Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

Annual Report 2014 年報

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Message from the Chairman
主席獻辭

The Pharmacy and Poisons Board ("the Board") had undergone another eventful year in 2014 in the discharge of its statutory functions empowered by the Pharmacy and Poisons Ordinance (Cap.138, Laws of Hong Kong).

As part of our effort to strengthen the regulation of pharmaceutical products and to implement the recommendations of the Review Committee on Regulation of Pharmaceutical Products in Hong Kong which required legislative amendment to the Pharmacy and Poisons Ordinance, the Pharmacy and Poisons (Amendment) Bill 2014 was introduced into the Legislative Council (LegCo) on 26 March 2014. By the end of 2014, the Bills Committee concluded its deliberation and raised no objection to the resumption of the Second Reading on the Bill at the LegCo meeting of 21 January 2015.

In parallel, the Board continued with the drafting of the codes of practice for various pharmaceutical traders and the code of conduct for registered pharmacists. These codes set out to provide practical guidance to traders and personnel working in the pharmaceutical industry to follow in order to enhance the quality of their services to the community and to attain a high quality standard in their practice. Besides, the codes of practice were drafted based on the legal requirements of the Pharmacy and Poisons Ordinance and other drug-related legislations, as well as professional good practice standards in other countries.

As part of the upgrade in the Hong Kong's Good Manufacturing Practice (GMP) standard, the Pharmacy and Poisons (Manufacturers Licensing) Committee has decided that all licensed manufacturers were required to fully comply with the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP Guide with effect from 1 October 2015. Furthermore, to assist the local pharmaceutical manufacturers in their upgrade to PIC/S standards, some Guidance Notes have been prepared and uploaded onto the website of the Drug Office of the Department of Health, to provide guidance in the areas of contract testing laboratories, quality risk management, product quality review, etc.

In addition, for the protection of public health, the safety and benefits of medicines in the market were continuously monitored and reviewed. In this connection, the Board de-registered oral ketoconazole products and rectal domperidone products in July and October 2014 respectively after taking into consideration that their benefits did not outweigh their risks. Besides, the sales control of oral domperidone products were strengthened by being reclassified from Part 1 poisons (i.e. pharmacy medicines) to Schedule 1, Schedule 3 and Part 1 of Schedule 10 poisons (i.e. prescription medicines).

Furthermore, the Board had begun a series of reviews with proposals to strengthen the registration requirements of pharmaceutical products, which included the endorsement of the World Health Organization guidelines and acceptance limits for the evaluation of bio-availability and bio-equivalence (BABE) studies in Hong Kong as well as consultation with the stakeholder groups on the draft registration guidelines for biosimilar products.

Moreover, to facilitate the process of applications for clinical trial certificate, the Board adopted the definition of clinical trial of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Besides, a new scheme for applications of clinical trial certificate using a risk-based approach was introduced on 1 May 2014 in determining the different levels of application documents required.

I am privileged to have the support and assistance of the Members of the Board and its committees in achieving better health protection. I would like to take this opportunity to thank Members for their unfailing contribution and commitment in the past years. In the coming years, the Board will continue the mission of maintaining a high standard of healthcare services to the community.

Dr Constance CHAN
Chairman
Pharmacy and Poisons Board

二零一四年，本局繼續致力執行香港法例第138章《藥劑業及毒藥條例》所訂明的各項法定職能，績效斐然，成果豐碩。

為了加強規管藥劑製品和落實香港藥物監管制度檢討委員會就《藥劑業及毒藥條例》提出的修訂建議，政府於二零一四年三月二十六日向立法會提交《2014年藥劑業及毒藥(修訂)條例草案》。法案委員會已於二零一四年年底前完成審議工作，也不反對在二零一五年一月二十一日的立法會會議上恢復該條例草案的二讀。

與此同時，本局繼續為不同藥劑業界人士草擬執業守則，以及為註冊藥劑師擬訂專業守則。制訂這些守則的目的，是為藥劑業界和從業員提供實務指引，讓他們得以遵從，提升向市民提供服務的質素，並達至高執業水平。此外，本局在草擬執業守則時，也參考了《藥劑業及毒藥條例》和其他藥物相關法例的規定，以及其他國家的專業規範標準。

為了提升香港藥劑製品生產質量管理規範標準，藥劑業及毒藥(製造商牌照)委員會已決定由二零一五年十月一日起，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。為此，本局就合約檢測實驗所、質量風險管理、產品質量覆檢等範疇擬備了指引，並上載至衞生署藥物辦公室網站，以助本地藥劑製造商提升至協約組織訂明的標準。

另一方面，本局持續監察和檢視市面上所出售藥物的安全及成效，以保障市民健康。就此，本局經考慮口服酮康唑產品和肛門用多潘立酮產品的效益低於風險後，分別於二零一四年七月和十月取消該等產品的註冊。此外，本局亦加強管制口服多潘立酮產品的銷售情況，把該項產品重新分類，由屬第1部列明毒藥(即藥房專售藥物)，轉作屬附表1、附表3及附表10第1部列明毒藥(即處方藥物)。

年內，本局展開了一系列的檢討，並提出多個方案來加強藥劑製品的註冊規定。有關工作包括通過在評估香港藥劑製品的生物利用度和生物等效性研究時，須採用世界衞生組織所制訂的指引和可接受限度；以及就生物相似製劑註冊指引的草擬本諮詢相關團體。

為方便處理臨牀試驗證明書的申請，本局已採納人用藥品註冊技術要求國際協調會議就臨牀試驗所下的定義，並由二零一四年五月一日起推行新計劃，在處理臨牀試驗證明書的申請時，採用以風險為本的方法來決定申請人須提交文件的類別。

多年來，本局及轄下各委員會的成員均悉力以赴，使市民健康得到更佳的保障。本人謹此衷心致謝。展望將來，本局會繼續履行使命，確保市民繼續獲得優質的醫護服務。

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 2014. 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 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」)在二零一四年的工作。管理局希望透過這份年報，使所有註冊藥劑師以及藥劑業有關人士及團體了解管理局的職能及在這年內的工作；同時亦扼要介紹根據《藥劑業及毒藥條例》第30條成立的藥劑業及毒藥上訴審裁處的工作。

為使讀者可以更容易掌握有關內容，年報內對管理局及其轄下的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

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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 LAU Chau-ming, JP
劉秋銘博士

Ms Linda WOO
吳婉宜女士

Dr Cindy LAI, JP
黎潔廉醫生

Miss CHAN Oi-lai, Michelle
(Legal Adviser)
陳愛麗女士 (法律顧問)

Professor WONG Chi-kei, Ian
黃志基教授

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 CHEUNG Hon-ming
張漢明醫生

(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 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 2014 was as follows:

(a) Dr Constance CHAN, JP (Chairman)
(b) Dr LAU Chau-ming, JP
(c) Ms Linda WOO
(d) Dr Cindy LAI, JP
(e) Miss CHAN Oi-lai, Michelle (Legal Adviser)
(f) Professor WONG Chi-kei, Ian
(g) Professor LEE Wing-yan, Vivian
(h) Ms CHIANG Sau-chu
Mr KWONG Yiu-sum, Benjamin
Mr WONG Ka-kin, Andy
(i) Dr CHEUNG Hon-ming

Secretary
Miss Maggie CHOW

(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)。

在二零一四年十二月三十一日，管理局的成員計有：

(a) 陳漢儀醫生(主席)
(b) 劉秋銘博士
(c) 吳婉宜女士
(d) 黎潔廉醫生
(e) 陳愛麗女士(法律顧問)
(f) 黃志基教授
(g) 李詠恩教授
(h) 蔣秀珠女士
鄺耀深先生
黃家健先生
(i) 張漢明醫生

秘書
周韻琴女士

(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 2014

Professor WONG Chi-kei, Ian (Chairman)

Dr LAU Chau-ming, 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) 截至二零一四年十二月三十一日的成員名單

黃志基教授 (主席)

劉秋銘博士

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 2014

Ms Linda WOO (Chairman)
Mr CHAN Wing-kai
Mr HUI Siu-chor, Samuel
Mr NG Yick-hung, Eddie
Mr TAM Hung-pun
Ms TANG Mui-fun
Mr WONG Yim-pui
Ms Pamela LI (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 2014

Ms Linda WOO (Chairman)
Mr CHIU Kwok-leung, Philip
Mr LAU Kwok-fai, Andy
Mr LAU Oi-kwok
Mr LEUNG Chi-ming
Mr Andrew WONG
Mr LAU Ka-wing (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) 截至二零一四年十二月三十一日的成員名單

吳婉宜女士(主席)
陳永佳先生
許肇礎先生
吳奕鴻先生
譚鴻彬先生
鄧梅芬女士
黃炎沛先生
李文蓓女士(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) 截至二零一四年十二月三十一日的成員名單

吳婉宜女士(主席)
趙國亮先生
劉國輝先生
劉愛國先生
梁志明先生
黃志賢先生
劉家榮先生(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。

(4) Pharmacy and Poisons (Manufacturers Licensing) Committee

(i) Membership as at 31 December 2014

Ms Linda WOO (Chairman)

Ms Sabrina CHAN

Dr Celine CHENG

Mrs Mary CHENG

Dr LAU Ying-kei, Henry

Mr TSUI Kai-hung, William

Dr WONG Sai-yin, Samson

Dr WONG Yiu-chung

Dr Ken YEUNG

Mr Edwin LAM (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 2014

Ms Linda WOO (Chairman)

Dr CHANG Chee-siu

Professor CHEUNG Man-yung, Bernard

Dr CHUK Sheung-ying, Shirley Veronica

Dr KWAN Wing-hong

Dr LAU Chau-ming, JP

Dr LIM Wei-ling, Wilina, JP

Ms Teresa NGAN

Dr TAM Cheuk-ming, JP

Mr Clive CHAN (Secretary)

(4) 藥劑業及毒藥 (製造商牌照) 委員會

(i) 截至二零一四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

鄭陳佩華女士

劉應機博士

徐啓雄先生

黃世賢博士

黃耀松博士

楊樹英博士

林豐盛先生(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》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) 截至二零一四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

張文勇教授

竺湘瑩獸醫

關永康醫生

劉秋銘博士

林微玲醫生

顏文珊女士

譚卓明醫生

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 carries out the following functions in accordance with Part 8 of the Pharmacy and Poisons Regulations:

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

(b) deregister any pharmaceutical product or substance;

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

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

(6) Poisons Committee

(i) Membership as at 31 December 2014

Dr LAU Chau-ming, JP (Chairman)

Dr CHEUNG Hon-ming

Ms CHIANG Sau-chu

Mr KWONG Yiu-sum, Benjamin

Professor WONG Chi-kei, Ian

Ms Linda WOO

Ms Alice TANG (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 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.

(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8部所述的職能：

(a) 簽發藥劑製品或物質註冊證明書；

(b) 撤銷藥劑製品或物質的註冊；

(c) 考慮有關更改藥劑製品或物質註冊詳情的申請；及

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

(6) 毒藥委員會

(i) 截至二零一四年十二月三十一日的成員名單

劉秋銘博士(主席)

張漢明醫生

蔣秀珠女士

鄺耀深先生

黃志基教授

吳婉宜女士

鄧淑雯女士(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《毒藥表規例》及《藥劑業及毒藥規例》管制的藥劑製品的分類。

(7) Pharmacy Internship Training Committee

(i) Membership as at 31 December 2014

Professor WONG Chi-kei, Ian (Chairman)
Mr Frank CHAN
Ms Victoria CHAN
Dr Celine CHENG
Mr CHIU Kwok-leung, Philip
Dr HO Suk-san, Susan
Mr Antonio KWONG
Dr LAU Chau-ming, JP
Ms Anna LEE
Professor LEE Wing-yan, Vivian
Dr NG Chor-shan, Sian
Dr NG Ping-sum, Sammy
Ms Linda WOO
Ms Alice TANG (Secretary)

(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.

(7) 藥劑師實習培訓委員會

(i) 截至二零一四年十二月三十一日的成員名單

黃志基教授 (主席)
陳凌峯先生
陳慧琪女士
鄭香郡博士
趙國亮先生
何淑珊博士
鄺祖盛先生
劉秋銘博士
李詩詠女士
李詠恩教授
吳楚珊博士
吳秉琛醫生
吳婉宜女士
鄧淑雯女士(秘書)

(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 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) 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 2014. A total of 80 applicants cumulatively passed all the three subjects in the year 2014.

The results of these two registration examinations are shown in Table 1. Figures for the years 2010 to 2014 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.

(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) 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。

考試委員會在二零一四年分別在六月及十二月舉辦了兩次註冊考試。同年共有80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，以及二零一零年至二零一四年的有關數字，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 2,390 registered pharmacists were issued with practising certificates in the year 2014. Statistical data regarding registration of pharmacists and breakdown of fresh registration, removal from and restoration to the register of pharmacists for the years 2010 to 2014 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 is given in pages 22 to 23 of this report.

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in the years 2010 to 2014 are shown in Tables 4, 5 and 6.

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條的規定取得週年執業證明書。在二零一四年，共有2,390位註冊藥劑師獲發執業證明書。表2及3列出二零一零年至二零一四年有關藥劑師註冊，以及新註冊、刪除註冊及重新註冊的分項數字的統計資料。

(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22至23頁。

表4、5及6詳列管理局在二零一零年至二零一四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. 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 605 ASPs registered in Hong Kong as at end of year 2014. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of an ASP in the years 2010 to 2014 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。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《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。

截至二零一四年年終，香港共有605名獲授權毒藥銷售商。表7及8詳列二零一零年至二零一四年獲授權毒藥銷售商的總數、處所註冊申請及註冊續期申請的統計數字。

(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 to disqualification from being an ASP for a specified period of time.

Eight inquiries were held in the year of 2014 and eight ASPs were found guilty of misconduct. An ASP was issued with written warning whilst the remaining seven ASPs were disqualified from being an ASP for a period of time.

For minor infringement, the Board may decide not to initiate any disciplinary inquiry but direct the Assistant Director (Drug) 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 12 such interviews were held in the year 2014.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in the years 2010 to 2014 is shown in Table 9.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in the years 2010 to 2014 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，由書面警告以至在指定期間被吊銷銷售商資格不等。

在二零一四年，管理局舉行了8次紀律研訊及8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1名發出書面警告，其餘7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，管理局或會決定不展開紀律研訊，但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。管理局在二零一四年舉行了12次該類會面。

表9列出二零一零年至二零一四年由藥劑師督察對獲授權毒藥銷售商進行巡查及試買的數字。

表10、11、12及12A詳列二零一零年至二零一四年管理局處理有關獲授權毒藥銷售商的紀律個案的統計數字。

(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 3,951 LSPs as at end of year 2014. The number of licensed LSPs in the years 2010 to 2014 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 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 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 2010 to 2014 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。

截至二零一四年年終，香港共有3,951名列載毒藥銷售商。表13列出二零一零年至二零一四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。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列出二零一零年至二零一四年由藥劑師督察對列載毒藥銷售商進行巡查以及試買的數字。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 1 of the Poisons List. Sales are restricted to authorized persons only.

There were 727 holders of a wholesale poisons licence as at end of year 2014. Statistical data for the years 2010 to 2014 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.

(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1部所列毒藥的交易記錄，而銷售對象只限於獲授權人士。

截至二零一四年年終，香港共有727名毒藥批發牌照持有人。表18列出二零一零年至二零一四年的統計數字。

(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 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.

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 94 holders of a manufacturer's licence as at end of year 2014, of which 24 of them were in compliance with the Hong Kong Good Manufacturing Practices Guidelines for Pharmaceutical Products. Among the 94 holders, 63 holders of them were authorized to conduct secondary packaging of pharmaceutical products only. Statistical data for the years 2010 to 2014 are given in Table 19.

(iii) 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 should 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 90 holders of a registration certificate for importer and exporter of pharmaceutical products as at end of year 2014. Statistical figures for the years 2010 to 2014 are shown in Table 20.

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。

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。

截至二零一四年年終，香港共有94名製造商牌照持有人，當中有24名符合香港藥劑製品生產質量管理規範指引；63名只獲授權從事藥劑製品外包裝操作。表19列出二零一零年至二零一四年的統計數字。

(iii) 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。

截至二零一四年年終，香港共有90名藥劑製品進出口商證明書持有人。表20列出二零一零年至二零一四年的統計數字。

(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 19,209 registered pharmaceutical products in Hong Kong as at end of year 2014. The number of registered pharmaceutical products as at end of years 2010 to 2014 is shown in Table 21.

(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。

一經註冊，申請者會獲發註冊證明書，並獲告知產品的分類。

截至二零一四年年終，香港共有19,209種已註冊的藥劑製品。表21列出截至二零一零年至二零一四年年終的註冊藥劑製品數字。

(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 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 Poisons List	They can be sold only by authorized sellers of poisons under the supervision of registered pharmacists.
(b) **Schedule 1 Poisons:** Poisons included in Part 1 of the 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. 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) **Schedule 3 Poisons:** Poisons included in Part 1 of the 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 Poisons List	They can be sold by authorized sellers of poisons and listed sellers of poisons without the supervision of registered pharmacists.

(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：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。
(b) 第1部附表1毒藥：同時列於毒藥表第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。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1部附表3毒藥：同時列於毒藥表第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：毒藥表第2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。

Classification and distribution in the Poisons List and imposition of control through the two schedules were 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 2014 included adding 11 new substances to Part 1 of the Poisons List Regulations and to the Schedules 1 and 3 to the Pharmacy and Poisons Regulations respectively. Two lists of these substances are at Tables 22 and 23 respectively.

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

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。立法會在二零一四年批准管理局就藥劑製品分類對《毒藥表規例》和《藥劑業及毒藥規例》作出修訂：分別在《毒藥表規例》第1部和《藥劑業及毒藥規例》附表1及附表3內加入11種新的物質。這些物質分別列載於表22和23。

《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》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

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 2014, 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 2014 included:

Mr CHONG Tang-lung

Ms CHEW Leng-leng

Mr HO Hon-fai

Mr LEE Pak-hei

Mr LEUNG Kwong-hei, Kenneth

Mr NG Wing-yan

Mr NG Yu-chau, Patrick

Ms WONG Yuen-yin, Clara

Mr WU Siu-lung

Mr YAU Fuk-loi, Rico

(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二零一四年十二月三十一日的主席。曾在二零一四年出任成員的註冊藥劑師包括：

莊騰龍先生

周凌綾女士

何漢輝先生

李伯熙先生

梁廣熙先生

吳榮恩先生

吳如就先生

黃婉妍女士

胡少龍先生

邱福來先生

(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 poisons (ASP) or its partner or employee; or

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

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

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

(a) censure the registered pharmacist; or

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

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

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

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

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

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

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 for the past five years from 2010 to 2014.

(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) 當管理局認為有需要或適宜就任何該等人士或團體的行為操守進行研訊。

如研訊對象是註冊藥劑師，紀律委員會可在研訊完結時：

(a) 譴責該名註冊藥劑師；或

(b) 在紀律委員會指示的期間內，將其姓名從藥劑師名冊中刪除。

至於獲授權毒藥銷售商，紀律委員會可在研訊完結時作出下列指示：

(a) 在某一指定的期間內，取消該團體作為獲授權毒藥銷售商的資格；或

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

(c) 向該獲授權毒藥銷售商發出書面警告。

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

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。由二零一零年至二零一四年，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 2014 was as follows:

Name	Membership
Ms WONG Kwok-ying, Lisa, S.C.	Chairman
Dr WONG Koon-sang	Member
Dr LEE Chui-ping	Member
Professor CHAN Yan-keung, Thomas, BBS, JP	Member
Mr CHUI Chun-ming, William	Panel Member
Miss LEUNG Sik-yin, McShirley	Panel Member
Dr SUNG Kai-wing	Panel Member
Mr CHEUNG Yiu-kwong	Panel Member
Ms FAN Yuen-sze	Panel Member
Mr TSE Kin-on, Andrew	Panel Member
Mr HO Po-man	Panel Member
Mr LAU Oi-kwok	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。

在二零一四年十二月三十一日，審裁處的成員如下：

姓名	成員
黃國瑛女士	主席
王冠生醫生	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
梁錫燕女士	小組委員
宋佳穎博士	小組委員
張耀光先生	小組委員
范遠詩女士	小組委員
謝建安先生	小組委員
何保民先生	小組委員
劉愛國先生	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 for the past five years from 2010 to 2014.

(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。

由二零一零年至二零一四上訴審裁處沒有研訊上訴個案。

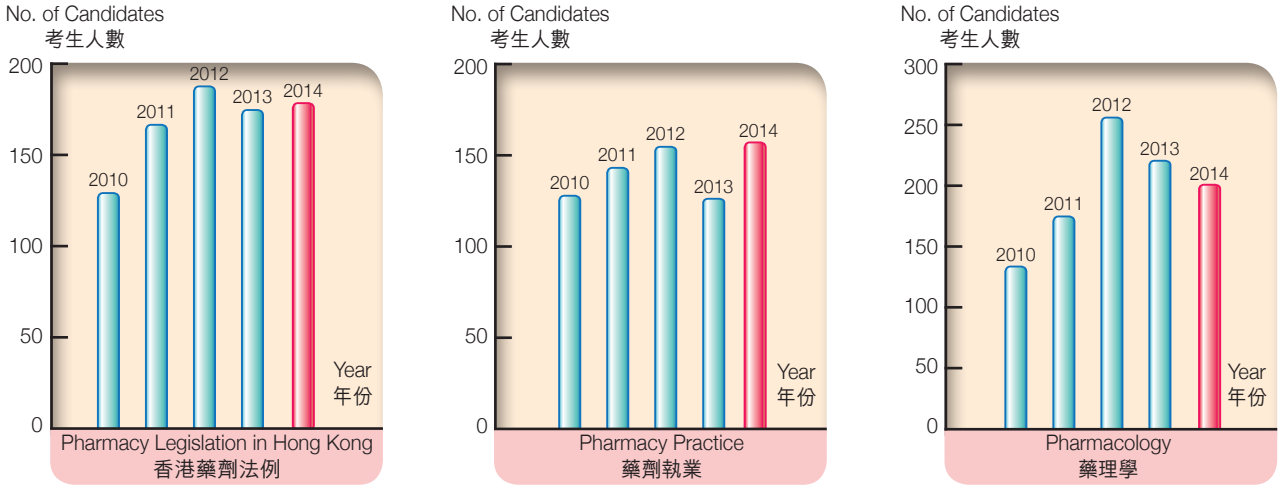
Statistical Tables and Charts
統計圖表

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
2010	130	78	60	130	92	70.8	135	75	55.6
2011	167	72	43.1	144	104	72.2	176	49	27.8
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

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

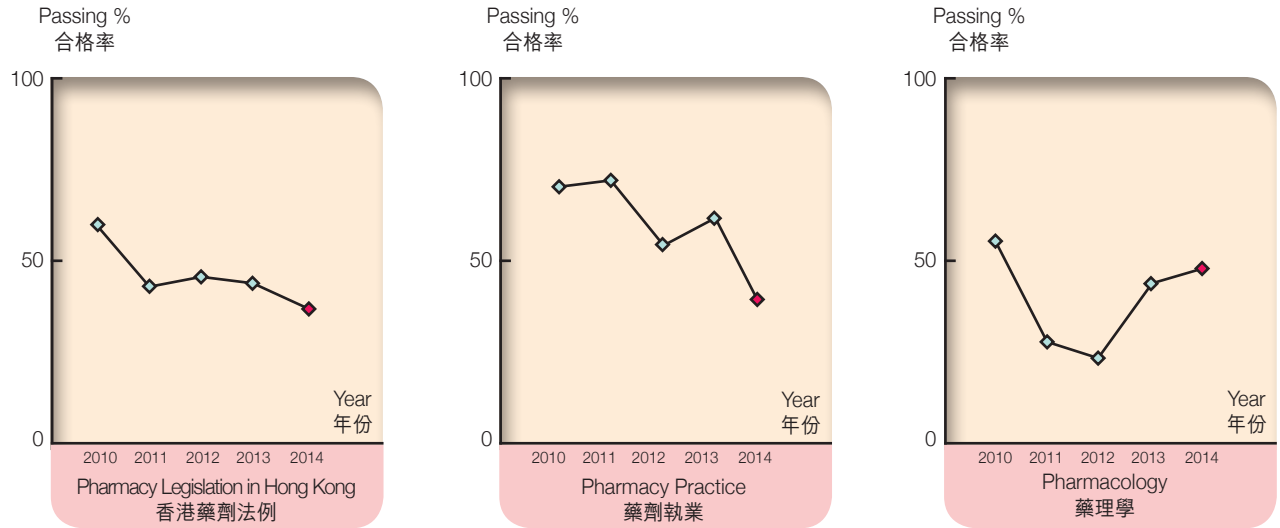


Table 表 2

Number of Registered Pharmacists in Hong Kong 香港註冊藥劑師人數					
Year 年份	2010	2011	2012	2013	2014
No. of registered pharmacists as at end of year 截至年終的註冊藥劑師人數	1,954	2,050	2,127	2,285	2,390

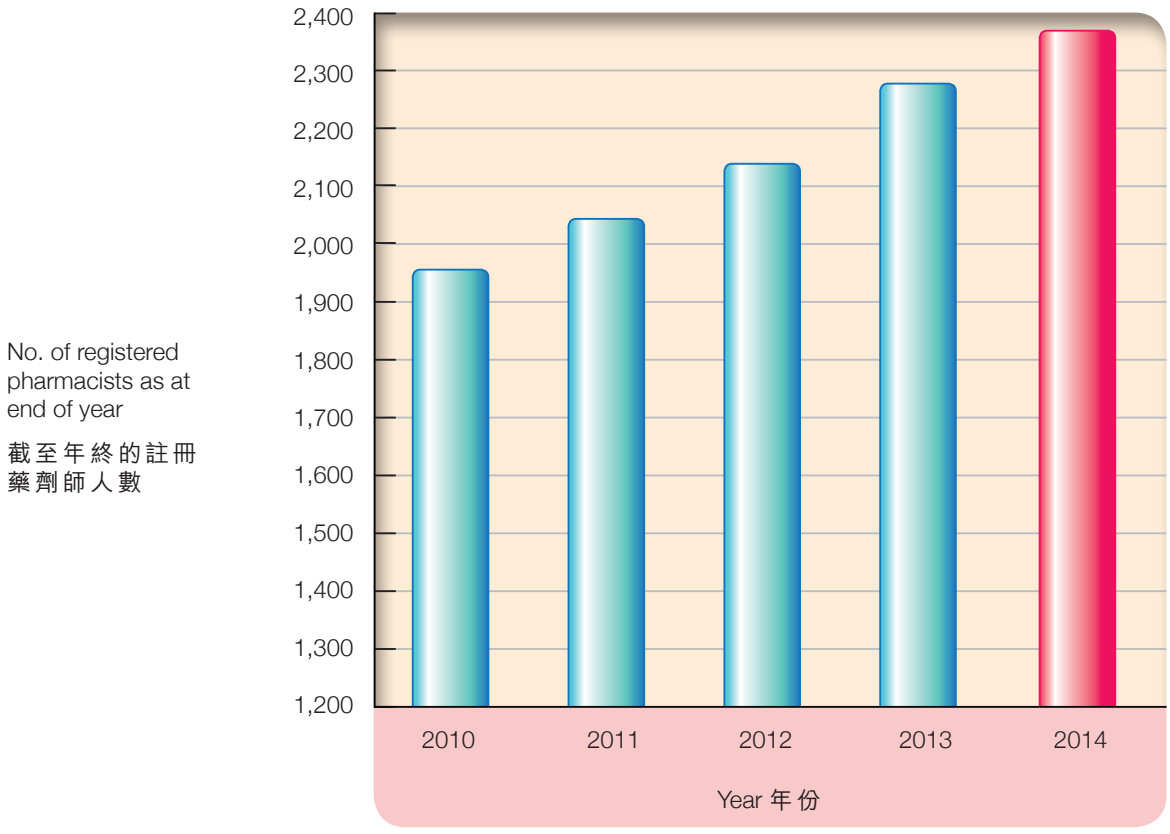


Table 表 3

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	2010	2011	2012	2013	2014
Fresh registration (Non-local graduates) 新註冊(非本地畢業)	57	68	52	107	63
Fresh registration (Local graduates) 新註冊(本地畢業)	27	35	26	57	51
Removal from the register* 刪除註冊*	10	11	10	10	14
Restoration to the register 重新註冊	2	4	9	4	5
Net increase 淨增長	76	96	77	158	105

*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				
	2010	2011	2012	2013	2014
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)	3	1	4	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				
	2010	2011	2012	2013	2014
Charge dismissed 指控不成立	0	1	0	0	0
Guilty of the charge 指控成立	3	0	4	1	1
Directions of the Disciplinary Committee 紀律委員會的指示					
Censure 譴責	2	0	3	0	1
Removed from the register for a period of time 由名冊除名一段時間	1	0	1	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 counts 次數				
	2010	2011	2012	2013	2014
(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	0	0	1	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	1	0	0
(3) Failing to store Schedule 1 poison in a receptacle reserved solely for the storage of poisons, which receptacle shall be locked with an adequate lock the key for which shall be retained by the registered pharmacist 沒有將附表1的毒藥貯存於專門的盛器內,而該盛器須以完備的鎖鎖上,並且由註冊藥劑師保管該鎖的鑰匙	1	1	0	0	0
(4) Failing to keep proper records of dangerous drugs 沒有備存有關危險藥物的登記冊或紀錄	1	0	0	0	0
(5) Behaving in a disorderly manner in public place 在公眾地方作出擾亂秩序的行為	0	0	2	0	0
(6) Manufacturing pharmaceutical product without a licence 沒有牌照而製造藥劑製品	0	0	21#	0	0

Table 表 6 (Con't) (續)

Nature of offences* 個案性質*	Number of counts 次數				
	2010	2011	2012	2013	2014
(7) Fraud 欺詐案	0	0	0	1	0
(8) 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	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

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	2010	2011	2012	2013	2014
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	546	557	570	597	605

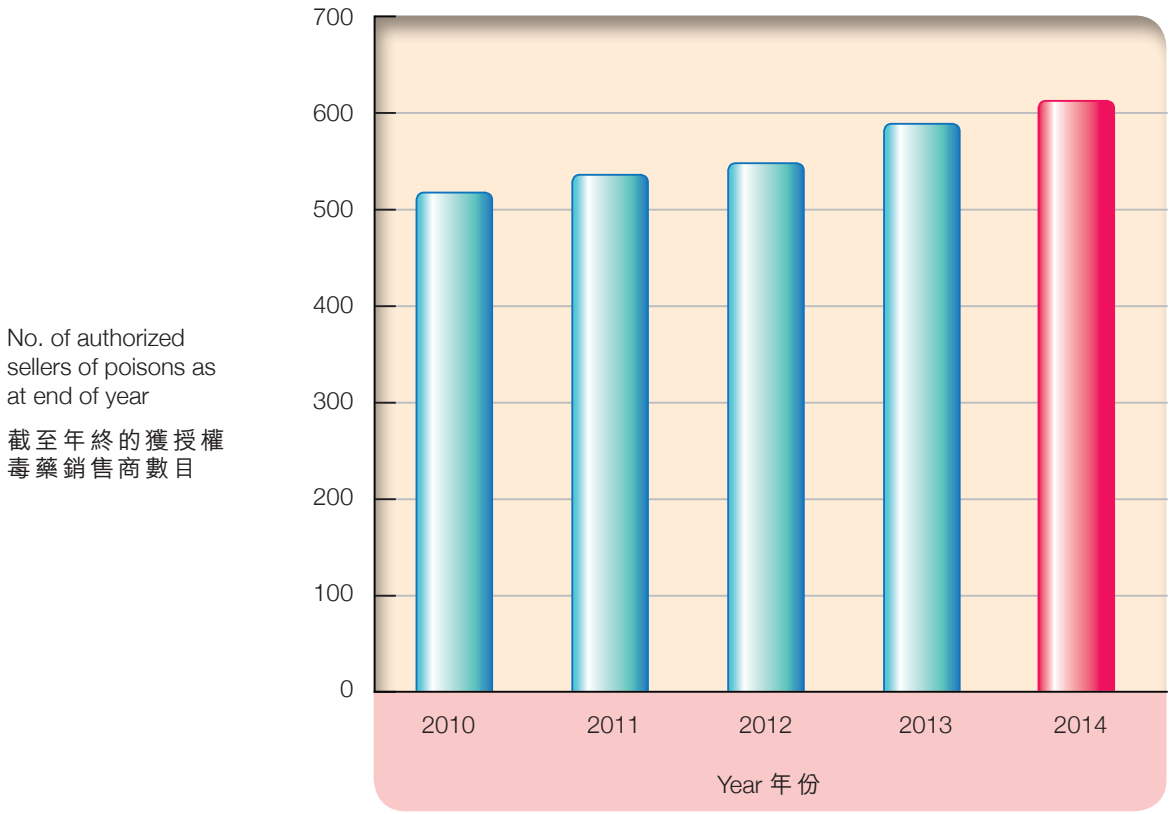


Table 表 8

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	2010	2011	2012	2013	2014
No. of applications for registration of premises approved 接納處所註冊申請的數目	67	47	45	106	39
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	2	1	0	0	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	2010	2011	2012	2013	2014
No. of inspections conducted 巡查數目	960	1,138	1,222	1,186	1,229
No. of test purchases conducted 試買數目	2,360	3,863	5,942	5,707	4,363

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				
	2010	2011	2012	2013	2014
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)	21	21	20	10	8
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)	31	19	25	13	12
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	0	0
The authorized seller of poisons ceased operation during the course of inquiry 該銷售商於紀律研訊過程中結業	1	0	0	0	0
Total 總數	53	40	45	23	20

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				
	2010	2011	2012	2013	2014
Charge dismissed 指控不成立	1	2	0	0	0
Guilty of the charge 指控成立	20	19	20	10	8
Directions of the Disciplinary Committee 紀律委員會的指示					
Issue of written warning 發出書面警告	6	7	8	2	1
Disqualified from being an authorized seller of poisons for a period of time 取消銷售商資格一段時間	14	12	12	8	7

Table 表 12

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

Nature of offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2010	2011	2012	2013	2014
(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	3 (6.98%)	6 (9.52%)	4 (5%)	2 (6.07%)	2 (9.1%)
(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	11 (25.58%)	12 (19.05%)	26 (32.5%)	6 (18.18%)	5 (22.72%)
(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	7 (16.28%)	4 (6.35%)	20 (25%)	7 (21.21%)	0 (0%)
(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 (2.33%)	0 (0%)	2 (2.5%)	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	1 (2.33%)	4 (6.35%)	0 (0%)	3 (9.09%)	2 (9.1%)
(6) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	2 (4.64%)	1 (1.6%)	6 (7.5%)	0 (0%)	2 (9.1%)

Table 表 12 (Con't) (續)

Nature of offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2010	2011	2012	2013	2014
(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	2 (4.64%)	4 (6.35%)	4 (5%)	0 (0%)	3 (13.63%)
(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	5 (11.63%)	2 (3.17%)	1 (1.25%)	4 (12.12%)	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	3 (6.98%)	0 (0%)	2 (2.5%)	0 (0%)	0 (0%)
(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 (2.33%)	21 (33.33%)	1 (1.25%)	3 (9.09%)	5 (22.72%)
(11) Trafficking in a dangerous drug 危險藥物的販運	0 (0%)	2 (3.17%)	0 (0%)	0 (0%)	0 (0%)
(12) Unlawful sale of Part 1 poison 非法銷售第1部毒藥	1 (2.33%)	2 (3.17%)	0 (0%)	6 (18.18%)	0 (0%)
(13) Possession of a dangerous drug 管有危險藥物	0 (0%)	1 (1.6%)	0 (0%)	0 (0%)	0 (0%)

Table 表 12 (Con't) (續)

Nature of offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2010	2011	2012	2013	2014
(14) Selling substance to which the Antibiotics Ordinance applies 售賣《抗生素條例》適用的物質	0 (0%)	0 (0%)	1 (1.25%)	0 (0%)	3 (13.63%)
(15) Failing to store poison properly 未能妥善存放毒藥	2 (4.64%)	2 (3.17%)	5 (6.25%)	0 (0%)	0 (0%)
(16) Failing to keep register or records of a dangerous drug 沒有備存有關危險藥物的登記冊或紀錄	1 (2.33%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(17) Illegal sale of unregistered pharmaceutical product 非法銷售未經註冊的藥劑製品	3 (6.98%)	0 (0%)	4 (5%)	0 (0%)	0 (0%)
(18) Possession of antibiotic 管有抗生素	0 (0%)	2 (3.17%)	0 (0%)	0 (0%)	0 (0%)
(19) Selling unlabelled pharmaceutical product 售賣沒有加上標籤的藥劑製品	0 (0%)	0 (0%)	2 (2.5%)	0 (0%)	0 (0%)
(20) Supply false trade description goods 供應虛假商品說明的貨品	0 (0%)	0 (0%)	1 (1.25%)	1 (3.03%)	0 (0%)
(21) Failing to comply with conditions for registration No. 5 set out in the certificate of registration of premises, namely, approval of the Pharmacy and Poisons Board must be obtained prior to any change in the ownership or person in charge of the authorized seller of poisons 未能遵守處所註冊證明書內列明的註冊條件第五條的規定，即：獲授權毒藥銷售商的擁有人或負責人如有任何更改，必須事先獲得藥劑業及毒藥管理局的批准	0 (0%)	0 (0%)	1 (1.25%)	0 (0%)	0 (0%)
(22) Selling goods to which a forged trade mark was applied 出售應用偽造商標的貨品	0 (0%)	0 (0%)	0 (0%)	1 (3.03%)	0 (0%)

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

Table 表 12A

Disciplinary Inquiries into Authorized Sellers of Poisons in 2014
2014年有關獲授權毒藥銷售商的紀律研訊個案

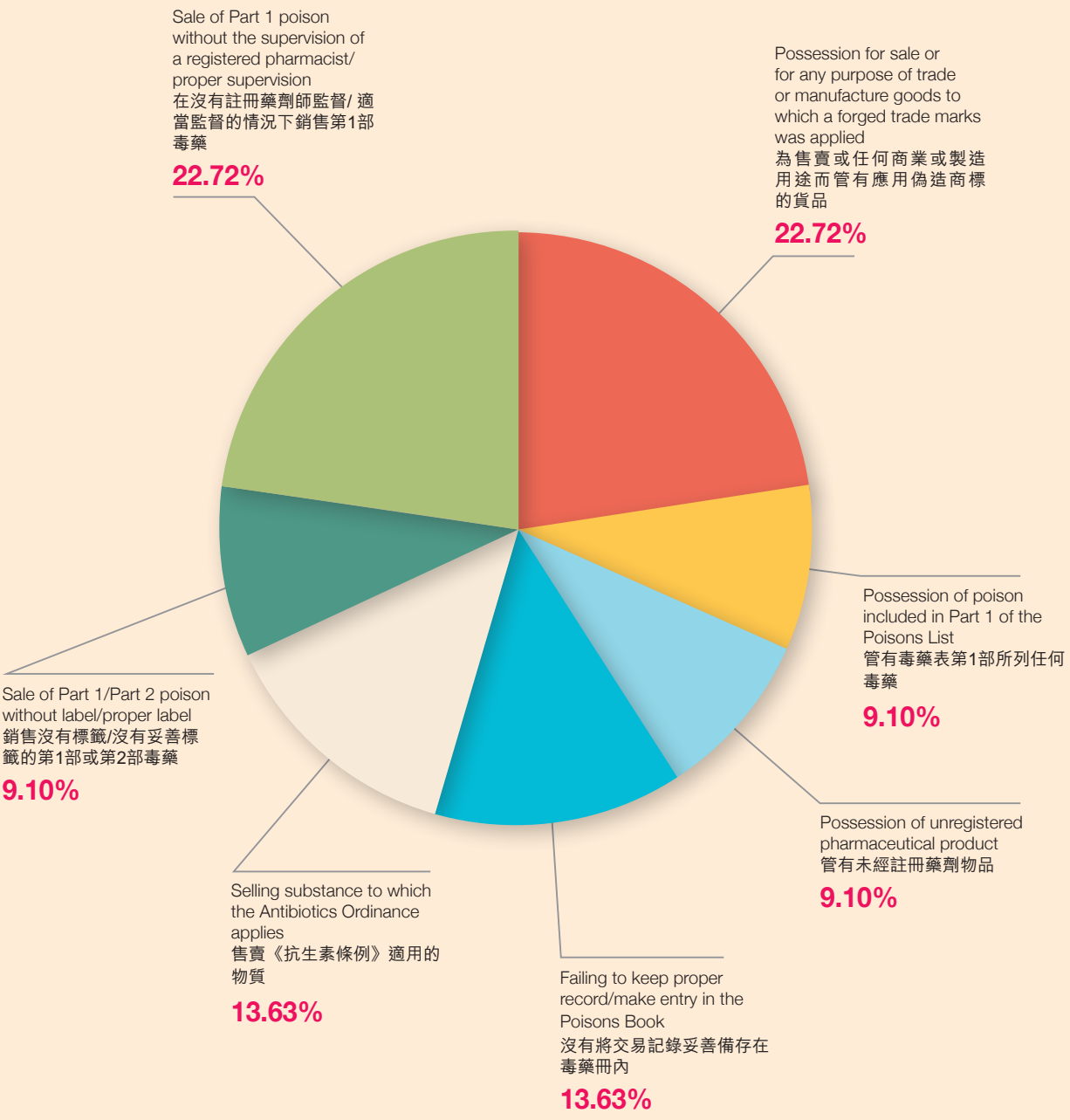


Table 表 13

Number of Listed Sellers of Poisons in Hong Kong 香港的列載毒藥銷售商數目					
Year 年份	2010	2011	2012	2013	2014
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	3,499	3,572	3,827	3,907	3,951

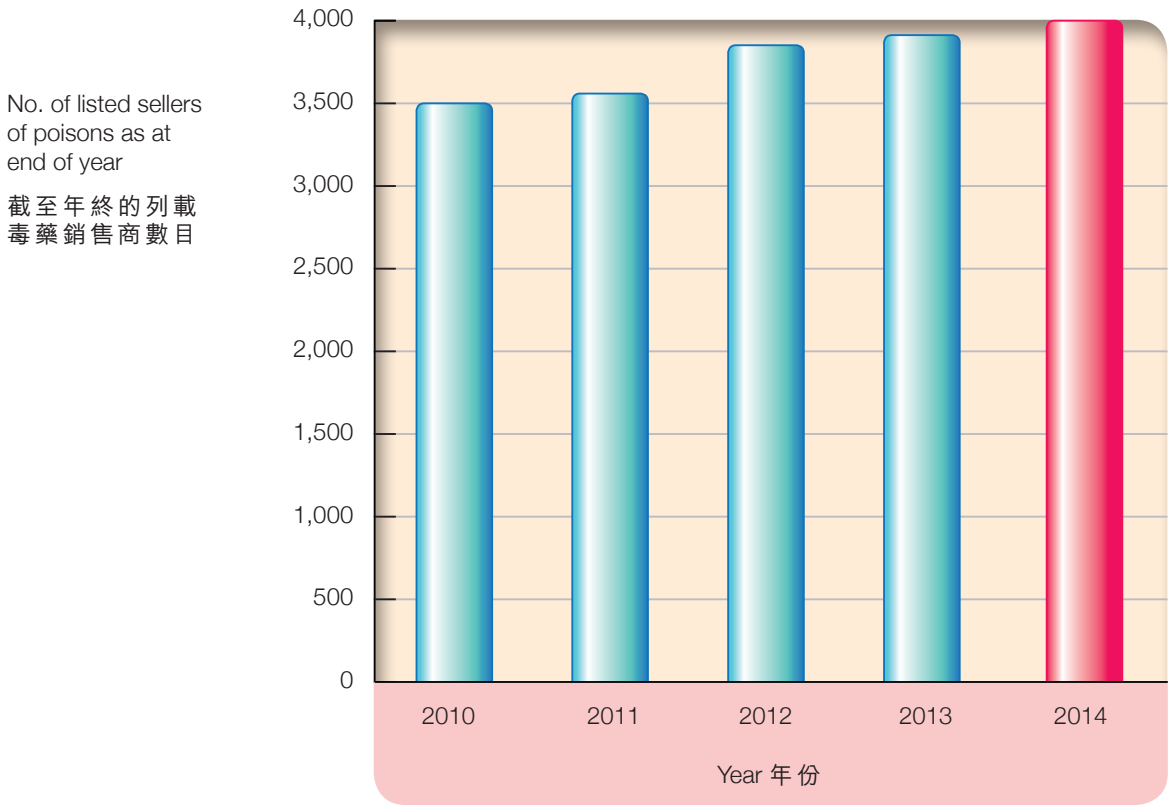


Table 表 14

Applications for Licensing as Listed Sellers of Poisons 申請列載毒藥銷售商牌照					
Year 年份	2010	2011	2012	2013	2014
No. of applications approved 接納列載毒藥銷售商的牌照申請數目	272	325	375	701	311
No. of applications rejected 拒絕列載毒藥銷售商的牌照申請數目	1	9	5	1	2

Table 表 15

Regulatory Control of Listed Sellers of Poisons 列載毒藥銷售商的規管					
Year 年份	2010	2011	2012	2013	2014
No. of inspections conducted 巡查數目	7,042	7,141	7,426	7,746	7,878
No. of test purchases conducted 試買數目	2,866	3,496	3,887	1,983	2,601

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				
	2010	2011	2012	2013	2014
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名單除名	9	4	4	1	9
Issue of written warning 發出書面警告	2	1	1	2	2
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	3	0	1
Total 總數	11	5	8	3	12

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)				
	2010	2011	2012	2013	2014
(1) Sale of Part 1 poison 銷售第1部毒藥	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)	0 (0%)
(2) Sale of Schedule 3 poison 銷售附表3毒藥	0 (0%)	0 (0%)	1 (11.11%)	0 (0%)	0 (0%)
(3) Possession of Part 1 poison 管有第1部毒藥	9 (40.9%)	3 (25%)	1 (11.11%)	0 (0%)	5 (20%)
(4) Possession of antibiotic 管有抗生素	3 (13.64%)	0 (0%)	1 (11.11%)	0 (0%)	0 (0%)
(5) Possession of a dangerous drug 管有危險藥物	0 (0%)	1 (8.33%)	0 (0%)	0 (0%)	0 (0%)
(6) Possession of unregistered pharmaceutical product 管有未經註冊藥劑製品	6 (27.27%)	2 (16.67%)	0 (0%)	0 (0%)	3 (12%)
(7) Possession of substances to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	3 (13.64%)	0 (0%)	0 (0%)	0 (0%)	4 (16%)
(8) 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 (4.55%)	1 (8.33%)	5 (55.56%)	1 (11.11%)	6 (24%)
(9) 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説明的貨品	0 (0%)	5 (41.67%)	0 (0%)	0 (0%)	1 (4%)
(10) Publishing an undesirable medical advertisement 發布不良醫藥廣告	0 (0%)	0 (0%)	0 (0%)	8# (88.89%)	2 (8%)
(11) 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説明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (8%)
(12) Sale of an unregistered pharmaceutical product 售賣未經註冊藥劑藥品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (4%)
(13) 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%)	0 (0%)	0 (0%)	1 (4%)

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

\# Involving 2 List 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

Table 表 17A

Disciplinary Cases regarding Listed Sellers of Poisons in 2014
2014年有關列載毒藥銷售商的紀律個案

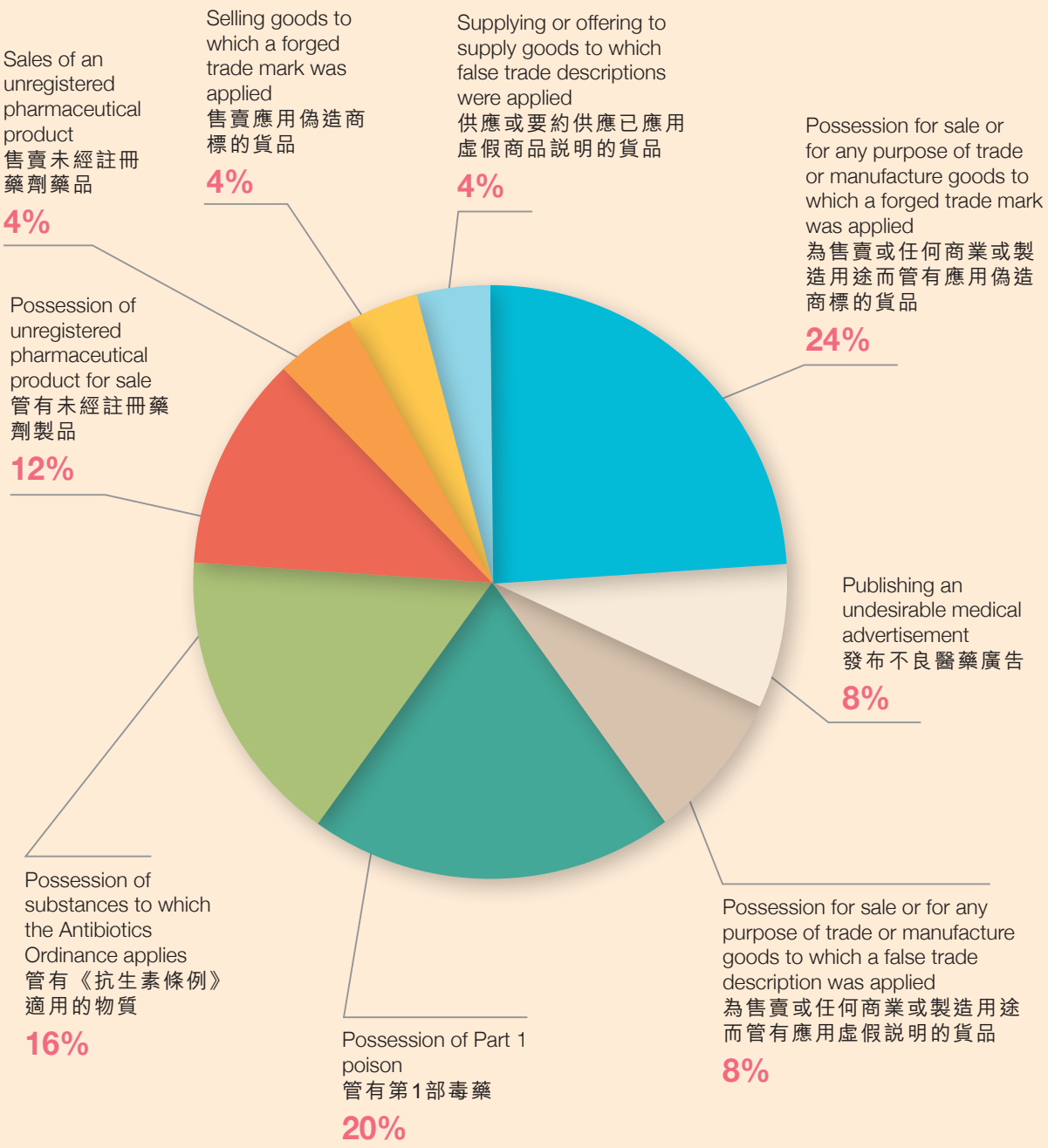


Table 表 18

Issue of Wholesale Poisons Licences 毒藥批發牌照的簽發					
Year 年份	2010	2011	2012	2013	2014
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	857	767	737	714	727
No. of wholesale poisons licences revoked/ suspended 撤銷或吊銷毒藥批發牌照的數目	1	2	2	1	1

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	2010	2011	2012	2013	2014
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	38	38	37	63#	94#
No. of holders of manufacturer's licences who were in compliance with the Hong Kong Good Manufacturing Practices (GMP)* Guidelines for Pharmaceutical Products as at end of year 截至年終符合香港藥劑製品生產質量管理規範指引的製造商牌照持有人的數目	26	25	25	24	24
No. of manufacturer's licences revoked/suspended 撤銷或吊銷製造商牌照的數目	3	0	0	0	0

There were 27 and 63 holders who were authorized to conduct secondary packing of pharmaceutical products only in 2013 and 2014 respectively.

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

* GMP is a quality assurance approach used by the drug manufacturing industry worldwide to ensure that products are consistently produced and controlled throughout the manufacturing process. In 2014, Hong Kong adopted the GMP standard promulgated by the World Health Organization in 1995.

藥劑製品生產質量管理規範指引是全球藥物製造商所採用的品質保證準則，以確保藥劑製品切實一貫地按照其品質標準而生產和監控。本港於2014年採用的標準，是世界衞生組織於1995年發佈的。

Table 表 20

Registration of Importers & Exporters of Pharmaceutical Products 藥劑製品進出口商的註冊					
Year 年份	2010	2011	2012	2013	2014
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	180	136	96	94	90
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	2010	2011	2012	2013	2014
No. of registered pharmaceutical products as at end of year 截至年終的註冊藥劑製品數目	19,189	18,903	19,093	18,912	19,209

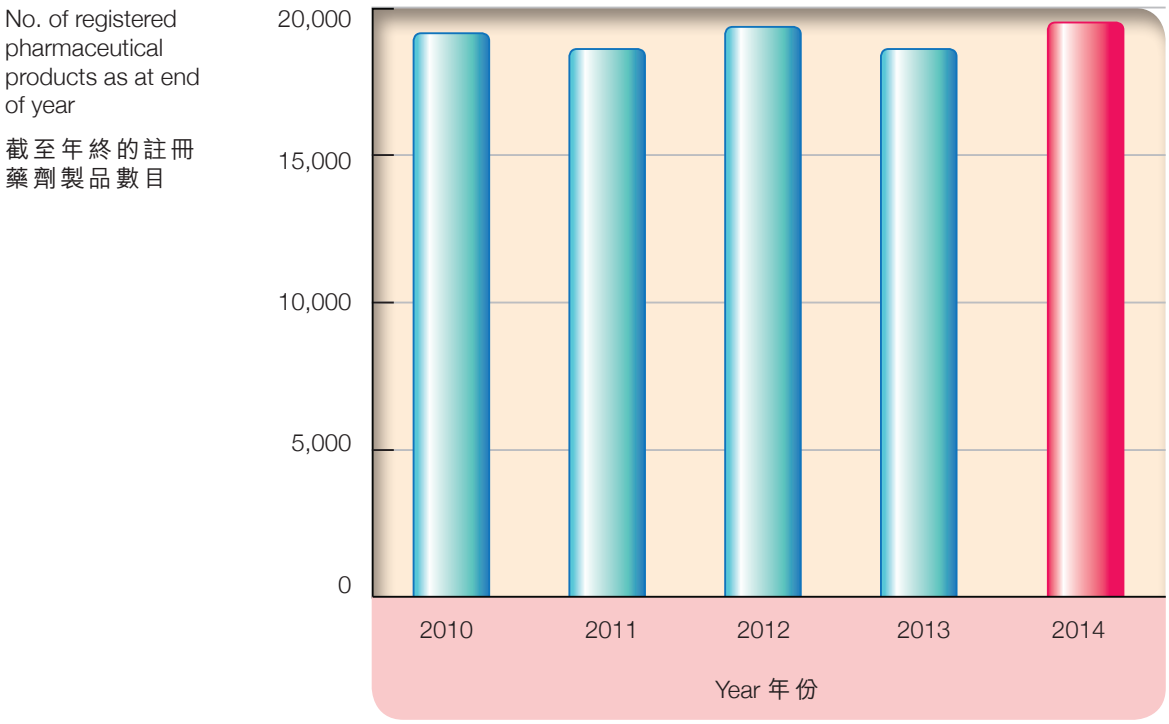


Table 表 22

New Substances Added to Part 1 of the Poisons List Regulations in 2014 2014年在《毒藥表規例》第1部加入的新物質	
1. 5-Aminolevulinic acid; its salts; its derivatives; their salts	5-氨基酮戊酸；其鹽類；其衍生物；它們的鹽類
2. Cobicistat; its salts	考比司他；其鹽類
3. Dapagliflozin; its salts	達格列淨；其鹽類
4. Elvitegravir; its salts	艾維雷韋；其鹽類
5. Lixisenatide	利司那肽
6. Mifepristone; its salts; its esters; their salts	米非司酮；其鹽類；其酯類；它們的鹽類
7. Perampanel	吡侖帕奈
8. Pertuzumab	培妥珠單抗
9. Regorafenib; its salts	瑞戈非尼；其鹽類
10. Tofacitinib; its salts	托法替布；其鹽類
11. Vilanterol; its salts	維蘭特羅；其鹽類

Table 表 23

New Substances Added to Schedules 1 and 3 to the Pharmacy and Poisons Regulations in 2014 2014年在《藥劑業及毒藥規例》附表1和3加入的新物質	
1. 5-Aminolevulinic acid; its salts; its derivatives; their salts	5-氨基酮戊酸；其鹽類；其衍生物；它們的鹽類
2. Cobicistat; its salts	考比司他；其鹽類
3. Dapagliflozin; its salts	達格列淨；其鹽類
4. Elvitegravir; its salts	艾維雷韋；其鹽類
5. Lixisenatide	利司那肽
6. Mifepristone; its salts; its esters; their salts	米非司酮；其鹽類；其酯類；它們的鹽類
7. Perampanel	吡侖帕奈
8. Pertuzumab	培妥珠單抗
9. Regorafenib; its salts	瑞戈非尼；其鹽類
10. Tofacitinib; its salts	托法替布；其鹽類
11. Vilanterol; its salts	維蘭特羅；其鹽類