

Dr TO Kwong-yuk

Ms Linda WOO

Mr WONG Ka-kin, Andy

Ms Alice TANG (Secretary)

(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1部及第2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》管制的藥劑製品的分類。

(7) 藥劑師實習培訓委員會

(i) 截至二零一六年十二月三十一日的成員名單

李詠恩教授（主席）

陳凌峯先生

陳慧琪女士

鄭香郡博士

鄺祖盛先生

梁栢行博士

駱永煊先生

吳楚珊博士

吳秉琛醫生

杜健華教授

杜光旭博士

吳婉宜女士

黃家健先生

鄧淑雯女士(秘書)

(ii) Functions

The Pharmacy Internship Training Committee is set up under the Board to:

(a) assist the Board in the registration of internship training institutions and preceptors;

(b) assist the Board in drawing up the criteria for the approval of the content of the preceptor's quarterly appraisal forms and the intern's annual assessment forms proposed by the different training institutions and in implementing the criteria, and to establish sub-committees for these purposes where necessary;

(c) assist the Board in drawing up the criteria for the evaluation of the preceptor's quarterly appraisals and the intern's annual assessments and in implementing the criteria, and to establish sub-committees for these purposes where necessary;

(d) advise the Board on matters pertaining to pharmacy internship training;

(e) liaise with internship training institutions and with preceptors on matters pertaining to internship training as necessary; and

(f) carry out such other functions connected with internship training as may be permitted or assigned to the Committee by the Board.

(ii) 職能

藥劑師實習培訓委員會由管理局成立，負責：

(a)協助管理局處理實習培訓機構及導師註冊事宜；

(b)協助管理局制訂準則用以批核由不同培訓機構提交的導師所用的季度評核表格及實習人員所用的年度評核表格，以及執行這些準則並按需要設立小組委員會；

(c)協助管理局制訂準則用以審核導師提交的季度評核表格及實習人員提交的年度評核表格，以及執行這些準則並按需要設立小組委員會；

(d)就有關藥劑師實習培訓的事宜向管理局提供意見；

(e)按需要與實習培訓機構及導師緊密聯絡；及

(f)執行管理局所容許並賦予的有關實習培訓的其他職能。

The Work of the Board and its Committees
管理局及其委員會的工作

(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 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) 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.

(ii) Examination

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

The Examination Committee conducted two registration examinations in June and December 2016. A total of 42 applicants cumulatively passed all the three subjects in the year 2016.

The results of these two registration examinations are shown in **Table 1**. Figures for the years 2012 to 2016 are also included for comparison purpose.

(iii) Training

Applicants holding a pharmacy degree awarded by a recognized university in Hong Kong 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.

(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。

(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。

考試委員會在二零一六年分別在六月及十二月舉辦了兩次註冊考試。同年共有42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，以及二零一二年至二零一六年的有關數字，以供比較。

(iii) 實習

持有香港認可大學頒授的藥劑學學位的申請人，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) 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 2,659 registered pharmacists were issued with practising certificates in the year 2016. Statistical data regarding registration of pharmacists and breakdown of fresh registration, removal from and restoration to the register of pharmacists for the years 2012 to 2016 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 written warning, 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 is given in pages 24 to 26 of this report.

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in the years 2012 to 2016 are shown in **Tables 4, 5** and **6**.

(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條的規定取得週年執業證明書。在二零一六年，共有2,659位註冊藥劑師獲發執業證明書。**表2**及**3**列出二零一二年至二零一六年有關藥劑師註冊，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，包括警告信、被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24至26頁。

表4、5及6詳列管理局在二零一二年至二零一六年對註冊藥劑師採取紀律行動的統計數字。

(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" or "dispensary", is a business authorized to sell poisons included in Part 1 of the Poisons List, by or under the supervision of a registered pharmacist. Any person wishing to operate as an ASP shall apply to the Board for registration of the premises where the retail sale of poisons is to be conducted. Besides, ASPs are also authorized to conduct retail sale of poisons included in Part 2 of the Poisons List at registered premises. 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 the 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 of the Pharmacy and Poisons Ordinance.

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 604 ASPs registered in Hong Kong as at end of year 2016. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of an ASP in the years 2012 to 2016 are shown in **Tables 7** and **8**.

(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"或"dispensary"),是獲授權銷售毒藥表內第1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。此外,獲授權毒藥銷售商亦會獲授權在註冊處所內零售毒藥表內第2部毒藥。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,在繳付訂明費用後生效。

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《藥劑業及毒藥條例》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週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。

截至二零一六年年終,香港共有604名獲授權毒藥銷售商。**表7**及**8**詳列二零一二年至二零一六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 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, variation on the conditions relating to the registration of premises to disqualification from being an ASP for a specified period of time.

12 inquiries were held in the year of 2016 and 12 ASPs were found guilty of misconduct. Four ASPs were issued with written warning whilst the remaining eight ASPs were disqualified from being an ASP for a period of time.

For minor infringement, if the pharmacist of the ASP concerned is directly involved in the case, the Board may direct the proprietor/ director and duty pharmacist of the ASP to be interviewed by the Assistant Director (Drug) of the Department of Health and the Secretary of the Board to give them verbal cautions. On the other hand, verbal caution may be given to the director/proprietor in the presence of the pharmacist when the pharmacist is not involved in the case. A total of 18 such interviews were held in the year 2016.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in the years 2012 to 2016 is shown in **Table 9**.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in the years 2012 to 2016 are given in **Tables 10, 11, 12 and 12A.**

(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或未經註冊藥劑製品的違法活動，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、更改處所註冊條件，以至在指定期間被取消銷售商資格。

在二零一六年，管理局舉行了12次紀律研訊及12名獲授權毒藥銷售商被裁定犯有不當行為。紀律委員會向其中4名發出書面警告，其餘8名獲授權毒藥銷售商則被取消銷售商資格一段時間。

至於輕微的違法行為，如獲授權毒藥銷售商的藥劑師直接牽涉其中，管理局會指示衞生署助理署長(藥物)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；如獲授權毒藥銷售商的藥劑師沒有牽涉在內，則獲授權毒藥銷售商的東主或董事必須於其藥劑師在場的情況下出席晤談，接受口頭警誡。管理局在二零一六年舉行了18次該類會面。

表9列出二零一二年至二零一六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詳列二零一二年至二零一六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) 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 2 of the Poisons List subject to the provision of the Pharmacy and Poisons Ordinance. Any person wishing to operate as a LSP should 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 3,937 LSPs as at end of year 2016. The number of licensed LSPs in the years 2012 to 2016 is shown in **Table 13**. Statistical data regarding applications for LSP 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 are held to inquire into the conduct of a LSP. If a LSP is convicted of any offence under the Pharmacy and Poisons Ordinance, the Antibiotics Ordinance, the Dangerous Drugs Ordinance, the Trade Descriptions Ordinance, or the LSP has contravened the Code of Practice or licensing conditions, his case will be submitted to the Board for consideration. His name will be removed or suspended for a period specified by the Board from the list of LSPs if the Board considers him not a fit and proper person to continue the retail business of Part 2 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 2012 to 2016 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**.

(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2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。

截至二零一六年年終，香港共有3,937名列載毒藥銷售商。**表13**列出二零一二年至二零一六年列載毒藥銷售商的總數。**表14**列出在上述五年申請發牌的統計數字。

(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干犯任何《藥劑業及毒藥條例》、《抗生素條例》、《危險藥物條例》、《商品説明條例》或違反其《執業守則》或發牌條件，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2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或在指明的期間內暫時吊銷其名列該名單內的資格。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列出二零一二年至二零一六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 Wholesalers and Manufacturers

(i) Wholesale Dealers of Pharmaceutical Products

Subject to the provisions of the Pharmacy and Poisons Regulations, any person wishing to deal in wholesale and/or import/export of poisons and/or pharmaceutical products should apply to the Pharmacy and Poisons (Wholesale Licences) Committee for an annual wholesale dealer licence.

A licensed wholesale dealer must keep a record of all transactions involving poisons included in Part 1 of the Poisons List or any pharmaceutical product. Sales of poisons are restricted to authorized persons only.

There were 779 holders of licensed wholesale dealers as at end of year 2016. Statistical data for the years 2012 to 2016 are shown in **Table 18**.

(ii) Manufacturers of Pharmaceutical Products

Any person wishing to manufacture any pharmaceutical product should 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 to ensure identity and purity, and to test its finished form to ensure identity and potency. 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.

(3) 批發商及製造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，任何人如欲經營毒藥及/或藥劑製品批發及/或進/出口，均須向藥劑業及毒藥(批發牌照)委員會申請一年期的批發商牌照。

持牌的批發商須備存所有涉及毒藥表第1部所列毒藥或所有藥劑製品的交易記錄，而銷售對象只限於獲授權人士。

截至二零一六年年終，香港共有779名毒藥批發牌照/批發商牌照持有人。**表18**列出二零一二年至二零一六年的統計數字。

(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。

每名製造商必須測試擬用於製造藥劑製品的每一批原料，確保原料的本質及純度；及測試製成品，以確保其本質及效力。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。

The manufacture of pharmaceutical products must be supervised by a registered pharmacist or persons with such other qualifications as approved by the Board. A manufacturer must also ensure that at least one authorized person is employed to be responsible for ensuring and certifying that the pharmaceutical products are manufactured in accordance with the Pharmaceutical Inspection Co-operation Scheme Good Manufacturing Practice ("PIC/S GMP") Guide and registration requirements.

There were 72 holders of a manufacturer's licence as at end of year 2016, and all of them were required to comply with the GMP Guide with effect from 1 October 2015. Among the 72 holders, 49 holders of them were authorized to conduct secondary packaging of pharmaceutical products only. Statistical data for the years 2012 to 2016 are given in **Table 19**.

(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 manufactured outside Hong Kong, the Committee may require the applicant to take any or all of the following actions:

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

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

(c) pay a fee as representing the expenditure incurred by or on behalf of the Committee in carrying out an inspection at the manufacturing premises.

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。製造商須僱用最少一名獲授權人士負責確保及保証所製造的藥劑製品符合國際醫藥品稽查協約組織的生產質量管理規範指引及註冊資格。

截至二零一六年年終，香港共有72名製造商牌照持有人。由2015年10月1日起，所有牌照持有人均須符合國際醫藥品稽查協約組織的生產質量管理規範指引。而72名製造商牌照持有人當中，49名只獲授權從事藥劑製品外包裝操作。**表19**列出二零一二年至二零一六年的統計數字。

(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：臨牀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人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。

(c)繳付由委員會釐定的費用，該筆費用相當於委員會或其代表在視察生產廠房時所招致或相當可能招致的開支。

A registration certificate will be issued on registration, and will be subject to any conditions the Committee thinks fit to impose. The applicant will also be advised of the classification of the product.

There were 18,584 registered pharmaceutical products in Hong Kong as at end of year 2016. The number of registered pharmaceutical products as at end of years 2012 to 2016 is shown in **Table 20**.

(ii) Classification of Pharmaceutical Products

On the advice of the Poisons Committee, the Board determines and 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 Schedules 1 and 3 of the Pharmacy and Poisons Regulations. The classification of pharmaceutical products in the Schedule 10, i.e. Poisons List, and restrictions on sales under the two schedules are:

Classification	Restriction(s) on sale
(a) Part 1 Poisons: Poisons included in Part 1 of the Schedule 10, i.e. Poisons List	They can be sold only by authorized sellers of poisons under the supervision of registered pharmacists. 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.
(b) Schedule 1 Poisons: Poisons included in Part 1 of the Schedule 10, i.e. Poisons List, and the Schedule 1 to the Pharmacy and Poisons Regulations	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.
(c) Schedule 3 Poisons: Poisons included in Part 1 of the Schedule 10, i.e. Poisons List, and the Schedule 3 to the Pharmacy and Poisons Regulations	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 2 Poisons: Poisons included in Part 2 of the Schedule 10, i.e. Poisons List	They can be sold by listed sellers of poisons and authorized sellers of poisons without the supervision of registered pharmacists.

一經註冊，申請者會獲發註冊證明書，並獲告知產品的分類。

截至二零一六年年終，香港共有18,584種已註冊的藥劑製品。**表20**列出截至二零一二年至二零一六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。藥劑製品在附表10，即毒藥表，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：

分類	銷售的限制
(a)第1部毒藥：附表10，即毒藥表，第1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。這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。
(b) 附表1毒藥：同時列於附表10，即毒藥表，第1部及《藥劑業及毒藥規例》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。
(c)附表3毒藥：同時列於附表10，即毒藥表，第1部及《藥劑業及毒藥規例》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2部毒藥：附表10，即毒藥表，第2部所列毒藥	無須藥劑師監督，由列載毒藥銷售商或獲授權毒藥銷售商銷售。

Regulatory provisions in other related areas are contained in the Schedule 2, Schedules 4 to 7 to the Pharmacy and Poisons Regulations:

Schedule	Provisions
Schedule 2	providing for certain articles to be exempted from some of the provisions of the Pharmacy and Poisons Ordinance and the Pharmacy and Poisons Regulations
Schedule 4	setting out the statement of particulars as to proportion of poisons in certain cases
Schedule 5	prescribing the labelling requirements for certain poisons
Schedule 6	listing out certain poisons which are exempted from labelling provisions when sold or supplied in certain circumstances
Schedule 7	listing out certain poisons which are required to be specially labelled for transport

Classification and distribution in the Schedule 10, i.e. Poisons List, and imposition of control through the various schedules were made through amendments to the Pharmacy and Poisons Regulations. Amendments proposed by the Board and approved by the Legislative Council in the year 2016 are shown in **Tables 21** to **22**.

《藥劑業及毒藥規例》附表2、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》一些條文規限的某些物品
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某些毒藥
附表7	列出為運輸而須特別加上標籤的某些毒藥

管理局透過修訂《藥劑業及毒藥規例》，將藥劑製品在附表10，即毒藥表內分類和分配，並透過多個附表對藥劑製品施加規管。立法會在二零一六年批准管理局就藥劑製品分類對《藥劑業及毒藥規例》作出的修訂分別列載於**表21**和**22**。

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 Pharmacy and Poisons 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 2016, the Chairman of the Disciplinary Committee was Dr Cindy LAI, JP, Deputy Director of the Department of Health. Registered pharmacists who had served as members in year 2016 included:

Mrs CHAN LAU Charm-ming

Mr CHAN Yat-ming

Ms CHAN Yin-yin, Ivy

Ms CHEW Leng-leng

Mr CHONG Tang-lung

Ms KWOK Ching-chi

Mr LEE Pak-hei

Mr LEE Siu-to

Mr LEUNG Kwong-hei, Kenneth

Mr NG Wing-yan

Mr SUNG Ming-tat, Dick

Ms TAM Hi

Mr WONG Chi-ming

Mr WONG Hing-mang, Matthew

Mr WONG Kwong-cheung, Aaron

Ms WONG Yuen-yin, Clara

(1) 成員

紀律委員會的成員包括下列人士：

(a)一名根據《藥劑業及毒藥條例》第3(2)(e)條由行政長官委任為管理局成員的衞生署醫生，並由其出任主席；

(b)兩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。

衞生署副署長黎潔廉醫生是紀律委員會在二零一六年十二月三十一日的主席。曾在二零一六年出任成員的註冊藥劑師包括：

陳劉湛明女士

陳日明先生

陳妍賢女士

周凌綾女士

莊騰龍先生

郭靜芝女士

李伯熙先生

李兆濤先生

梁廣熙先生

吳榮恩先生

沈明達先生

譚起女士

黃志明先生

黃興孟先生

黃廣長先生

黃婉妍女士

(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 if:

(a) a complaint is received by the Board regarding the conduct of a registered pharmacist or an employee of a registered pharmacist, or it appears to the Board that a registered pharmacist has contravened a code of conduct applicable to the registered pharmacist;

(b) a complaint is received by the Board regarding the conduct of an authorized seller of poisons ("ASP") or an employee, officer or partner of an ASP, or it appears to the Board that an ASP has contravened a code of practice applicable to the ASP;

(c) any of the persons mentioned in (a) or (b) above, is convicted of an offence under:

  i) the Pharmacy and Poisons Ordinance, the Dangerous Drugs Ordinance, the Antibiotics Ordinance, the Undesirable Medical Advertisements Ordinance; or

  ii) sections 52, 54 or 61 of the Public Health and Municipal Services Ordinance or section 7, 7A or 9 of the Trade Descriptions Ordinance;

(d) it appears to the Board that a condition imposed under section 13 of the Pharmacy and Poisons Ordinance in respect of the registration of any premises of an ASP has been contravened; or

(e) it otherwise appears necessary or desirable to the Board to inquire into the conduct of any of the persons mentioned in paragraph (a) or (b) above.

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

(a) censure the registered pharmacist;

(b) issue a warning letter to the registered pharmacist; or

(c) remove his name from the register of pharmacists and not to re-enter it thereon for such period as the Disciplinary Committee directs.

(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)當管理局接到有關某註冊藥劑師或其僱員的行為操守的投訴，或管理局覺得某藥劑師已違反適用於該藥劑師的《行為守則》；

(b)當管理局接到有關某獲授權毒藥銷售商、其僱員、高級人員或合夥人的行為操守的投訴；或管理局覺得某獲授權毒藥銷售商已違反適用於該銷售商的《執業守則》；

(c)當上述(a)或(b)項所述的任何人士被裁定干犯：

  (i)《藥劑業及毒藥條例》、《危險藥物條例》、《抗生素條例》或《不良廣告(醫藥)條例》所訂罪行；或

  (ii)《公眾衞生及市政條例》第52、54或61條或《商品説明條例》第7、7A或9條所訂罪行；

(d)當管理局覺得根據《藥劑業及毒藥條例》第13條就某獲授權毒藥銷售商的處所的註冊而施加的某條件，遭人違反；或

(e)當管理局在其他情況下，覺得有需要或適宜就任何在(a)或(b)段所述的人的行為操守進行研訊。

如研訊是就某註冊藥劑師或其僱員而進行，紀律委員會可在研訊完結時：

(a)譴責該藥劑師；

(b)向該藥劑師發出警告信；或

(c)在紀律委員會指示的期間內，將該藥劑師的姓名從藥劑師名冊中刪除。

As for an ASP or an employee, officer or partner of 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;

(b) any or all of the premises of that ASP be removed from the register of premises, either until the expiry of the certificate of registration issued to that authorized seller of poisons in respect of the premises, or for a shorter period as may be specified in the direction;

(c) variations to be made to the conditions relating to the registration of any or all of the premises of that ASP; or

(d) a warning letter be served on that ASP.

At the conclusion of a disciplinary inquiry, the direction of the Disciplinary Committee against the registered pharmacist or an ASP takes effect immediately if the Disciplinary Committee considers it in the public interest to bring the direction into immediate effect. In other cases, the direction takes effect on the date specified by the Disciplinary Committee if no appeal has been lodged before the expiry of the period for lodging an appeal. If an appeal has been lodged, on the date on which the appeal is finally determined.

The Disciplinary Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding three years (suspension period) the operation of a direction to remove a pharmacist's name from the register of pharmacists, disqualify a person from being an ASP, or remove any or all of the premises of an ASP from the register of premises so that the direction takes effect only if a condition so imposed is contravened during the suspension period.

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. There were no appeals to the Court of First Instance from 2012 to 2016.

至於獲授權毒藥銷售商或其僱員、高級人員或合夥人，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，取消該銷售商的獲授權毒藥銷售商的資格；

(b)從處所註冊記錄冊中刪除該銷售商的任何或全部處所，直至向該銷售商發出的有關處所註冊證明書的有效期屆滿，或為期一段在該項指示指明較短的時間；

(c)更改該銷售商的任何或全部處所的註冊條件；或

(d)向該獲授權毒藥銷售商送達警告信。

紀律委員會在研訊完結時，如認為其就某註冊藥劑師或某獲授權毒藥銷售商作出的指示即時生效是合乎公眾利益，可指示即時生效；或在其他情況下如沒有上訴在限期屆滿前提出，則於紀律委員會指明的日期生效或如有上訴提出，則於該上訴獲最終裁定的日期生效。

紀律委員會可在適宜施加的條件的規限下，暫緩執行其作出將某藥劑師的姓名從藥劑師名冊中除去、取消某銷售商的獲授權毒藥銷售商的資格，或將某獲授權毒藥銷售商的任何或全部處所從處所註冊紀錄冊中除去的指示，為期不超過三年(暫緩期)，令到只有如此施加的條件在暫緩期內遭違反，該指示才會生效。

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，並可刊登或不刊登有關研訊程序的報告。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。由二零一二年至二零一六年，原訟法庭沒有收到任何上訴。

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 Pharmacy and Poisons 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 2016 was as follows:

Name	Membership
Ms WONG Kwok-ying, Lisa, S.C.	Chairman
Dr TSANG Ho-fai, Thomas	Member
Dr LEE Chui-ping	Member
Professor CHAN Yan-keung, Thomas, BBS, JP	Member
Mr CHUI Chun-ming, William	Panel Member
Mr LAW Chun-cheong	Panel Member
Miss LEUNG Sik-yin, McShirley	Panel Member
Ms FAN Yuen-sze	Panel Member
Mr TSE Kin-on, Andrew	Panel Member
Mr WONG Cheong-moon	Panel Member
Mr HO Po-man	Panel Member
Mr LIM Sui-kweng	Panel Member
Mr MOK Ka-kui	Panel Member

(1) 成員

審裁處包括下列根據《藥劑業及毒藥條例》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士，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。

在二零一六年十二月三十一日，審裁處的成員如下：

姓名	成員
黃國瑛女士	主席
曾浩輝醫生	委員
李翠萍博士	委員
陳恩強教授	委員
崔俊明先生	小組委員
羅俊昌先生	小組委員
梁錫燕女士	小組委員
范遠詩女士	小組委員
謝建安先生	小組委員
黃昌滿先生	小組委員
何保民先生	小組委員
林瑞宏先生	小組委員
莫家駒先生	小組委員

(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 authorized seller of poisons;

(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 from 2012 to 2016.

(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。

由二零一二年至二零一六年上訴審裁處沒有研訊上訴個案。

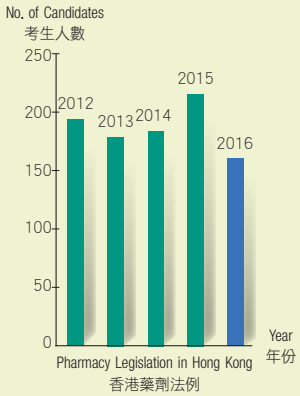
Statistical Tables and Charts
統計圖表

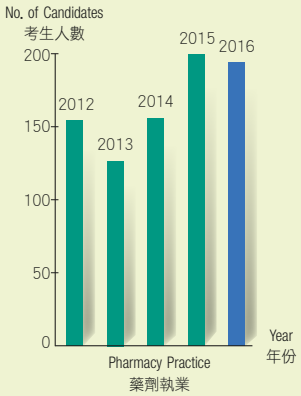
Table 表 1

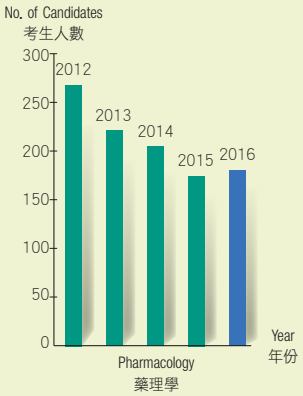
Results of the Registration Examinations
註冊考試成績

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	passing % 合格率	No. sat 參加人數	No. passed 合格人數	passing % 合格率	No. sat 參加人數	No. passed 合格人數	passing % 合格率
2012	193	89	46.1	155	82	52.9	268	61	22.8
2013	179	81	45.3	128	80	62.5	221	105	47.5
2014	184	74	40.2	156	71	45.5	205	107	52.2
2015	216	87	40.3	199	57	28.6	174	38	21.8
2016	159	68	42.8	194	46	23.7	181	44	24.3

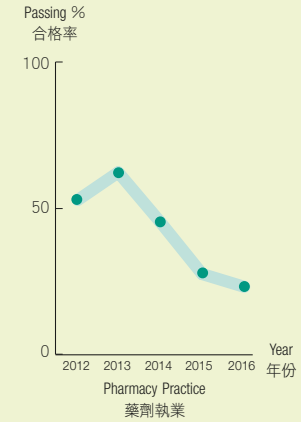
Number of Candidates Sitting Each Examination Subject
每科考試的考生人數

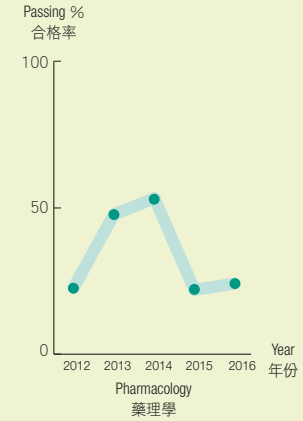






Passing Percentage in Each Examination Subject
每科考試的合格率



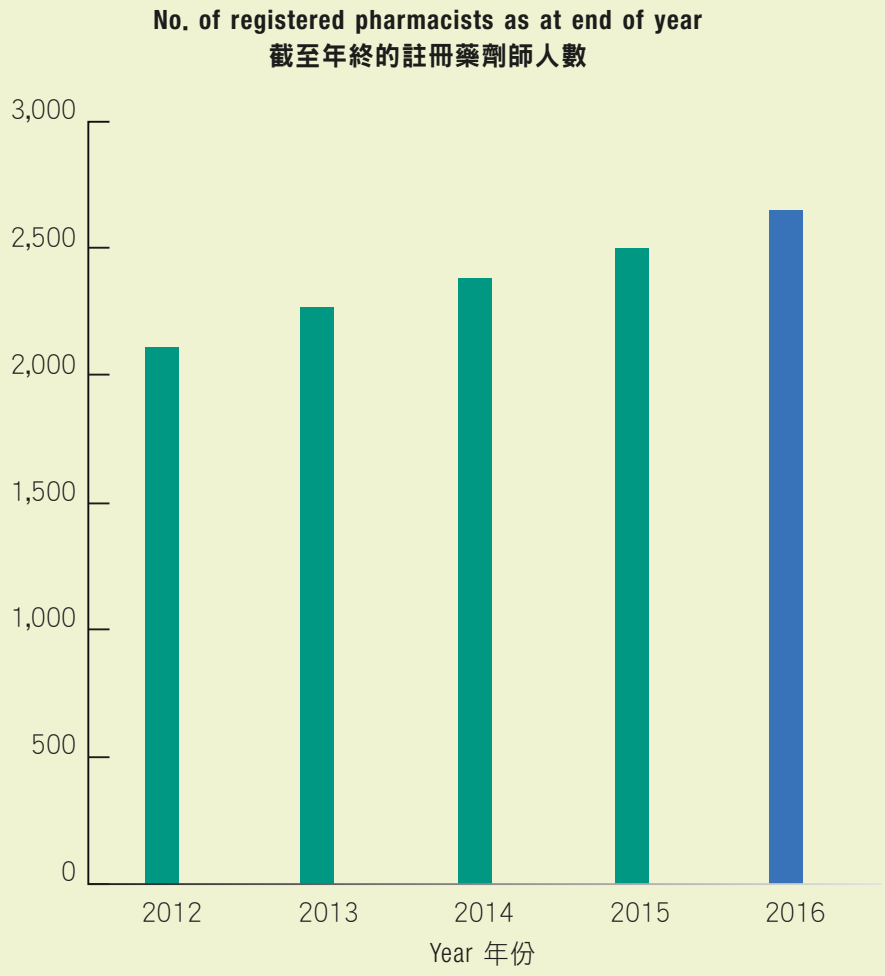


Statistical Tables and Charts
統計圖表

Table 表 2

Number of Registered Pharmacists in Hong Kong
香港註冊藥劑師人數

Year 年份	2012	2013	2014	2015	2016
No. of registered pharmacists as at end of year 截至年終的註冊藥劑師人數	2,127	2,285	2,390	2,504	2,659



Statistical Tables and Charts
統計圖表

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	2012	2013	2014	2015	2016
Fresh registration (Non-local graduates) 新註冊〔非本地畢業〕	52	107	63	75	67
Fresh registration (Local graduates) 新註冊〔本地畢業〕	26	57	51	51	98
Removal from the register* 刪除註冊*	10	10	14	14	12
Restoration to the register 重新註冊	9	4	5	2	2
Net increase 淨增長	77	158	105	114	155

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

Statistical Tables and Charts
統計圖表

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				
	2012	2013	2014	2015	2016
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	1	1	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				
	2012	2013	2014	2015	2016
Charge dismissed 指控不成立	0	0	0	0	1
Guilty of the charge 指控成立	4	1	1	1	0
Directions of the Disciplinary Committee 紀律委員會的指示					
Censure 譴責	3	0	1	0	0
Removed from the register for a period of time 由名冊除名一段時間	1	1	0	1	0

Statistical Tables and Charts
統計圖表

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 counts 次數				
	2012	2013	2014	2015	2016
(1) Sale of Schedule 3 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	1	0	0	0	0
(2) Selling substance to which the Antibiotics Ordinance, Cap. 137, applies without the authority of a prescription 未獲處方授權而銷售《抗生素條例》(第137章)適用的物質	1	0	0	0	0
(3) Behaving in a disorderly manner in public place 在公眾地方作出擾亂秩序的行為	2	0	0	0	0
(4) Manufacturing pharmaceutical product without a licence 沒有牌照而製造藥劑製品	21#	0	0	0	0
(5) Fraud 欺詐案	0	1	0	0	0
(6) Possession for sale or for any purpose of trade or manufacture goods to which a forged trade mark 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	1	0	0
(7) Supplying Part 1 poison from unlicensed premises 從沒有牌照的處所供應第1部毒藥	0	0	0	1	0
(8) Failing to keep proper record of Part 1 poison 沒有備存第1部毒藥的適當記錄	0	0	0	1	0

Statistical Tables and Charts
統計圖表

Table 表 6 (Con't)續

Nature of offences* 個案性質*	Number of counts 次數				
	2012	2013	2014	2015	2016
(9) Possession of substance to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	0	0	0	1	0
(10) Possession for sale or for any purpose of trade or manufacture goods to which a forged trade description was applied 管有應用虛假商品説明的貨品作銷售或任何商業或製造用途	0	0	0	1	0
(11) Professional misconduct 專業失德	0	0	0	0	1

* Some cases involve multiple nature of offences
* 部份個案涉及多個罪行
# Involving one pharmacist for 21 counts of same offence
# 一名藥劑師涉及21項同一罪行

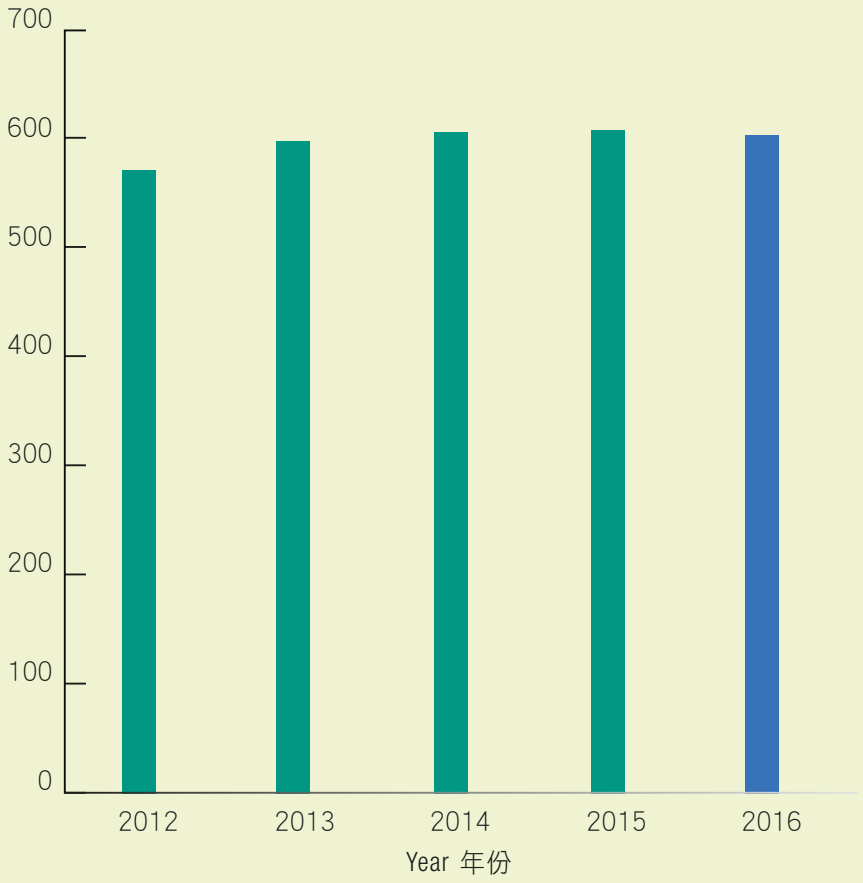
Statistical Tables and Charts
統計圖表

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	2012	2013	2014	2015	2016
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	570	597	605	607	604

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



Statistical Tables and Charts
統計圖表

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	2012	2013	2014	2015	2016
No. of applications for registration of premises approved 接納處所註冊申請的數目	45	106	39	34	29
No. of applications for registration of premises rejected 拒絕處所註冊申請的數目	0	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	0	0	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	2012	2013	2014	2015	2016
No. of inspections conducted 巡查數目	1,222	1,186	1,229	1,214	1,209
No. of test purchases conducted 試買數目	5,942	5,707	4,363	4,136	3,955

Statistical Tables and Charts
統計圖表

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 採取的紀律行動	Number of cases 個案數目				
	2012	2013	2014	2015	2016
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〕	20	10	8	13	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〕	25	13	12	18	18
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	0	1	1
Total 總數	45	23	20	32	31

Statistical Tables and Charts
統計圖表

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				
	2012	2013	2014	2015	2016
Charge dismissed 指控不成立	0	0	0	0	0
Guilty of the charge 指控成立	20	10	8	13	12
Directions of the Disciplinary Committee 紀律委員會的指示					
Issue of written warning 發出書面警告	8	2	1	4	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	12	8	7	9	8

Statistical Tables and Charts
統計圖表

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 counts (percentage) 次數 (百份比)				
	2012	2013	2014	2015	2016
(1) Sale of Part 1/Part 2 poison without label/proper label 銷售沒有標籤/沒有妥善標籤的第1部或第2部毒藥	4 (5%)	2 (6.07%)	2 (9.1%)	4 (10%)	0 (0%)
(2) Sale of Part 1 poison without the supervision of a registered pharmacist/proper supervision 在沒有註冊藥劑師監督/適當監督的情況下銷售第1部毒藥	26 (32.5%)	6 (18.18%)	5 (22.72%)	5 (12.5%)	4 (12.9%)
(3) Sale of Schedule 3 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	20 (25%)	7 (21.21%)	0 (0%)	9 (22.5%)	5 (16.13%)
(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	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(5) Possession of poison included in Part 1 of the Poisons List 管有毒藥表第1部所列任何毒藥	0 (0%)	3 (9.09%)	2 (9.1%)	1 (2.5%)	3 (9.68%)
(6) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	6 (7.5%)	0 (0%)	2 (9.1%)	4 (10%)	0 (0%)
(7) Failing to keep proper record/make entry in the Poisons Book 沒有將交易記錄妥善備存在毒藥冊內	4 (5%)	0 (0%)	3 (13.63%)	0 (0%)	0 (0%)
(8) Failing to store Schedule 1 poison in a receptacle solely for that purpose 沒有將附表1的毒藥貯存於專門的盛器內	1 (1.25%)	4 (12.12%)	0 (0%)	1 (2.5%)	0 (0%)
(9) 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	2 (2.5%)	0 (0%)	0 (0%)	2 (5%)	3 (9.68%)

Statistical Tables and Charts
統計圖表

Table 表 12 (Con't) 續

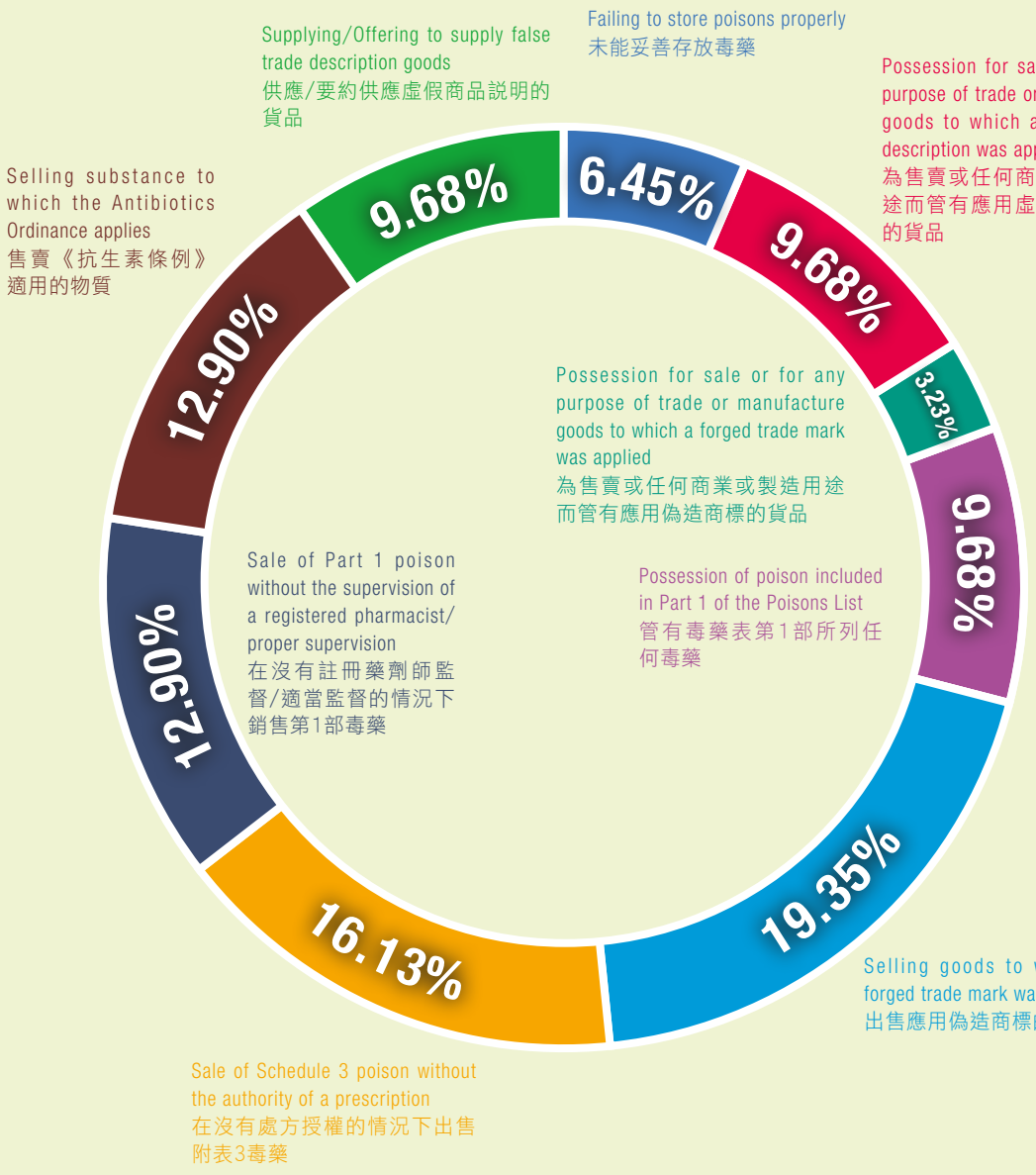
Nature of offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2012	2013	2014	2015	2016
(10) Possession for sale or for any purpose of trade or manufacture goods to which a forged trade mark was applied 為售賣或任何商業或製造用途而管有應用偽造商標的貨品	1 (1.25%)	3 (9.09%)	5 (22.72%)	2 (5%)	1 (3.23%)
(11) Unlawful sale of Part 1 poison 非法銷售第1部毒藥	0 (0%)	6 (18.18%)	0 (0%)	0 (0%)	0 (0%)
(12) Selling substance to which the Antibiotics Ordinance applies 售賣《抗生素條例》適用的物質	1 (1.25%)	0 (0%)	3 (13.63%)	0 (0%)	4 (12.9%)
(13) Failing to store poisons properly 未能妥善存放毒藥	5 (6.25%)	0 (0%)	0 (0%)	9 (22.5%)	2 (6.45%)
(14) Illegal sale of unregistered pharmaceutical product 非法銷售未經註冊的藥劑製品	4 (5%)	0 (0%)	0 (0%)	2 (5%)	0 (0%)
(15) Selling unlabelled pharmaceutical product 售賣沒有加上標籤的藥劑製品	2 (2.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(16) Supplying/Offering to supply false trade description goods 供應/要約供應虛假商品説明的貨品	1 (1.25%)	1 (3.03%)	0 (0%)	0 (0%)	3 (9.68%)
(17) Failing to seek prior approval from the Pharmacy and Poisons Board for change in the ownership/directorship or person-in-charge of the authorized seller of poisons 獲授權毒藥銷售商未事先獲得藥劑業及毒藥管理局的批准，更改了擁有人/董事或負責人	1 (1.25%)	0 (0%)	0 (0%)	1 (2.5%)	0 (0%)
(18) Selling goods to which a forged trade mark was applied 出售應用偽造商標的貨品	0 (0%)	1 (3.03%)	0 (0%)	0 (0%)	6 (19.35%)

* Some cases involve multiple nature of offences
* 部份個案涉及多個罪行

Statistical Tables and Charts
統計圖表

Table 表 12A

Disciplinary Inquiries into Authorized Sellers of Poisons in 2016
2016 年有關獲授權毒藥銷售商的紀律研訊個案



Statistical Tables and Charts
統計圖表

Table 表 13

Number of Listed Sellers of Poisons in Hong Kong
香港的列載毒藥銷售商數目

Year 年份	2012	2013	2014	2015	2016
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	3,827	3,907	3,951	4,012	3,937

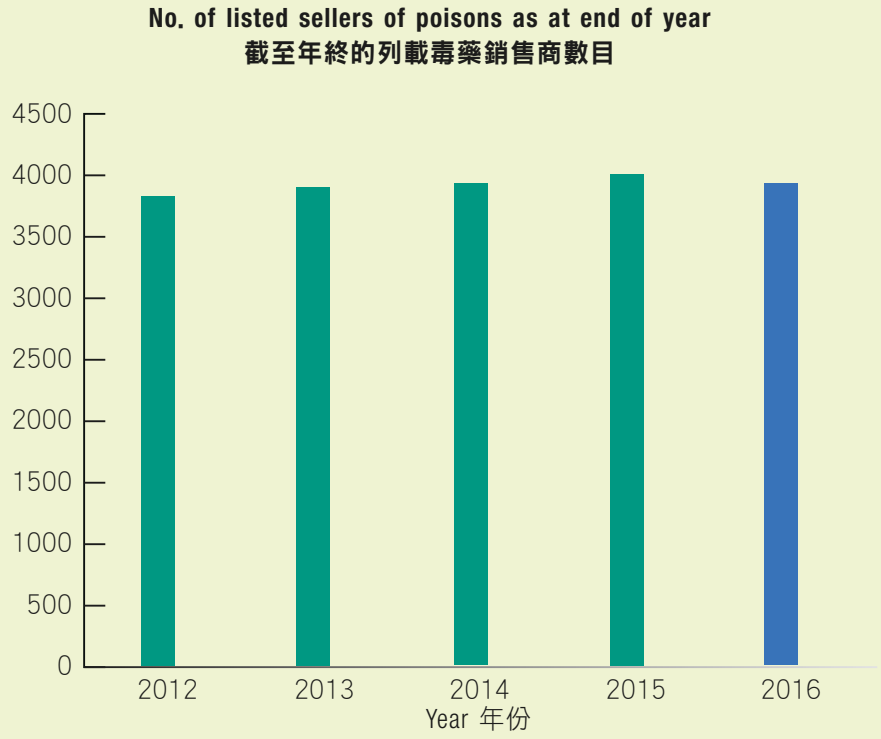


Table 表 14

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

Year 年份	2012	2013	2014	2015	2016
No. of applications approved 接納列載毒藥銷售商的牌照申請數目	375	701	311	277	231
No. of applications rejected 拒絕列載毒藥銷售商的牌照申請數目	5	1	2	2	2

Statistical Tables and Charts
統計圖表

Table 表 15

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

Year 年份	2012	2013	2014	2015	2016
No. of inspections conducted 巡查數目	7,426	7,746	7,878	7,977	7,956
No. of test purchases conducted 試買數目	3,887	1,983	2,601	3,008	4,021

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 採取的紀律行動	Number of cases 個案數目				
	2012	2013	2014	2015	2016
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名單除名	4	1	9	4	4
Issue of written warning 發出書面警告	1	2	2	6	3
Suspension of name from the list of listed sellers of poisons for a specified period of time 暫時吊銷名列列載毒藥銷售商名單內的資格一段時間	N/A 不適用	N/A 不適用	N/A 不適用	0	3
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	3	0	1	1	0
Total 總數	8	3	12	11	10

Statistical Tables and Charts
統計圖表

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 counts (percentage) 次數 (百份比)				
	2012	2013	2014	2015	2016
(1) Sale of Part 1 poison without the supervision of a registered pharmacist/ proper supervision 在沒有註冊藥劑師監督/適當監督的情況下銷售第1部毒藥	1 (11.11%)	0 (0%)	0 (0%)	1 (5.26%)	4 (10.81%)
(2) Sale of Schedule 3 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	1 (11.11%)	0 (0%)	0 (0%)	0 (0%)	3 (8.11%)
(3) Possession of Part 1 poison 管有第1部毒藥	1 (11.11%)	0 (0%)	5 (20%)	4 (21.05%)	6 (16.22%)
(4) Possession of antibiotic 管有抗生素	1 (11.11%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(5) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	0 (0%)	0 (0%)	3 (12%)	0 (0%)	1 (2.7%)
(6) Possession of substances to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	0 (0%)	0 (0%)	4 (16%)	0 (0%)	1 (2.7%)
(7) Possession for sale or for any purpose of trade or manufacture goods to which a forged trade mark 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	5 (55.56%)	1 (11.11%)	6 (24%)	3 (15.79%)	8 (21.63%)
(8) Supplying or offering to supply goods to which false trade descriptions were applied 供應或要約供應已應用虛假商品說明的貨品	0 (0%)	0 (0%)	1 (4%)	0 (0%)	0 (0%)
(9) Publishing an undesirable medical advertisement 發布不良醫藥廣告	0 (0%)	8# (88.89%)	2 (8%)	0 (0%)	0 (0%)

Statistical Tables and Charts
統計圖表

Table 表 17(Con't) 續

Nature of offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2012	2013	2014	2015	2016
(10) 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%)	2 (8%)	2 (10.53%)	0 (0%)
(11) Sale of an unregistered pharmaceutical product 售賣未經註冊藥劑藥品	0 (0%)	0 (0%)	1 (4%)	2 (10.53%)	0 (0%)
(12) Selling goods to which a forged trade mark was applied 售賣應用偽造商標的貨品	0 (0%)	0 (0%)	1 (4%)	1 (5.26%)	7 (18.92%)
(13) Applying a false trade description on goods in the course of any trade or business 在營商過程或業務運作中將虛假商品說明應用於貨品	0 (0%)	0 (0%)	0 (0%)	3 (15.79%)	1 (2.7%)
(14) Sale of Part 2 poison 銷售第2部毒藥	0 (0%)	0 (0%)	0 (0%)	3 (15.79%)	4 (10.81%)
(15) Illegal use of restricted title 非法使用名銜	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.7%)
(16) Illegal use of restricted logo 非法展示標籤	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (2.7%)

* Some cases involve multiple nature of offences

* 部份個案涉及多個罪行

\# Involving 2 Listed Sellers of Poisons for 1 count and 7 counts of same offence

\# 兩名列載毒藥銷售商分別涉及1項及7項該罪行

Statistical Tables and Charts
統計圖表

Table 表 17A

Disciplinary Cases regarding Listed Sellers of Poisons in 2016
2016年有關列載毒藥銷售商的紀律個案

Statistical Tables and Charts
統計圖表

Table 表 18

Issue of Wholesale Poisons Licences/Licensed Wholesale Dealers*
毒藥批發牌照/批發商牌照*的簽發

Year 年份	2012	2013	2014	2015	2016
No. of holders of wholesale poisons licences / licensed wholesale dealers as at end of year 截至年終的毒藥批發牌照/ 批發商牌照持有人的數目	737	714	727	797	779
No. of wholesale poisons licences/licensed wholesale dealers revoked/suspended 撤銷或吊銷毒藥批發牌照/批發商牌照的數目	2	1	1	1	1

* With effect from 6 February 2015, the wholesale dealer licence was introduced to replace the wholesale poisons licence and certificate of registration as an importer/exporter of pharmaceutical products. Holders of valid wholesale poisons licence or certificate of registration of importers and exporters are regarded as licensed wholesale dealers until the expiry of their licences or certificates.

* 由2015年2月6日起，批發商牌照已推出，以取代毒藥批發牌照及進/出口商註冊證明書。持有有效期毒藥批發牌照或進口商及出口商註冊證明書的人士，在其牌照或註冊證明書失效前，將會被視為持牌批發商。

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	2012	2013	2014	2015	2016
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	37	63#	94#	80#	72#
No. of manufacturer's licences revoked/ suspended 撤銷或吊銷製造商牌照的數目	0	0	0	0	0

* With effect from 1 October 2015, all licensed manufacturers were required to fully comply with the PIC/S GMP.

* 由2015年10月1日起，所有持牌製造商必須完全符合國際醫藥品稽查協約組織的生產質量管理規範指引。

\# There were 27, 63, 57 and 49 holders who were authorized to conduct secondary packing of pharmaceutical products only in 2013, 2014, 2015 and 2016 respectively.

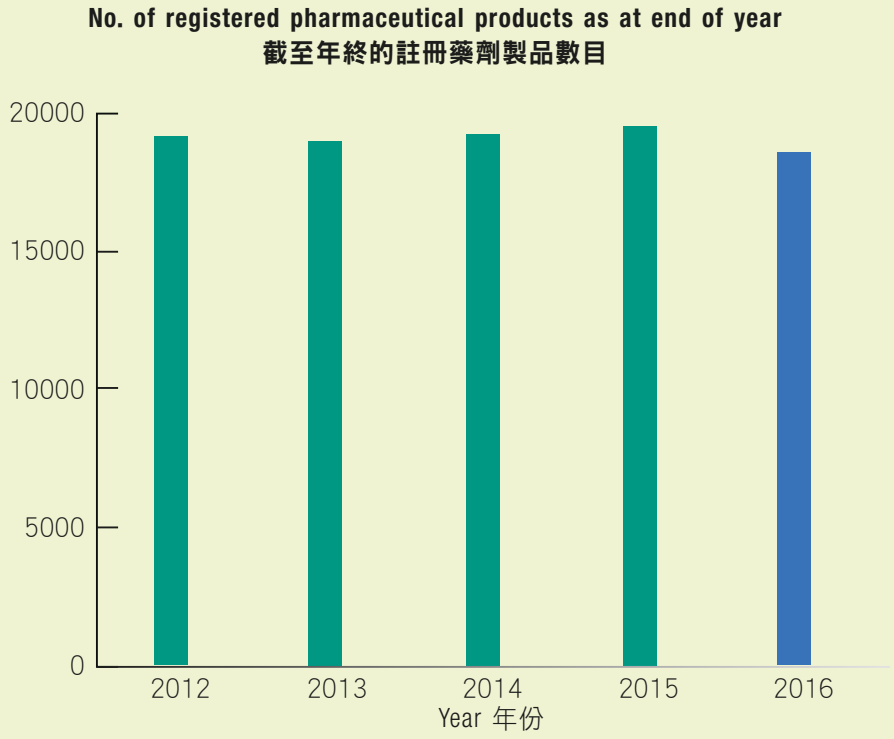
\# 於2013年、2014年、2015年及2016年，分別有27名、63名、57名及49名製造商牌照持有人只獲授權從事藥劑製品外包裝操作。

Statistical Tables and Charts
統計圖表

Table 表 20

Registration of Pharmaceutical Products
藥劑製品的註冊

Year 年份	2012	2013	2014	2015	2016
No. of registered pharmaceutical products as at end of year 截至年終的註冊藥劑製品數目	19,093	18,912	19,209	19,486	18,584



Statistical Tables and Charts
統計圖表

Table 表 21

Amendments to Schedules 1 and 3 to the Pharmacy and Poisons Regulations in 2016
2016年在《藥劑業及毒藥規例》附表1和3作出的修訂

New Substances Added 加入的新物質	
1. Aclidinium, its salt	阿地溴銨；其鹽類
2. Alectinib; its salts	阿來替尼；其鹽類
3. Alirocumab	阿利人單抗
4. Apremilast; its salts	阿瑞司特；其鹽類
5. Asunaprevir; its salt	阿舒瑞韋；其鹽類
6. Bedaquiline; its salts	Bedaquiline；其鹽類
7. Bivalirudin; its salts	比伐蘆定；其鹽類
8. Carfilzomib; its salts	卡非佐米；其鹽類
9. Cobimetinib; its salts	可美替尼；其鹽類
10. Daclatasvir; its salts	達拉他韋；其鹽類
11. Delamanid; its salts	德拉馬尼；其鹽類
12. Dimethyl fumarate when contained in pharmaceutical products	富馬酸二甲脂，但限於包含在藥劑製品內者
13. Edoxaban; its salt	艾多沙班；其鹽類
14. Elotuzumab	依洛珠單抗
15. Evolocumab	依伏庫人單抗
16. Idarucizumab	依達組單抗
17. Lenvatinib; its salts	侖伐替尼；其鹽類
18. Lurasidone; its salts	魯拉西酮；其鹽類
19. Macitentan; its salts	馬昔騰坦；其鹽類
20. Nintedanib; its salts	尼達尼布；其鹽類
21. Olaparib; its salts	奧拉帕利；其鹽類
22. Osimertinib; its salts	奧希替尼；其鹽類

Table 表 21 (Con't) 續

23. Palbociclib; its salts	哌柏西利；其鹽類
24. Panobinostat; its salts	帕比司他；其鹽類
25. Paracetamol when contained in pharmaceutical products for human parenteral administration	對乙醯氨基酚，但限於包含在供注射入人體的藥劑製品內者
26. Ramucirumab	雷莫蘆單抗
27. Sacubitril; its salts	沙庫巴曲；其鹽類
28. Siltuximab	司妥昔單抗
29. Simeprevir; its salts	西美瑞韋；其鹽類
30. Trametinib; its salts	曲莫替尼；其鹽類
Others 其他	
31. Repealed item "Pantoprazole; its salts" and substituted for "Pantoprazole; its salts; except when contained in oral preparations with 20 mg or less per solid dosage unit, indicated with the maximum daily dose of 20 mg for relief of heartburn symptoms associated with acid reflux in patients of 18 years old or above, and in packs with the maximum supply of 7 days"	廢除"泮托拉唑；其鹽類"項目代以"泮托拉唑；其鹽類；但每單一固體劑量包含20毫克或以下的口服製品，並標明每日最高劑量20毫克，供18歲或以上的病人，舒緩胃灼熱症狀相關的胃酸倒流，及包裝大小含有最多7日的供應量除外"
32. Repealed item "Tenofovir; its salt; its esters; their salts" and substituted for "Tenofovir; its salts; its derivatives; their salts"	廢除"替諾福韋；其鹽類；其脂類；它們的鹽類"項目代以"替諾福韋；其鹽類；其衍生物；它們的鹽類"

Statistical Tables and Charts
統計圖表

Table 表 22

Amendments to Part 1 of Schedule 10 to the Pharmacy and Poisons Regulations in 2016
2016年在《藥劑業及毒藥規例》附表10第1部作出的修訂

New Substances Added 加入的物質	
1. Aclidinium, its salt	阿地溴銨；其鹽類
2. Alectinib; its salts	阿來替尼；其鹽類
3. Alirocumab	阿利人單抗
4. Apremilast; its salts	阿瑞司特；其鹽類
5. Asunaprevir; its salt	阿舒瑞韋；其鹽類
6. Bedaquiline; its salts	Bedaquiline；其鹽類
7. Bivalirudin; its salts	比伐蘆定；其鹽類
8. Carfilzomib; its salts	卡非佐米；其鹽類
9. Cobimetinib; its salts	可美替尼；其鹽類
10. Daclatasvir; its salts	達拉他韋；其鹽類
11. Delamanid; its salts	德拉馬尼；其鹽類
12. Dimethyl fumarate when contained in pharmaceutical products	富馬酸二甲脂，但限於包含在藥劑製品內者
13. Edoxaban; its salt	艾多沙班；其鹽類
14. Elotuzumab	依洛珠單抗
15. Evolocumab	依伏庫人單抗
16. Idarucizumab	依達組單抗
17. Lenvatinib; its salts	侖伐替尼；其鹽類
18. Lurasidone; its salts	魯拉西酮；其鹽類
19. Macitentan; its salts	馬昔騰坦；其鹽類
20. Nintedanib; its salts	尼達尼布；其鹽類
21. Olaparib; its salts	奧拉帕利；其鹽類
22. Osimertinib; its salts	奧希替尼；其鹽類

Table 表 22 (Con't) 續

23. Palbociclib; its salts	哌柏西利；其鹽類
24. Panobinostat; its salts	帕比司他；其鹽類
25. Paracetamol when contained in pharmaceutical products for human parenteral administration	對乙醯氨基酚，但限於包含在供注射入人體的藥劑製品內者
26. Ramucirumab	雷莫蘆單抗
27. Sacubitril; its salts	沙庫巴曲；其鹽類
28. Siltuximab	司妥昔單抗
29. Simeprevir; its salts	西美瑞韋；其鹽類
30. Trametinib; its salts	曲莫替尼；其鹽類
Others 其他	
31. Repealed item "Tenofovir; its salt; its esters; their salts" and substituted for "Tenofovir; its salts; its derivatives; their salts"	廢除"替諾福韋；其鹽類；其脂類；它們的鹽類"項目代以"替諾福韋；其鹽類；其衍生物；它們的鹽類"