PHARMACY AND POISONS BOARD OF HONG KONG
香港藥劑業及毒藥管理局

2023
ANNUAL REPORT
年報

Contents
目 錄

Message from the Chairman 2
主席獻辭

Introduction 4
引言

Membership and Functions of the Board 5
管理局的成員及職能

Membership and Functions of the Committees 8
管理局委員會的成員及職能

The Work of the Board and its Committees 14
管理局及其委員會的工作

Membership and Functions of the Disciplinary Committee 23
紀律委員會的成員及職能

Membership and Functions of the Pharmacy and Poisons Appeal Tribunal 26
藥劑業及毒藥上訴審裁處的成員及職能

Statistical Tables and Charts 28
統計圖表

Message from the Chairman
主席獻辭

Year 2023 was another busy and fruitful year for the Pharmacy and Poisons Board ("the Board"). As the Board Chairman, I take pride in reporting our work and highlighting some notable achievements attained during the year.

To safeguard public health, the Board keeps the sales control of medicines under constant review to align our practices with international regulatory standards. In September 2023, we decided to strengthen the sales restriction on medicines containing codeine to deter potential abusive use of the substance. By classifying pharmaceutical products containing no more than 0.1% of codeine as Schedule 1 and Part 1 of Schedule 10 Poisons under the Pharmacy and Poisons Regulations (Cap. 138A, Laws of Hong Kong), authorized sellers of poisons ("ASPs") are required to maintain sale records of such products, including relevant details of purchasers. The measure has come into effect on 26 January 2024.

Based on practices of overseas regulatory authorities and the recommendations of local experts regarding pholcodine (a centrally acting cough suppressant for use in adults and children), the Board had agreed to deregister pharmaceutical products containing pholcodine with effect from 1 January 2024. In reaching the decision, the Board had taken into account the serious health risk posed by the use of pholcodine for developing anaphylaxis, the absence of effective risk mitigation strategies and the availability of alternative cough preparations in the market.

In response to the increased utilisation of medical gases during the COVID-19 pandemic, the Board had embarked on a review on the regulatory control of medical gases in Year 2022. After careful consideration, it was decided in September 2023 that medical gases should be regulated as pharmaceutical products under the Pharmacy and Poisons Ordinance (Cap. 138, Laws of Hong Kong). To facilitate the industry in understanding and complying with the regulatory framework, comprehensive guidance notes covering the registration and licensing requirements for medical gases manufacturers and wholesalers, and updated qualifications and training requirements for authorized persons and key personnel of related licensed manufacturers had been drawn up. In addition, the Department of Health had conducted a public consultation exercise in November 2023. Feedback received from the public and relevant stakeholders were in support of the initiative.

In addition to the above regulatory functions, the Board had reviewed and streamlined the licensing procedures and requirements in connection with the retail sale of poisons. Taking into consideration the general practices in both local and international healthcare settings, a document entitled "Guiding Principles on Assessing Fitness and Properness of an Authorized Seller of Poisons and Appointed Person-in-charge" was published in October 2023 to increase transparency of relevant work of the Board.

香港藥劑業及毒藥管理局(下稱「管理局」)在 2023 年的工作依舊繁重,但成果豐碩。作為管理局主席,我為管理局過去一年所取得的成績感到自豪,並在此分享當中一些顯著成果。

為保障公眾健康,管理局持續檢視藥物的銷售管控,以確保本港的藥物規管措施與國際監管制度保持一致。2023 年 9 月,管理局決定加強對含可待因的藥劑製品的銷售管制,將含有不超過 0.1% 可待因的藥劑製品,根據香港法例第 138A 章《藥劑業及毒藥規例》歸類為附表 1 和附表 10 第 1 部毒藥,以防出現藥物濫用的情況。獲授權毒藥銷售商須備存該等產品的相關銷售記錄,包括購買者的相關資料。該措施由 2024 年 1 月 26 日起生效。

管理局參考海外監管當局的做法和本地專家的建議,決定由 2024 年 1 月 1 日起撤銷含嗎啉乙基嗎啡(一種用於成人和兒童的中樞性止咳藥)藥劑製品的註冊。考慮到使用嗎啉乙基嗎啡有可引致過敏性休克的嚴重健康風險,但缺乏相關風險緩減措施,而目前市場上有其他止咳製劑替代品,管理局遂作出上述決定。

本港醫療氣體的使用量在 2019 冠狀病毒病疫情期間有所增加。有見及此,管理局於 2022 年主動審視醫療氣體的規管。經仔細考慮,管理局於 2023 年 9 月決定將醫療氣體納入按香港法例第 138 章《藥劑業及毒藥條例》規管的藥劑製品。為協助業界了解及遵守規管框架,管理局制定詳盡指南,說明醫療氣體製造商和批發商的註冊和發牌條件,以及更新了相關持牌製造商的獲授權人和關鍵人員的資格和培訓要求。此外,衞生署於 2023 年 11 月進行公眾諮詢,結果顯示公眾和相關持份者均支持對醫療氣體作出規管。

除上述規管職務外,管理局亦檢討及精簡了有關毒藥零售的發牌程序和要求。在考慮本地和國際醫療衞生界別的一般做法後,管理局於 2023 年 10 月發布了題為《評估獲授權毒藥銷售商及其主管是否適當的指導原則》的文件,以提高管理局處理相關工作的透明度。

The Board's successful accession to the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") as an observer on 31 October 2023 marked a significant milestone in our pursuit of the Government's mission of developing Hong Kong into an international health and medical innovation hub. Through the ICH, we would be able to get familiarised with the latest development of drug regulation worldwide for enhancement of the local drug regulatory regime, thereby paving the way for developing Hong Kong into an internationally recognised drug regulatory authority in the long run.

Another major initiative of the Board was the introduction of the "1+" mechanism on 1 November 2023 to facilitate the approval of new drugs. This mechanism allows holders of registration from one (instead of two or more) of the recognised drug regulatory authorities to apply for registration of new drugs for treating life-threatening or severely debilitating diseases in Hong Kong, subject to other application conditions concerning submission of sufficient local clinical data and endorsement from local experts being met. The new measure which expedites the approval of new drugs while ensuring that all drugs approved for registration meet the stringent standards of safety, efficacy and quality will benefit needy patients. It will also strengthen Hong Kong's capacity for drug evaluation, which is an important step towards adopting a primary evaluation approach in drug registration in the long run.

The Board is dedicated to upholding the standard and quality of locally trained pharmacists. To this end, we appointed an Accreditation Panel cum Visiting Team ("AP/VT") comprising esteemed local and international pharmacy experts to conduct a re-accreditation exercise for the Bachelor of Pharmacy ("BPharm") programme of the University of Hong Kong ("HKU"). In June 2023, we endorsed the AP/VT's recommendation to grant full re-accreditation to HKU's BPharm programme for a period of five years.

Preparatory work for the implementation of a continuing pharmacy education ("CPE") scheme for registered pharmacists had carried on. Fully recognising the importance of ongoing professional development, the Board endorsed the framework of a voluntary CPE Programme in June 2023 and approved in principle the relevant implementation guidelines in November 2023 in preparation for launching of the Programme on 1 June 2024.

The success of the Board counts on the support and assistance of all members. We will continue to work in a concerted effort to fulfill our roles in safeguarding public health and elevating the quality of healthcare services by working closely with the pharmaceutical community and other healthcare professionals.

Dr LAM Man-kin, Ronald, JP
Chairman
Pharmacy and Poisons Board

政府銳意將香港發展為國際醫療創新樞紐。管理局在 2023 年 10 月 31 日成功以觀察員身分加入國際醫藥法規協調會議，是邁向上述目標的重大里程碑。透過加入國際醫藥法規協調會議，管理局得以掌握全球藥物監管的最新發展，從而提升本地藥物規管制度，為發展香港成為國際藥械權威的長遠目標鋪路。

管理局在 2023 年 11 月 1 日實施了另一項重要措施，推出促進新藥審批的「1+」機制。在此機制下，用以治療嚴重或罕見疾病的新藥，若符合有關提供充分本地臨床數據及獲得本地專家認可的申請要求，只須提交一個（而非兩個或以上）認可藥物監管機構發出的註冊許可，便可在香港註冊。新措施既可加快新藥審批，亦確保所有獲批准註冊的藥物均符合嚴謹的安全性、效能和質量標準，惠及有需要的病人，更能強化香港的藥物審批能力，為長遠邁向「第一層審批」藥物註冊制度踏出重要一步。

管理局致力確保本地培訓的藥劑師的水平和質素。為此，管理局成立了評審委員會暨訪問團，委派備受尊崇的本地及國際藥劑專家為成員，覆審香港大學（下稱「港大」）的藥劑學學士課程。管理局於 2023 年 6 月通過評審委員會暨訪問團的建議，授予港大藥劑學學士課程全面認證，有效期為五年。

此外，推行註冊藥劑師持續專業教育計劃的籌備工作持續進行。深明持續專業發展的重要性，管理局於 2023 年 6 月批准註冊藥劑師自願持續專業教育計劃的框架，並於 2023 年 11 月原則上批准相關實施指引，為 2024 年 6 月 1 日推出計劃作好準備。

管理局的工作卓有所成，端賴全體成員鼎力支持、竭誠襄助。今後我們定當繼續羣策羣力，與藥劑業和其他醫療衞生專業人員通力合作，履行守護公眾健康及提升醫療服務水平的使命。

藥劑業及毒藥管理局主席
林文健醫生，JP

Introduction
引 言

This annual report covers the calendar year 2023. 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 with 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
46/F, Revenue Tower
5 Gloucester Road
Wan Chai, Hong Kong

Facsimile : (852) 2865 5540
Telephone : (852) 2527 8432
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」)在二零二三年的工作。管理局希望透過這份年報,使所有註冊藥劑師以及藥劑業有關人士及團體了解管理局的職能及在這年內的工作;同時亦扼要介紹根據《藥劑業及毒藥條例》第 30 條成立的藥劑業及毒藥上訴審裁處(「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:

香港灣仔告士打道 5 號
稅務大樓 46 樓
藥劑業及毒藥管理局秘書處

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

Dr LAM Man-kin, Ronald, JP (Chairman)
林文健醫生，JP (主席)

Dr LEE Wai-on
李偉安博士

Mr CHAN Ling-fung, Frank, JP
陳凌峯先生，JP

Dr CHIU Pui-yin, Amy, JP
趙佩燕醫生，JP

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

Professor WONG Chi-kei, Ian
黃志基教授

Professor YOU Hoi-sze, Joyce
姚凱詩教授

Mr SUNG Ming-tat, Dick
沈明達先生

Ms TAM Hi, Beverley
譚起女士

Mr YAU Fook-wing, Edward William
邱福榮先生

Dr MARCET, Marcus Mitchell
馬思特醫生

(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 2023 was as follows:

(a) Dr LAM Man-kin, Ronald, JP (Chairman)
(b) Dr LEE Wai-on
(c) Mr CHAN Ling-fung, Frank, JP
(d) Dr CHIU Pui-yin, Amy, JP
(e) Mr WONG Wai-hung, Geoffrey (Legal Adviser)
(f) Professor WONG Chi-kei, Ian
(g) Professor YOU Hoi-sze, Joyce
(h) Mr SUNG Ming-tat, Dick
Ms TAM Hi, Beverley
Mr YAU Fook-wing, Edward William
(i) Dr MARCET, Marcus Mitchell

Secretary
Ms WONG Wai-yee, Catherine

(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）。

在二零二三年十二月三十一日，管理局的成員計有：

(a) 林文健醫生，JP（主席）
(b) 李偉安博士
(c) 陳凌峯先生，JP
(d) 趙佩燕醫生，JP
(e) 黃惠鴻先生（法律顧問）
(f) 黃志基教授
(g) 姚凱詩教授
(h) 沈明達先生
譚起女士
邱福榮先生
(i) 馬思特醫生

秘書
黃慧儀女士

(2) Functions

The Board is established under section 3 of the Pharmacy and Poisons Ordinance, Cap. 138, Laws of Hong Kong 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 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 on policies and actions in relation to the carrying out 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 2023

Professor WONG Chi-kei, Ian (Chairman)
Mr CHAN Ling-fung, Frank, JP
Ms CHU Kwok-pui, Jody
Mr LAM Fung-shing, Edwin
Dr LAM Tai-ning, Teddy
Dr LEE Pui-man, Jeff
Dr LEE Wai-on
Professor NG Kwok-wai, Enders
Ms CHAN Wai, Harriet (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) 截至二零二三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，JP
朱幗珮女士
林豐盛先生
林泰寧博士
李培文醫生
李偉安博士
吳國偉教授
陳慧女士（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 2023

Mr CHAN Ling-fung, Frank, JP (Chairman)
Mr HUNG Hon-wing, Gary
Mr KAN Kin-hang, Michael
Ms LEUNG Chau-yung, Catherine
Mr MUI Cheuk-nang, Kenny
Mr TING Wing-fai, MH
Mr YAU Fook-wing, Edward William
Mr LEE Hi-fung, Lees (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 2023

Mr CHAN Ling-fung, Frank, JP (Chairman)
Mr CHAN King-che, Stephen
Mr CHAN Tai-fu
Mr TSE Ka-wing
Mr TSOI Chick-lai, Samson
Mr WONG Kei, Eric
Mr LAU Moon-tong (Secretary)

(ii) Functions

The Pharmacy and Poisons (Wholesale Licences) Committee is established to carry out the following functions in accordance with regulation 26 of the Pharmacy and Poisons Regulations:

(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.

(2) 藥劑業及毒藥（列載毒藥銷售商）委員會

(i) 截至二零二三年十二月三十一日的成員名單

陳凌峯先生，JP（主席）
洪漢榮先生
簡健恒先生
梁秋容女士
梅卓能先生
丁志輝先生，MH
邱福榮先生
李浠鋒先生（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) 截至二零二三年十二月三十一日的成員名單

陳凌峯先生，JP（主席）
陳鏡治先生
陳泰夫先生
謝家榮先生
蔡節禮先生
黃騏先生
劉滿堂先生（秘書）

(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) Pharmacy and Poisons (Manufacturers Licensing) Committee

(i) Membership as at 31 December 2023

Mr CHAN Ling-fung, Frank, JP (Chairman)
Dr CHAN Sing-kwok, Theobald
Dr CHENG Chi-chung, Vincent
Dr CHOW Shing-fung, Aviva
Mr LEE Foo-wing
Professor LEUNG Kam-tong
Professor LEUNG Shui-yee, Sharon
Dr LIU, Diana
Mr TSE Kin-on, Andrew
Mr YUNG Siu-lung, Stephen
Ms CHEUNG Ching, Christine (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;

(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.

(4) 藥劑業及毒藥（製造商牌照）委員會

(i) 截至二零二三年十二月三十一日的成員名單

陳凌峯先生，JP（主席）
陳醒覺博士
鄭智聰醫生
周聖峰博士
李富榮先生
梁錦堂教授
梁水意教授
劉寒青博士
謝建安先生
容兆龍先生
張靜女士（秘書）

(ii) 職能

藥劑業及毒藥（製造商牌照）委員會根據《藥劑業及毒藥規例》，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) 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 2023

Mr CHAN Ling-fung, Frank, JP (Chairman)
Ms CHAK Man-lee, Charlotta
Mr CHEUNG Yiu-ming
Professor CHEUNG Yin-ting
Dr HO Chin-ho, Kenny
Professor LOONG Ho-fung, Herbert
Dr NG Fook-hong
Dr NG Kwok-keung
Professor TSE Wai-choi, Eric
Mr WONG Yik-cheong, Anthony
Mr YEUNG Yee-fai, Raphael (Secretary)

(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.

(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) 截至二零二三年十二月三十一日的成員名單

陳凌峯先生，JP（主席）
翟敏莉女士
張耀明先生
張彥婷教授
何展豪獸醫
龍浩鋒教授
吳福康醫生
吳國強醫生
謝偉財教授
黃益昌先生
楊義輝先生（秘書）

(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 2023

Dr LEE Wai-on (Chairman)
Mr CHAN Ling-fung, Frank, JP
Dr MARCET, Marcus Mitchell
Mr SUNG Ming-tat, Dick
Ms TAM Hi, Beverley
Professor WONG Chi-kei, Ian
Ms CHAN Wai, Harriet (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.

(7) Postgraduate Pharmacy Training and Development Committee

(i) Membership as at 31 December 2023

Professor ZUO Zhong, Joan (Chairman)
Mr CHAN Ling-fung, Frank, JP
Mr CHAN Sze-tao, Lot
Ms CHAN Wai-kei, Victoria
Mr CHEUNG, Kenny
Mr CHEUNG Po-yan, Edmund
Mr CHEUNG Yiu-kwong, Alex
Dr HO, Clare
Ms HSUEH Cheung-mei, Vivian
Dr LAU Sze-ngar, Grace
Dr LEE Pui-man, Jeff
Mr LO Cheuk-fei, Jeffrey
Mr SO Pak-yin, Stephen
Mr SUNG Ming-tat, Dick
Ms TAM Hi, Beverley
Ms TAM Yuen-ting, Eliza
Ms CHAN Wai, Harriet (Secretary)

(6) 毒藥委員會

(i) 截至二零二三年十二月三十一日的成員名單

李偉安博士（主席）
陳凌峯先生，JP
馬思特醫生
沈明達先生
譚起女士
黃志基教授
陳慧女士（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《藥劑業及毒藥規例》管制的藥劑製品的分類。

(7) 藥劑師持續進修及實習培訓委員會

(i) 截至二零二三年十二月三十一日的成員名單

左中教授（主席）
陳凌峯先生，JP
陳詩濤先生
陳慧琪女士
張卓然先生
張寶仁先生
張耀光先生
何嘉麗博士
薛長薇女士
劉思雅博士
李培文醫生
盧卓飛先生
蘇栢賢先生
沈明達先生
譚起女士
譚宛婷女士
陳慧女士（秘書）

(ii) Functions

The Postgraduate Pharmacy Training and Development 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;

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

(g) advise the Board on matters pertaining to the continuous professional development ("CPD") requirements in upkeeping the practising standards of registered pharmacists in Hong Kong, which include but not limited to the following –

i. devise policies and implementation strategies in regard to the CPD / continuous professional education ("CPE") for registered pharmacists;

ii. accredit CPE administrators and CPE programme providers; and

iii. implement, monitor (include record-keeping) and review the progress of the CPE scheme.

(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；

(f) 執行管理局所容許並賦予的有關實習培訓的其他職能；及

(g) 就香港註冊藥劑師持續專業發展的要求向管理局提供包括下列範疇的意見，以維持其執業水平：

i. 就註冊藥劑師持續專業發展／教育制訂政策及推行策略；

ii. 審定負責管理及籌辦持續專業教育課程的機構；以及

iii. 推行及監管（包括備存記錄）持續專業教育計劃，並就其進度進行檢討。

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 recognised university in Hong Kong; or

(b) a non-locally trained applicant 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 in (i)(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 2023. A total of 20 applicants cumulatively passed all the three subjects in the year 2023.

The results of these two registration examinations are shown in Table 1. Figures for 2019 to 2023 are also included for comparison purpose.

(iii) Training

Applicants holding a pharmacy degree awarded by a recognised university in Hong Kong are required to undergo Board-approved training for one year before they can be registered as pharmacists.

Applicants holding a recognised pharmacy degree awarded elsewhere should have had an aggregate of relevant pre-registration training and/or 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 (i) (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。

考試委員會在二零二三年分別在六月及十二月舉辦了兩次註冊考試。同年共有 20 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，以及二零一九年至二零二三年的有關數字，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／或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.

As at 31 December 2023, there were 3 317 registered pharmacists in Hong Kong. Statistical data regarding registration of pharmacists and breakdown of fresh registration, removal from the register and re-registration of pharmacists for 2019 to 2023 are shown in **Tables 2 and 3**.

(v) Practising Certificates

All practising pharmacists must obtain a practising certificate annually in accordance with section 10A of the Pharmacy and Poisons Ordinance.

(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, written warning, 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 23 to 25 of this report.

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in 2019 to 2023 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。

截至二零二三年十二月三十一日，香港共有 3 317 位註冊藥劑師。**表 2 及 3** 列出二零一九年至二零二三年有關藥劑師註冊，以及新註冊、刪除註冊及重新註冊的分項數字的統計資料。

(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。

(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，包括被譴責、警告信或在指定的時期內從藥劑師名冊上除名。有關紀律委員會的組成及工作詳情，可參閱本年報第 23 至 25 頁。

表 4、5 及 6 詳列管理局在二零一九年至二零二三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 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 an ASP. The ASP may also display a logo prescribed under section 13A of the Pharmacy and Poisons Ordinance.

ASPs must apply for renewal of registration annually. All records of an ASP will be taken into account when the Board assesses its 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 623 ASPs registered in Hong Kong as at the end of 2023. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of ASPs in 2019 to 2023 are shown in **Tables 7 and 8**.

(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.

(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。

截至二零二三年年終，香港共有 623 名獲授權毒藥銷售商。**表 7 及 8** 詳列二零一九年至二零二三年獲授權毒藥銷售商的總數、處所註冊申請及註冊續期申請的統計數字。

(ii) 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。

Five inquiries were held in 2023 and all of the ASPs concerned were found guilty of misconduct. One ASP was issued with a written warning whilst four others 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 and be given verbal cautions. 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 seven such interviews were held in 2023.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in 2019 to 2023 is shown in **Table 9**.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in 2019 to 2023 are given in **Tables 10, 11, 12 and 12A**.

(iii) Listed Sellers of Poisons: Licensing

A listed seller of poisons ("LSP"), commonly known as a medicine company, is a person approved to conduct the retail sale of poisons included in Part 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 4 143 LSPs in Hong Kong as at the end of 2023. The number of licensed LSPs in 2019 to 2023 is shown in **Table 13**. Statistical data regarding applications for LSP licences in these five years are shown in **Table 14**.

在二零二三年，管理局舉行了五次紀律研訊，全部涉事的獲授權毒藥銷售商被裁定犯有不當行為。紀律委員會向其中一名獲授權毒藥銷售商發出書面警告，四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。管理局在二零二三年舉行了七次該類會面。

表 9 列出二零一九年至二零二三年由藥劑師督察對獲授權毒藥銷售商進行巡查及試買的數字。

表 10、11、12 及 12A 詳列二零一九年至二零二三年管理局處理有關獲授權毒藥銷售商的紀律個案的統計數字。

(iii) 列載毒藥銷售商：發牌工作

列載毒藥銷售商一般稱為藥行，是根據《藥劑業及毒藥條例》的規定，獲准經營毒藥表內第 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。

截至二零二三年年終，香港共有 4 143 名列載毒藥銷售商。**表 13** 列出二零一九年至二零二三年列載毒藥銷售商的總數。**表 14** 列出在上述五年申請發牌的統計數字。

(iv) Listed Sellers of Poisons: Discipline

Like ASPs, LSPs are also subject to inspection by pharmacist inspectors but unlike 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. If the Board considers him not a fit and proper person to continue the retail business of Part 2 poisons, his name will be removed or suspended for a period specified by the Board from the list of LSPs. 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 2019 to 2023 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**.

(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.

(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》、《商品說明條例》所訂罪行或違反《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 列出二零一九年至二零二三年由藥劑師督察對列載毒藥銷售商進行巡查以及試買的數字。**表 16、17 及 17A** 詳列管理局在上述五年處理有關列載毒藥銷售商的紀律個案的統計數字。

(3) 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。

Wholesale dealers are subject to inspection by pharmacist inspectors of the Department of Health. If a wholesale dealer has been convicted of any offence under the Pharmacy and Poisons Ordinance, the Dangerous Drugs Ordinance, the Antibiotics Ordinance, the Undesirable Medical Advertisements Ordinance, specified provisions under the Import and Export Ordinance, the Public Health and Municipal Services Ordinance or the Trade Description Ordinance ("the relevant Ordinances"), or the Pharmacy and Poisons (Wholesale Licences) Committee is of the opinion that a licensed wholesale dealer has contravened the licensing conditions or Code of Practice, the Pharmacy and Poisons (Wholesale Licences) Committee may revoke the wholesale dealer licence or suspend the licence for a period that it thinks fit, issue a warning letter or vary its licensing condition.

There were 1 002 holders of wholesale dealer licence in Hong Kong as at the end of 2023. Statistical data regarding the wholesale dealer licences and related disciplinary cases handled by the Board for 2019 to 2023 are shown in **Tables 18 and 19**.

(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 is properly kept.

衞生署的藥劑師督察會巡查批發商。批發商如被裁定干犯任何《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《進出口條例》、《公眾衞生及市政條例》或《商品說明條例》(以下統稱「相關條例」)的指明條文,或被藥劑業及毒藥(批發牌照)委員會認為違反了牌照條件或執業守則,藥劑業及毒藥(批發牌照)委員會即可撤銷或在認為合適的期間內暫時吊銷有關的批發商牌照、向有關批發商發出警告信或更改其牌照條件。

截至二零二三年年終,香港共有 1 002 名批發商牌照持有人。**表 18 及 19** 列出二零一九年至二零二三年的統計數字及管理局對批發商所採取的紀律行動的統計數字。

(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.

Similar to wholesale dealers, manufacturers are also subject to inspection by pharmacist inspectors of the Department of Health. If a licensed manufacturer has been convicted of any offence under the relevant Ordinances, or the Pharmacy and Poisons (Manufacturers Licensing) Committee is of the opinion that the licensed manufacturer has contravened the licensing conditions, Code of Practice or Good Manufacturing Practice Guide, the Pharmacy and Poisons (Manufacturers Licensing) Committee may revoke the licence to manufacture pharmaceutical products or suspend the licence for a period that it thinks fit, issue a warning letter or vary its licensing condition.

There were 61 holders of a manufacturer's licence in Hong Kong as at the end of 2023, and all of them were required to comply with the PIC/S GMP Guide with effect from 1 October 2015. Among these 61 holders, 40 holders were only authorized to conduct secondary packaging of pharmaceutical products. Statistical data of manufacturer's licences, the number of authorized persons, and related disciplinary cases handled by the Board for 2019 to 2023 are given in **Tables 20 to 23** respectively.

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。

除了巡查批發商，衞生署的藥劑師督察亦會巡查製造商。持牌製造商如被裁定干犯相關條例中的任何罪行，或被藥劑業及毒藥（製造商牌照）委員會認為違反了牌照條件、執業守則或《生產質量管理規範指引》，藥劑業及毒藥（製造商牌照）委員會即可撤銷或在認為合適的期間內暫時吊銷有關的藥劑製品製造商牌照、向有關製造商發出警告信或更改其牌照條件。

截至二零二三年年終，香港共有 61 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 61 名製造商牌照持有人當中，40 名只獲授權從事藥劑製品外包裝操作。**表 20 至 23** 分別列出二零一九年至二零二三年製造商牌照及獲授權人士的統計數字及管理局對製造商牌照及獲授權人士所採取的紀律行動的統計數字。

(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 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.

A registration certificate will be issued on registration of a pharmaceutical product, 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 14 463 registered pharmaceutical products in Hong Kong as at the end of 2023. The number of registered pharmaceutical products as at the end of 2019 to 2023 is shown in **Table 24**.

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

(4) 藥劑製品的註冊及分類

(i) 藥劑製品的註冊

根據《藥劑業及毒藥規例》第 36 條的規定，任何人如欲銷售、要約出售、分銷或管有任何藥劑製品或物質，均須將有關製品或物質向藥劑業及毒藥（藥劑製品及物質註冊：臨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註冊時，委員會會考慮該藥品的安全程度、效能及素質。處理在香港境外製造的產品的申請時，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；

(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；及

(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。

一經註冊，受委員會認為適宜施加的條件的規限下，申請者會獲發註冊證明書，並獲告知產品的分類。

截至二零二三年年終，香港共有 14 463 種已註冊的藥劑製品。**表 24** 列出截至二零一九年至二零二三年年終的註冊藥劑製品數字。

(ii) 藥劑製品的分類

就毒藥委員會的建議，管理局會決定及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）的各種不同分類及在附表 1 和附表 3 內的銷售規管分述如下：

Classification	Restriction(s) on sale
(a) Part 1 Poisons: Poisons included in Part 1 of 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 Schedule 10 (i.e. Poisons List) and 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 Schedule 10 (i.e. Poisons List) and 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 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.

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

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

Classification and distribution in 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 2023 are shown in **Tables 25 and 26**.

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。

《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
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
4	詳列在某些情況下有關毒藥比例的詳情說明
5	說明對某些毒藥的標籤要求
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
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。立法會在二零二三年批准管理局就藥劑製品分類對《藥劑業及毒藥規例》作出的修訂列載於**表 25 及 26**。

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 2023, the Chairman of the Disciplinary Committee was Dr CHIU Pui-yin, Amy, JP, Controller, Regulatory Affairs of the Department of Health. Registered pharmacists who had served as members in 2023 included:

Ms CHAN Yin-yin, Ivy
Mr CHEN Wen-ben, Benny
Ms CHEUNG Oi-ling
Mr HO Hon-fai
Ms KUNG Wai-yiu
Mr LEE Siu-to
Mr NG Pan-pan, Rex
Mr NG Wing-yan
Mr NG Yu-chau, Patrick
Mr WONG Chi-ming

(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。

衞生署規管事務總監趙佩燕醫生，JP是紀律委員會在二零二三年十二月三十一日的主席。曾在二零二三年出任成員的註冊藥劑師包括：

陳妍賢女士
陳文斌先生
張靄玲女士
何漢輝先生
龔瑋珧女士
李兆濤先生
吳彬賓先生
吳榮恩先生
吳如就先生
黃志明先生

(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 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) section 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 (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《商品說明條例》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 ASP in respect of the premises, or for a shorter period as may be specified in the direction;

(c) variations 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 a 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, the direction takes effect 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 was no appeal to the Court of First Instance in 2023.

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。二零二三年，原訟法庭沒有收到任何上訴申請。

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 2023 was as follows:

Name	Membership
Mr Jenkin SUEN, S.C.	Chairman
Professor CHOW Yee-kwan, Elaine	Member
Dr LAM Pui-san, May	Member
Dr TSE Sut-yee	Member
Mr CHAN Tai-fu	Panel Member
Mr CHEUNG, Ian	Panel Member
Mr CHENG Kin-tung, Johnny	Panel Member
Mr CHUNG Wing-fai	Panel Member
Mr LO Yin-cheung	Panel Member
Mr PANG Hok-ming	Panel Member
Mr YEUNG Chi-fat	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。

在二零二三年十二月三十一日，審裁處的成員如下：

姓名	成員
孫靖乾先生，SC	主席
周怡君教授	委員
林珮珊博士	委員
謝雪兒醫生	委員
陳泰夫先生	小組委員
張力行先生	小組委員
鄭健東先生	小組委員
鍾榮輝先生	小組委員
盧彥璋先生	小組委員
彭鶴鳴先生	小組委員
楊志發先生	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 suspension or 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 received by the Tribunal from 2019 to 2023.

(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暫時吊銷或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。

由二零一九年至二零二三年審裁處沒有收到研訊上訴。

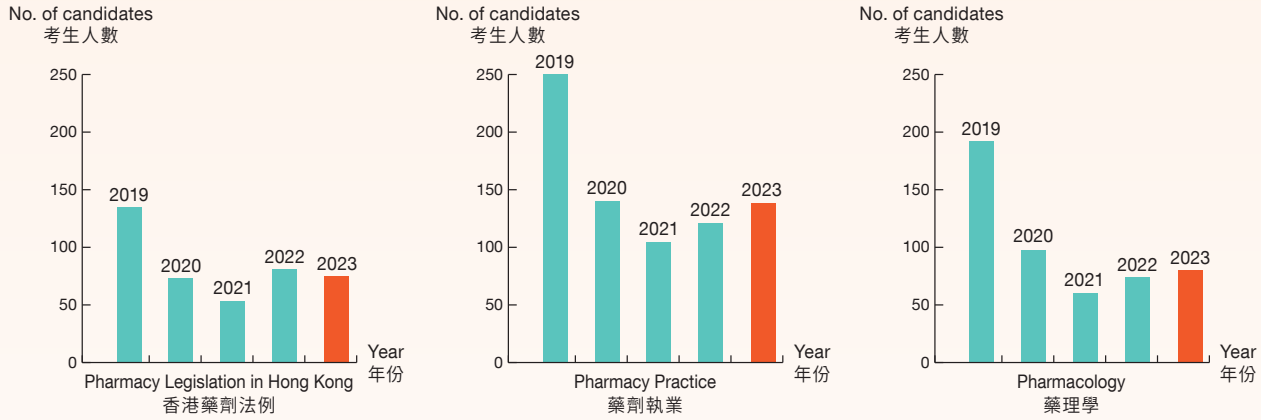
Statistical Tables and Charts
統計圖表

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
2019	135	77	57.0	250	82	32.8	192	71	37.0
2020	73	49	67.1	140	37	26.4	98	56	57.1
2021	53	22	41.5	105	24	22.9	60	36	60.0
2022	81	53	65.4	121	42	34.7	74	36	48.6
2023	75	48	64.0	138	22	15.9	80	46	57.5

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

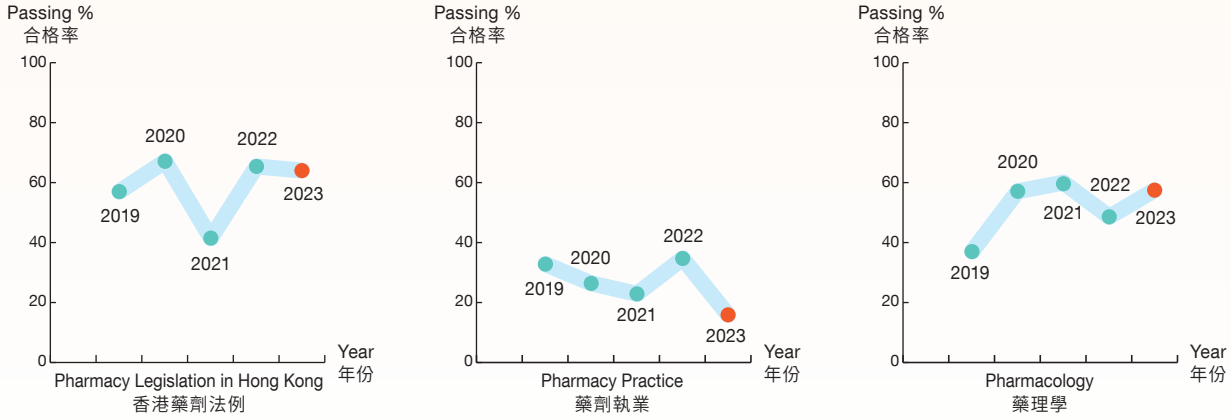
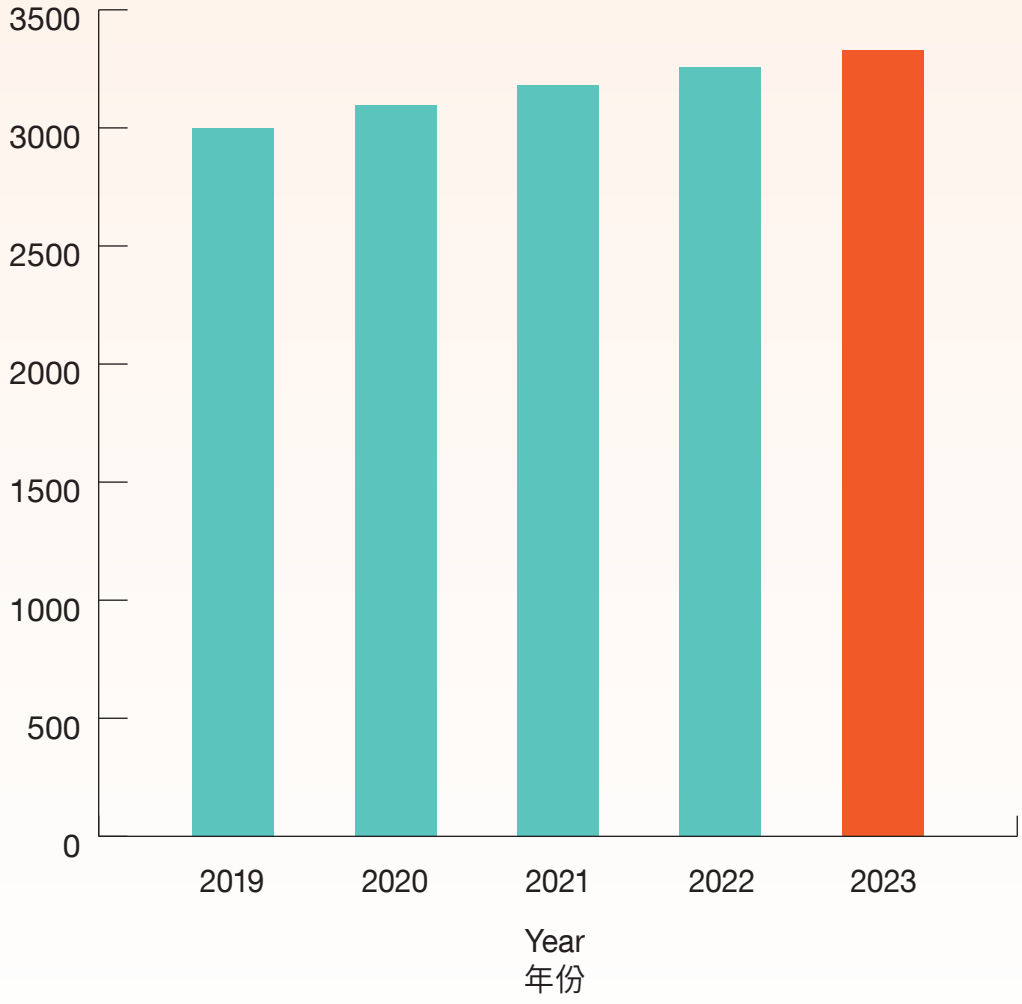


Table 表 2

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

Year 年份	2019	2020	2021	2022	2023
Number of registered pharmacists as at the end of the year 截至年終的註冊藥劑師人數	3 001	3 097	3 181	3 259	3 317

Number of registered pharmacists as at the end of the year
截至年終的註冊藥劑師人數



Statistical Tables and Charts
統計圖表

Table 表 3

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

Year 年份	2019	2020	2021	2022	2023
Fresh registration (Non-local graduates) 新註冊 (非本地畢業)	55	53	43	45	21
Fresh registration (Local graduates) 新註冊 (本地畢業)	75	73	81	60	52
Removal from the register* 刪除註冊 *	21	30	43	32	21
Re-registration 重新註冊	2	0	3	5	6
Net increase 淨增長	111	96	84	78	58

* 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				
	2019	2020	2021	2022	2023
Formal disciplinary actions (i.e. Inquiry by Disciplinary Committee) 正式紀律行動 (即由紀律委員會進行紀律研訊)	1	0	0	1	0

Statistical Tables and Charts
統計圖表

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				
	2019	2020	2021	2022	2023
Charge dismissed 指控不成立	0	0	0	0	0
Guilty of the charge 指控成立	1	0	0	1	0
Directions of the Disciplinary Committee 紀律委員會的指示					
Censure 譴責	1	0	0	1	0
Removed from the register for a period of time 由名冊除名一段時間	0	0	0	0	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				
	2019	2020	2021	2022	2023
(1) Professional misconduct 專業失德	0	0	0	0	0
(2) Selling Schedule 3 poison(s) 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
(3) Failing to keep proper record of antibiotics 沒有備存抗生素的適當記錄	1	0	0	1	0

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

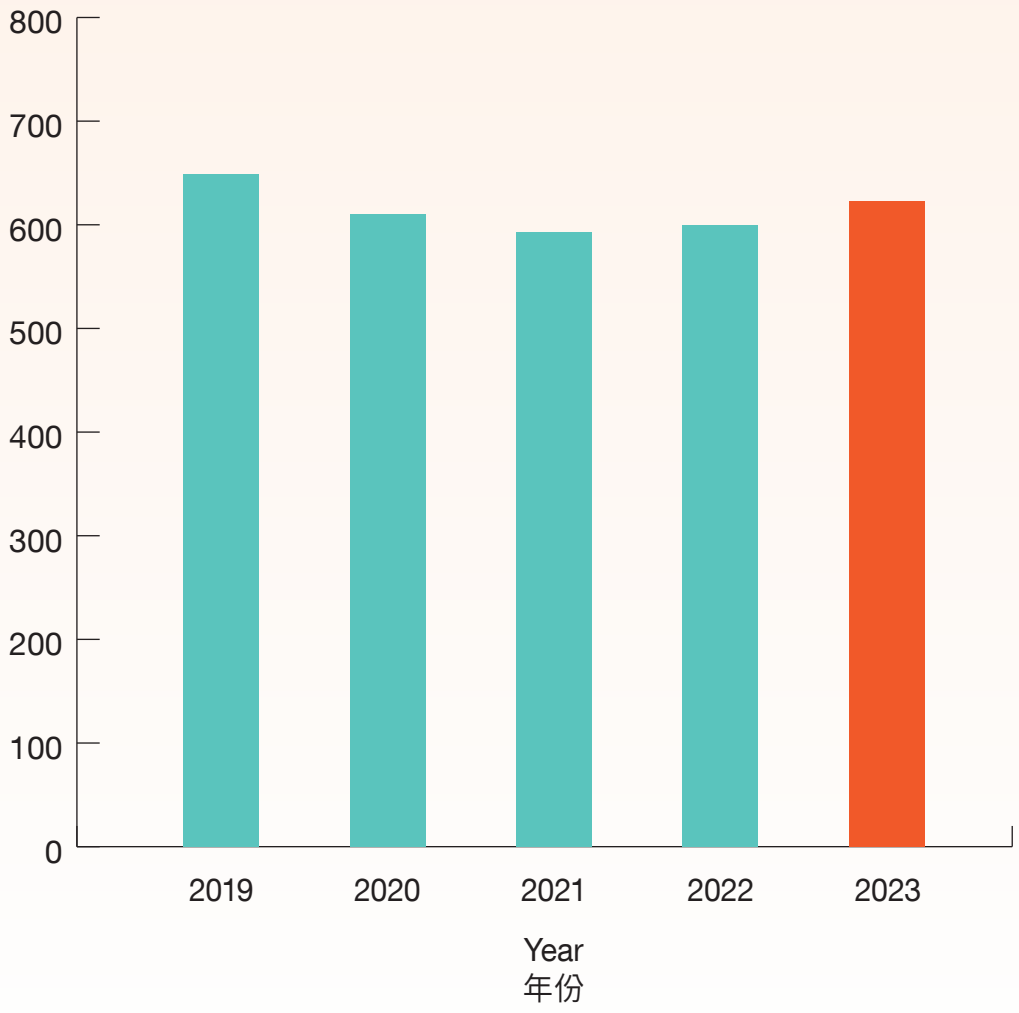
Statistical Tables and Charts
統計圖表

Table 表 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	2019	2020	2021	2022	2023
Number of authorized sellers of poisons as at the end of the year 截至年終的獲授權毒藥銷售商數目	649	610	593	600	623

Number of authorized sellers of poisons as at the end of the 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	2019	2020	2021	2022	2023
Number of applications for registration of premises approved 接納處所註冊申請的數目	51	23	19	33	51
Number of applications for registration of premises rejected 拒絕處所註冊申請的數目	0	0	0	0	0
Number 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	0	2

Table 表 9

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

Year 年份	2019	2020	2021	2022	2023
Number of inspections conducted 巡查數目	1 305	1 060	1 213	1 250	1 242
Number of test purchases conducted 試買數目	4 101	2 664	6 033	5 615	5 156

Note: The numbers of inspections and/or test purchases in 2020 to 2021 were subject to the impact of the COVID-19 pandemic and the social distancing measures.

註： 2020 至 2021 年的巡查及 / 或試買數目受 2019 冠狀病毒病疫情及社交距離措施影響。

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				
	2019	2020	2021	2022	2023
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)	11	4	7	5	5
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)	6	12	6	8	7
The authorized seller of poisons ceased operation before action taken by the Board 該銷售商在管理局採取紀律行動前已經結業	1	2	1	0	0
Total 總數	18	18	14	13	12

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				
	2019	2020	2021	2022	2023
Charge dismissed 指控不成立	0	0	0	0	0
Guilty of the charge 指控成立	11	4	7	5	5
Directions of the Disciplinary Committee 紀律委員會的指示					
Issue of written warning 發出書面警告	6	1	5	3	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	5	3	2	2	4

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)				
	2019	2020	2021	2022	2023
(1) Sale of Part 1/Part 2 poison(s) 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	0 (0%)	0 (0%)	1 (4.55%)	3 (16.67%)	0 (0%)
(2) Sale of Part 1 poison(s) 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	5 (10%)	2 (20%)	4 (18.18%)	2 (11.11%)	1 (8.33%)
(3) Sale of Schedule 3 poison(s) without the authority of a prescription 在沒有處方授權的情況下出售附表 3 毒藥	12 (24%)	2 (20%)	4 (18.18%)	2 (11.11%)	1 (8.33%)
(4) Sale of antibiotics without the authority of a prescription 在沒有處方授權的情況下銷售抗生素	5 (10%)	1 (10%)	8 (36.36%)	4 (22.21%)	0 (0%)
(5) Possession of poison(s) included in Part 1 of the Poisons List 管有毒藥表第 1 部所列任何毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)
(6) Possession of unregistered pharmaceutical product(s) 管有未經註冊藥劑製品	6 (12%)	2 (20%)	1 (4.55%)	1 (5.56%)	2 (16.68%)
(7) Possession of substance to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)
(8) Possession for sale or for any purpose of trade or manufacture goods to which a false trade description was applied 為售賣或任何商業或製造用途而管有應用虛假商品說明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(9) 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	2 (4%)	1 (10%)	0 (0%)	0 (0%)	1 (8.33%)

Statistical Tables and Charts
統計圖表

Table 表 12 (Cont'd) 續

Nature of offences* 個案性質	Number of counts (percentage) 次數 (百份比)				
	2019	2020	2021	2022	2023
(10) Failing to store poison(s) properly 沒有適當地貯存毒藥	3 (6%)	1 (10%)	3 (13.63%)	3 (16.67%)	2 (16.68%)
(11) Illegal sale of unregistered pharmaceutical product(s) 非法銷售未經註冊的藥劑製品	2 (4%)	0 (0%)	0 (0%)	2 (11.11%)	1 (8.33%)
(12) Selling Part 1 poison(s) without making an entry in the poisons book 銷售第 1 部毒藥時沒有記入在毒藥冊	0 (0%)	0 (0%)	1 (4.55%)	1 (5.56%)	0 (0%)
(13) 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 (2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(14) Selling goods to which a forged trade mark was applied 出售應用偽造商標的貨品	12 (24%)	1 (10%)	0 (0%)	0 (0%)	1 (8.33%)
(15) Failing to ensure that all the keys of the lockable receptacle in the dispensing area were kept by the registered pharmacist 未能確保配藥室可上鎖盛器的所有鎖匙由註冊藥劑師保管	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(16) Failing to provide written order(s) in relation to purchasing of controlled medicines 未能提供有關訂購受管制藥物的書面訂單	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(17) Failing to provide sales invoice(s) for controlled medicines 未能提供有關受管制藥物的銷售發票	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(18) Failing to keep proper record of psychotropic substances in psychotropic substances book 未能在精神藥物記錄冊內保存精神藥物有關的妥善記錄	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(19) Trafficking in dangerous drug 販運危險藥物	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)
(20) Failing to maintain proper record of antibiotics 沒有備存合適的抗生素紀錄	2 (4%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

* 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

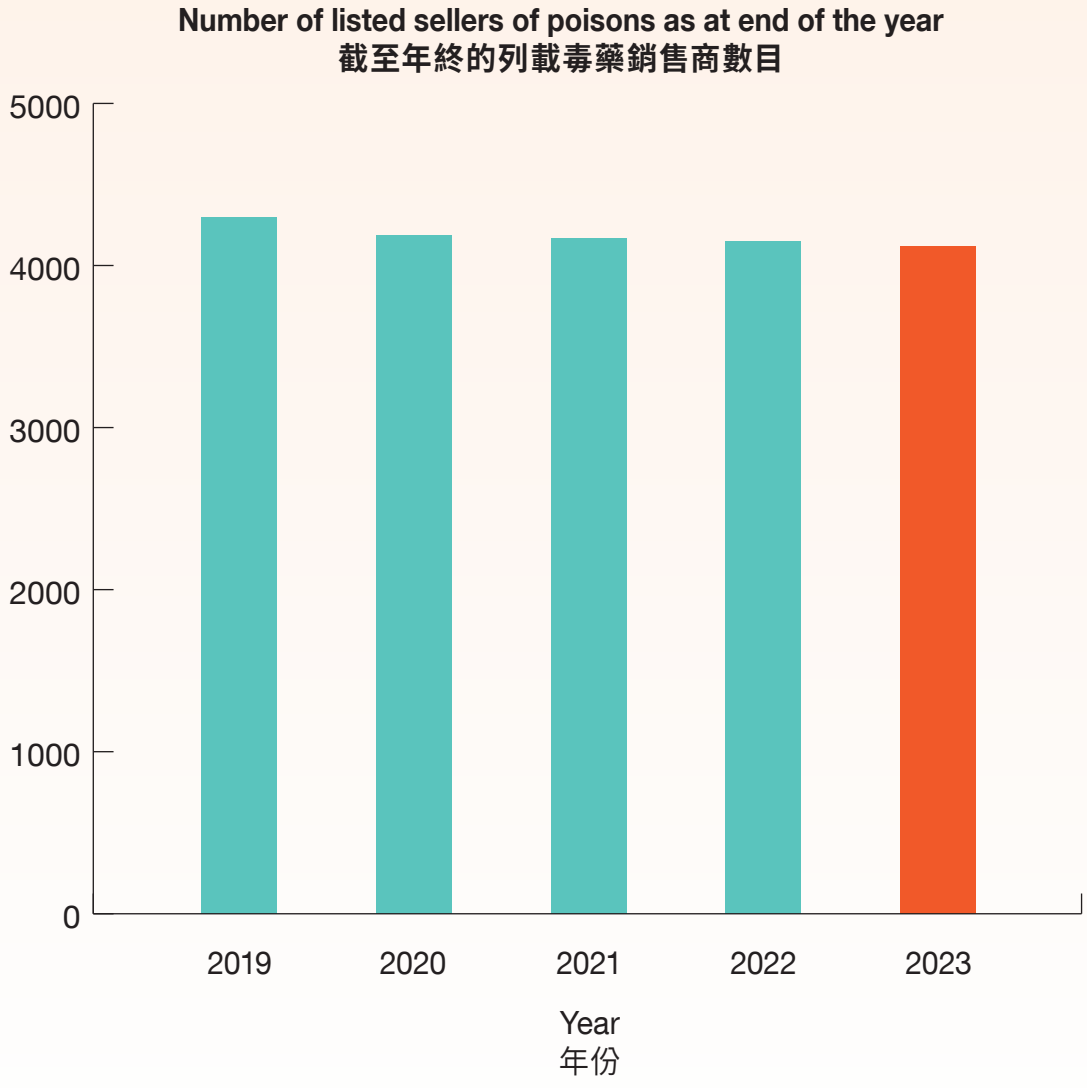
Table 表 12A

Disciplinary Inquiries into Authorized Sellers of Poisons in 2023
2023 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	2019	2020	2021	2022	2023
Number of listed sellers of poisons as at the end of the year 截至年終的列載毒藥銷售商數目	4 295	4 187	4 170	4 151	4 143



Statistical Tables and Charts
統計圖表

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	2019	2020	2021	2022	2023
Number of applications approved 接納的牌照申請數目	624	198	305	221	235
Number of applications rejected 拒絕的牌照申請數目	1	0	0	0	0

Table 表 15

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

Year 年份	2019	2020	2021	2022	2023
Number of inspections conducted 巡查數目	8 323	3 268	6 975	8 385	8 348
Number of test purchases conducted 試買數目	3 353	2 144	1 984	1 948	2 412

Note: The numbers of inspections and/or test purchases in 2020 to 2021 were subject to the impact of the COVID-19 pandemic and the social distancing measures.

註： 2020 至 2021 年的巡查及 / 或試買數目受 2019 冠狀病毒病疫情及社交距離措施影響。

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				
	2019	2020	2021	2022	2023
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名單除名	1	0	0	0	1
Issue of written warning 發出書面警告	5	2	4	0	2
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	6	3	0	1	4
The listed seller of poisons ceased operation before action taken by the Board 該銷售商在管理局採取紀律行動前已經結業	0	1	0	0	0
Total 總數	12	6	4	1	7

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)				
	2019	2020	2021	2022	2023
(1) Sale of Part 1 poison(s) 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	2 (7.14%)	2 (15.38%)	0 (0%)	0 (0%)	1 (8.33%)
(2) Sale of Schedule 3 poison(s) without the authority of a prescription 在沒有處方授權的情況下出售附表 3 毒藥	2 (7.14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(3) Possession of Part 1 poison(s) 管有第 1 部毒藥	3 (10.72%)	2 (15.38%)	2 (15.39%)	1 (50%)	2 (16.67%)
(4) Possession of unregistered pharmaceutical product(s) 管有未經註冊藥劑製品	6 (21.43%)	3 (23.10%)	1 (7.69%)	1 (50%)	3 (25%)
(5) Possession of substance(s) to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	2 (7.14%)	0 (0%)	0 (0%)	0 (0%)	2 (16.67%)
(6) Possession of unregistered proprietary Chinese medicine 管有未經註冊的中成藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (16.67%)
(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	2 (7.14%)	2 (15.38%)	5 (38.46%)	0 (0%)	0 (0%)
(8) Possession for sale or for any purpose of trade or manufacture goods to which a false trade description was applied 為售賣或任何商業或製造用途而管有應用虛假商品說明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(9) Sale of unregistered pharmaceutical product(s) 售賣未經註冊藥劑藥品	2 (7.14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(10) Selling goods to which a forged trade mark was applied 售賣應用偽造商標的貨品	4 (14.30%)	4 (30.76%)	5 (38.46%)	0 (0%)	1 (8.33%)
(11) 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	1 (3.57%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 表 17 (Cont'd) 續

Nature of offences* 個案性質	Number of counts (percentage) 次數 (百份比)				
	2019	2020	2021	2022	2023
(12) Unlawful sale of Part 2 poison(s) 非法銷售第 2 部毒藥	2 (7.14%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(13) Illegal use of restricted title 非法使用名銜	1 (3.57%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(14) Illegal use of restricted logo 非法展示標籤	1 (3.57%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(15) Sale of Part 1 poison(s) 銷售第 1 部毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)
(16) Sale of Schedule 1 Chinese herbal medicine without prescription 沒有按照處方銷售附表 1 中藥材	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(17) Failing to store poison(s) properly 沒有適當地貯存毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(18) Engaging in relation to a consumer in a commercial practice that is a misleading omission 就消費者作出屬誤導性遺漏的營業行為	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

* 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 17A

Disciplinary Cases regarding Listed Sellers of Poisons in 2023
2023 年有關列載毒藥銷售商的紀律個案

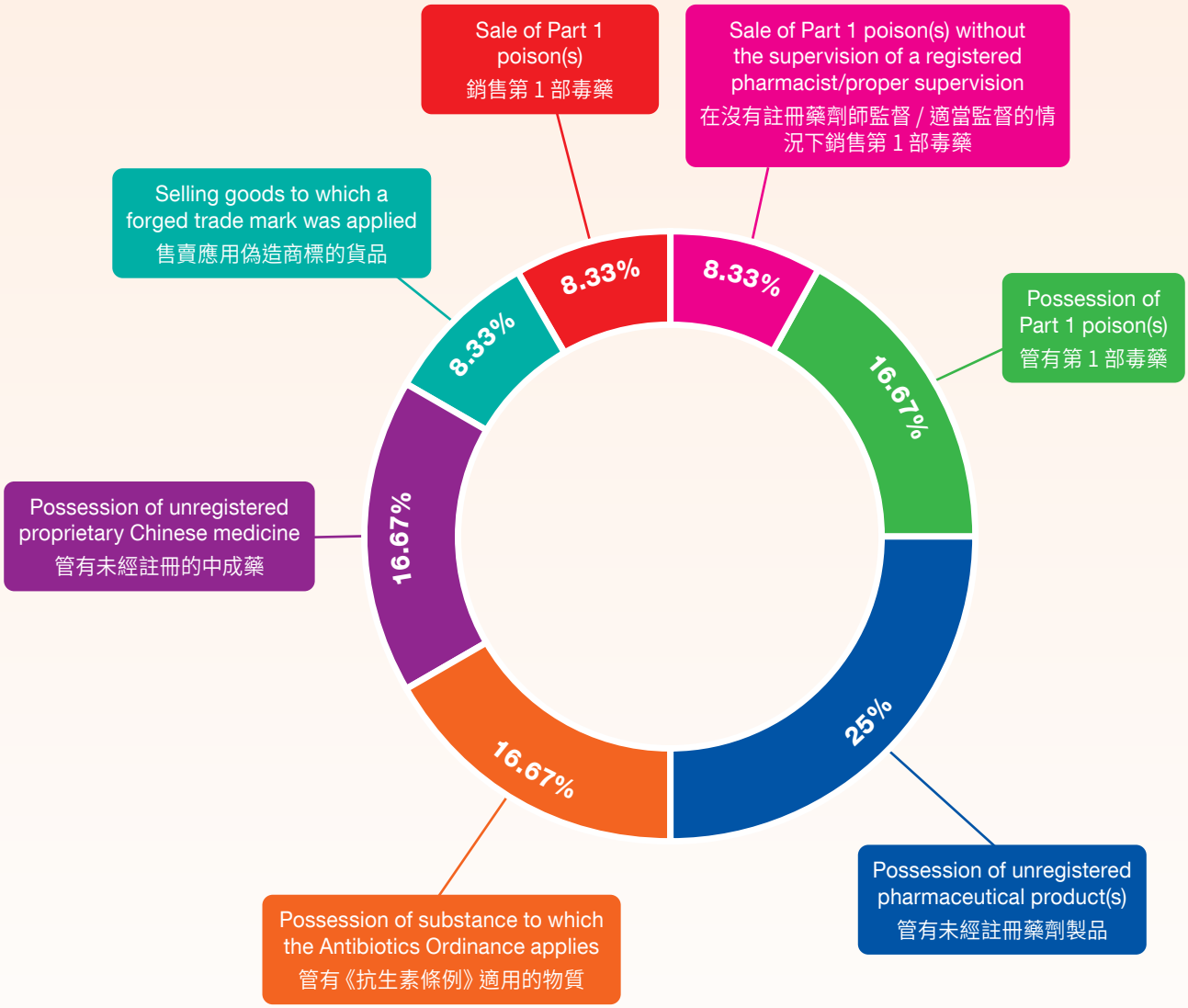


Table 表 18

Issue of Wholesale Dealer Licences and Related Disciplinary Actions Taken by the Pharmacy and Poisons Board
批發商牌照的簽發及由藥劑業及毒藥管理局採取的相關紀律行動

Year 年份	2019	2020	2021	2022	2023
Number of holders of wholesale dealer licences as at the end of the year 截至年終的批發商牌照持有人的數目	770	786	854	931	1002
Number of wholesale dealer licences revoked/ suspended 撤銷或吊銷批發商牌照的數目	2	1	2	0	0
Number of warning letters issued 發出警告信的數目	5	5	2	3	6

Statistical Tables and Charts
統計圖表

Table 表 19

Disciplinary Cases regarding Wholesale Dealer Licences Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關批發商牌照的紀律個案

Nature of cases* 個案性質	Number of counts (percentage) 次數 (百份比)				
	2019	2020	2021	2022	2023
(1) Causing to be published an Undesirable Medical Advertisement 安排發布不良醫藥廣告	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(2) Exporting pharmaceutical products and medicines not under and in accordance with an export licence 未有根據及按照出口許可證的規定而輸出藥劑製品及藥物	2 (25%)	1 (12.5%)	3 (42.84%)	0 (0%)	0 (0%)
(3) Failing to keep proper record of pharmaceutical products 未能在藥劑製品記錄冊內保存妥善記錄	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (16.67%)
(4) Furnishing false or misleading information in licence application 申請許可證時提供虛假的或具誤導性的資料	0 (0%)	1 (12.5%)	1 (14.29%)	0 (0%)	0 (0%)
(5) Illegal sale of unregistered pharmaceutical products 非法售賣未經註冊藥劑製品	1 (12.5%)	1 (12.5%)	1 (14.29%)	3 (75%)	3 (50%)
(6) Importing pharmaceutical products and medicines not under and in accordance with an import licence 未有根據及按照進口許可證的規定而輸入藥劑製品及藥物	4 (50%)	5 (62.5%)	0 (0%)	0 (0%)	0 (0%)
(7) Possession for sale of goods to which a false trade description was applied 為售賣用途而管有應用偽造商標的貨品	0 (0%)	0 (0%)	1 (14.29%)	0 (0%)	0 (0%)
(8) Possession of pharmaceutical product which was not registered for the purpose of sale, distribution or other use 為銷售、分發或其他用途而管有未經註冊藥劑製品	0 (0%)	0 (0%)	0 (0%)	1 (25%)	1 (16.67%)
(9) Selling a drug with a label which falsely describes the drug 出售具有虛假說明標籤的藥物	0 (0%)	0 (0%)	1 (14.29%)	0 (0%)	0 (0%)
(10) Selling drug not of the nature, substance or quality demanded by the purchaser 售賣藥物，而其性質、物質或品質與購買人所要求的藥物所具有者不符	1 (12.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(11) Unlawful supply of poisons 非法售賣毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(12) Contravening the conditions of a dangerous drugs licence or certificate 違反危險藥物許可證或證明書的規限條件	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (16.66%)

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

Table 表 20

Issue of Manufacturer's Licences for Pharmaceutical Products and Related Disciplinary Actions Taken by the Pharmacy and Poisons Board
藥劑製品製造商牌照的簽發及由藥劑業及毒藥管理局採取的相關紀律行動

Year 年份	2019	2020	2021	2022	2023
Number of holders of manufacturer's licences as at the end of the year 截至年終的製造商牌照持有人的數目	70	69	67	65	61
Number of holders of manufacturer's licences only authorized to conduct secondary packaging of pharmaceutical products as at the end of the year 截至年終只獲授權從事藥劑製品外包裝操作的製造商牌照持有人數目	47	46	45	43	40
Number of manufacturer's licences revoked/ suspended 撤銷或吊銷製造商牌照的數目	0	0	0	0	0
Number of warning letters issued 發出警告信的數目	0	0	1	2	2

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

Statistical Tables and Charts
統計圖表

Table 表 21

Disciplinary Cases regarding Manufacturer's Licences for Pharmaceutical Products Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關藥劑製品製造商牌照的紀律個案

Nature of cases* 個案性質	Number of counts (percentage) 次數 (百份比)				
	2019	2020	2021	2022	2023
(1) Conviction of an offence specified under Regulation 29 of the Pharmacy and Poisons Regulations 被裁定違反《藥劑業及毒藥規例》第 29 條所指明的罪行	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(2) Contravention of the Code of Practice for Licensed Manufacturers and Registered Authorized Persons or condition of the licence 違反《持牌製造商及註冊獲授權人執業守則》或發牌條件	0 (0%)	0 (0%)	1 (50%)	0 (0%)	1 (33.33%)
(3) Contravention of the Good Manufacturing Practice Guide 違反生產質量管理規範指引	0 (0%)	0 (0%)	1 (50%)	2 (100%)	2 (66.67%)

* Some cases involve multiple nature of non-compliances
部份個案涉及多個違規

Table 表 22

Number of Registered Authorized Persons and Related Disciplinary Actions Taken by the Pharmacy and Poisons Board
註冊為獲授權人的人數及由藥劑業及毒藥管理局採取的相關紀律行動

Year 年份	2019	2020	2021	2022	2023
Number of registered authorized persons for pharmaceutical manufacturers as at the end of the year 截至年終註冊為藥物製造商獲授權人的數目	146	149	153	153	149
Number of registered authorized persons for secondary packaging manufacturers as at the end of the year 截至年終註冊為外包裝製造商的獲授權人數目	95	94	93	93	87
Number of registered authorized persons for pharmaceutical manufacturers of advanced therapy products as at the end of the year 截至年終註冊為先進療法製品製造商的獲授權人數目	0	6	10	10	12
Number of registration of authorized persons cancelled or suspended 取消或暫時吊銷獲授權人註冊的數目	0	0	0	0	0
Number of warning letters issued 發出警告信的數目	0	0	3	0	1

Note: With effect from 14 September 2018, authorized persons for pharmaceutical manufacturers of advanced therapy products should comply with the requirements set out in the "*Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong*" for registration.

註： 由 2018 年 9 月 14 日起，先進療法製品製造商的獲授權人須符合《香港持牌製造商獲授權人及其他關鍵人員的資格、經驗與培訓要求指引》所列的要求方可獲註冊。

Statistical Tables and Charts
統計圖表

Table 表 23

Disciplinary Cases regarding Registered Authorized Persons Handled by the Pharmacy and Poisons Board
藥劑業及毒藥管理局處理有關註冊為獲授權人的紀律個案

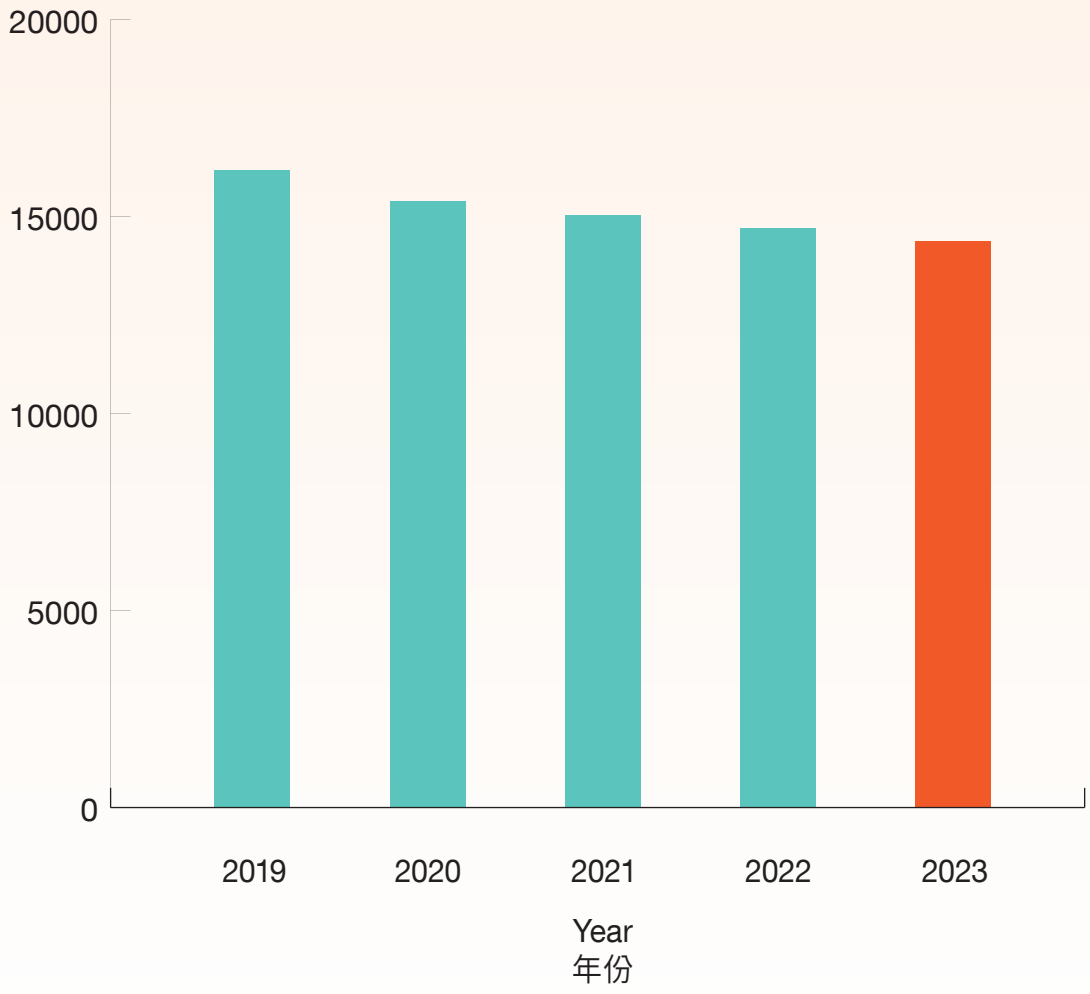
Nature of cases 個案性質	Number of counts (percentage) 次數 (百份比)				
	2019	2020	2021	2022	2023
(1) Conviction of an offence specified under Regulation 29 of the Pharmacy and Poisons Regulations 被裁定違反《藥劑業及毒藥規例》第 29 條所指明的罪行	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(2) Contravention of the Code of Practice for Licensed Manufacturers and Registered Authorized Persons or condition of the registration 違反《持牌製造商及註冊獲授權人執業守則》或註冊條件	0 (0%)	0 (0%)	3 (100%)	0 (0%)	1 (100%)

Table 表 24

Registration of Pharmaceutical Products
藥劑製品的註冊

Year 年份	2019	2020	2021	2022	2023
Number of registered pharmaceutical products as at the end of the year 截至年終的註冊藥劑製品數目	16 186	15 396	15 028	14 704	14 463

Number of registered pharmaceutical products as at the end of the year
截至年終的註冊藥劑製品數目



Statistical Tables and Charts
統計圖表

Table 表 25

Amendments to Schedules 1 and 3 to the Pharmacy and Poisons Regulations in 2023
2023 年在《藥劑業及毒藥規例》附表 1 及 3 作出的修訂

New Substances Added 加入的新物質	
1. Antisera, antitoxins, immunoglobulins and vaccines against Respiratory Syncytial Virus	用於對付呼吸道合胞病毒的抗血清、抗毒素、免疫球蛋白與疫苗
2. Asfotase alfa	阿司福酶 α
3. Belzutifan; its salts	貝組替凡；其鹽類
4. Bempedoic acid; its salts; its esters; their salts	貝派度酸；其鹽類；其酯類；它們的鹽類
5. Cenobamate; its salts	西諾氨酯；其鹽類
6. Deucravacitinib, its salts	氘可來昔替尼；其鹽類
7. Enfortumab vedotin	維恩妥尤單抗
8. Filgotinib; its salts	非戈替尼；其鹽類
9. Fosnetupitant; its salts	磷奈匹坦；其鹽類
10. Glofitamab	格菲妥單抗
11. Gozetotide; its salts	戈澤肽；其鹽類
12. Lurbinectedin; its salts	蘆比替定；其鹽類
13. Lutetium (177Lu) vipivotide tetraxetan; its salts	鐳〔177Lu〕特昔維匹肽；其鹽類
14. Maralixibat; its salts	馬昔巴特；其鹽類
15. Mavacamten; its salts	瑪伐凱泰；其鹽類
16. Mobocertinib; its salts	莫博賽替尼；其鹽類
17. Mosunetuzumab	莫妥珠單抗
18. Naldemedine; its salts	納地美定；其鹽類
19. Netarsudil; its salts	奈舒地爾；其鹽類
20. Revefenacin; its salts	瑞維那新；其鹽類
21. Rimegepant; its salts	瑞美吉泮；其鹽類
22. Selpercatinib; its salts	塞普替尼；其鹽類
23. Somatrogon	曲更生長素
24. Spesolimab	佩索利單抗
25. Tagraxofusp	他拉芙普
26. Tazemetostat; its salts	他澤司他；其鹽類
27. Teclistamab	特立妥單抗
28. Tenapanor; its salts	替那帕諾；其鹽類
29. Tezepelumab	特澤利尤單抗

Table 表 26

Amendments to Schedule 10 to the Pharmacy and Poisons Regulations in 2023
2023 年在《藥劑業及毒藥規例》附表 10 作出的修訂

New Substances Added 加入的新物質	
1. Antisera, antitoxins, immunoglobulins and vaccines against Respiratory Syncytial Virus	用於對付呼吸道合胞病毒的抗血清、抗毒素、免疫球蛋白與疫苗
2. Asfotase alfa	阿司福酶 α
3. Belzutifan; its salts	貝組替凡；其鹽類
4. Bempedoic acid; its salts; its esters; their salts	貝派度酸；其鹽類；其酯類；它們的鹽類
5. Cenobamate; its salts	西諾氨酯；其鹽類
6. Deucravacitinib, its salts	氘可來昔替尼；其鹽類
7. Enfortumab vedotin	維恩妥尤單抗
8. Filgotinib; its salts	非戈替尼；其鹽類
9. Fosnetupitant; its salts	磷奈匹坦；其鹽類
10. Glofitamab	格菲妥單抗
11. Gozetotide; its salts	戈澤肽；其鹽類
12. Lurbinectedin; its salts	蘆比替定；其鹽類
13. Lutetium (177Lu) vipivotide tetraxetan; its salts	鐀〔177Lu〕特昔維匹肽；其鹽類
14. Maralixibat; its salts	馬昔巴特；其鹽類
15. Mavacamten; its salts	瑪伐凱泰；其鹽類
16. Mobocertinib; its salts	莫博賽替尼；其鹽類
17. Mosunetuzumab	莫妥珠單抗
18. Naldemedine; its salts	納地美定；其鹽類
19. Netarsudil; its salts	奈舒地爾；其鹽類
20. Revefenacin; its salts	瑞維那新；其鹽類
21. Rimegepant; its salts	瑞美吉泮；其鹽類
22. Selpercatinib; its salts	塞普替尼；其鹽類
23. Somatrogon	曲更生長素
24. Spesolimab	佩索利單抗
25. Tagraxofusp	他拉芙普
26. Tazemetostat; its salts	他澤司他；其鹽類
27. Teclistamab	特立妥單抗
28. Tenapanor; its salts	替那帕諾；其鹽類
29. Tezepelumab	特澤利尤單抗

香港藥劑業及毒藥管理局

PHARMACY AND POISONS BOARD OF HONG KONG

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