Pharmacy and Poisons Board of Hong Kong
香港藥劑業及毒藥管理局

2024年報
Annual Report

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Message from the Chairman
主席獻辭

I am pleased to present the 2024 Annual Report covering the significant milestones achieved over the past year. These accomplishments underscore the efforts and commitment of the Pharmacy and Poisons Board ("the Board") to safeguarding public health and advancing standards of the pharmaceutical profession in Hong Kong.

As part of our continuous pursuit of upkeeping pharmaceutical product quality on par with international best practices, the Board has adopted the "Guide to Good Manufacturing Practice for Medicinal Products" (version 17) published by the Pharmaceutical Inspection Co-operation Scheme for licensed pharmaceutical manufacturers, and correspondingly updated the "Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products". Both guides were gazetted on 26 July 2024 for adoption from 1 July 2025 onwards to reinforce the framework for advancing local pharmaceutical manufacturing standards and preserving public trust in the local drug regulatory system.

Protecting public health remains our core mission. In 2024, the Board has taken a series of decisive steps to strengthen regulatory controls on drug substances with potential for abuse to safeguard the community against emerging health risks. On 28 June 2024, the Board regulated the sales of hexahydro derivatives of cannabinol (including hexahydrocannabihexol) by classifying them as Part 1 poisons under the Pharmacy and Poisons Regulations ("PPR") (Cap. 138A). Substances structurally related to nicotine, apart from nicotine itself, were likewise regulated as Part 1 poisons with effect from 13 December 2024, with exemptions confined to nicotine in conventional smoking products as defined by the Smoking (Public Health) Ordinance (Cap. 371). With the gazettal on 10 October 2024, injectable glutathione (including its salts and derivatives) was also added to the Poisons Lists under Schedule 1, Schedule 3 and Part 1 of Schedule 10 of the PPR as prescription-only medicines with effect from 10 April 2025 such that this substance could be sold only under the prescription of registered medical practitioners. Furthermore, having balanced the potential drug interactions and health risks with accessibility concerns, oral contraceptives previously categorised as non-poisons were reclassified as Part 2 poisons, with a view to restricting the conduct of their retail sale to licensed retailers starting from 28 June 2025.

我欣然向各位發表2024年報，回顧香港藥劑業及毒藥管理局(下稱「管理局」)過去一年的重要里程碑。這些成果充分展現管理局在保障公眾健康及提升本地藥劑專業水平上所作出的努力和承擔。

為持續確保本地藥劑製品的生產和質素達至國際最佳水平，管理局於年內採納藥品檢查合作計劃(PIC/S)向持牌藥物製造商發出的《藥品生產質量管理規範指引》(第十七版)，並相應更新《香港藥劑製品外包裝生產質量管理規範指引》。該兩份指引於2024年7月26日刊憲，並由2025年7月1日起生效，進一步鞏固本地製藥標準的框架，並加強公眾對本地藥物監管制度的信心。

守護公眾健康一直是我們的核心使命。在2024年，管理局採取一系列果斷措施，加強規管具濫用風險的藥物，避免對社會構成健康風險。為有效規管大麻酚六氫衍生物(包括六氫大麻酚)的銷售，管理局於2024年6月28日將其歸類為《藥劑業及毒藥規例》(第138A章)下的第1部毒藥。由2024年12月13日起，除尼古丁外，與尼古丁結構相似的物質，亦同樣被規管為第1部毒藥，只有《吸煙(公眾衞生)條例》(第371章)所界定的傳統吸煙產品中所含有的尼古丁，方可獲得豁免。此外，隨著2024年10月10日刊憲，注射式穀胱甘肽(包括其鹽類及衍生物) 由2025年4月10日起被納入《藥劑業及毒藥規例》附表1、附表3和附表10第1部所載列的毒藥表，即被歸類為處方藥物，只可在註冊醫生的處方下方可購買。另外，管理局在權衡潛在藥物相互作用、健康風險和藥物可及性各因素後，於2025年6月28日起，將原屬非毒藥的口服避孕藥歸類為第2部毒藥，以限制該類藥物只可由持牌零售商售賣。

Recognising the increasing use of medical gases for life-saving purposes, as prominently demonstrated during the COVID-19 pandemic, the Board has initiated proactive actions to establish regulatory control of medical gases as pharmaceutical products. After consulting the relevant stakeholders between November 2023 and January 2024 and with their support, the Board has decided to implement a new regulatory framework of medical gases under the Pharmacy and Poisons Ordinance (Cap. 138) with effect from 14 June 2026. To ensure the quality, safety and availability of medical gases, comprehensive guidance notes were promulgated in June 2024, covering registration and licensing requirements for medical gases manufacturing and wholesaling, as well as the updated qualification and training requirements for key personnel of manufacturers.

The launch of the voluntary Continuing Pharmacy Education ("CPE") Programme on 1 June 2024 marked yet another milestone of the Board's work. This initiative encourages registered pharmacists to continually enhance their professional knowledge and skills to uphold the highest standards of the pharmacy profession. By the end of 2024, seven organisations have been accredited by the Board as CPE Administrators to facilitate the promotion and implementation of the CPE Programme among various sectors of the profession.

The Board has continued to facilitate the registration of pharmaceutical products containing New Chemical or Biological Entities ("NCE products") in Hong Kong by introducing a series of refinements to the "1+" mechanism, which allows holders of registration from one (instead of two or more) of the recognised drug regulatory authorities to apply for registration of new drugs, provided that specified conditions are met. The introduction of the "stop-clock" approach on 1 May 2024 sets a target of 150 working days for processing NCE product registration applications to enhance the transparency, consistency and efficiency of the evaluation processes. In parallel, the membership of the Expert Group on Drug Registration has been expanded to include additional local and international experts, broadening the advisory expertise and ensuring impartial and robust assessments of drug applications. On 1 November 2024, the scope of the "1+" mechanism was extended to cover all new drugs, beyond those for life-threatening or severely debilitating diseases. By the end of 2024, nine new drug products with initial marketing approval from regulatory authorities in the Chinese Mainland, the United States or Japan have been successfully registered under this mechanism, thereby significantly expanding treatment options and accessibility for patients in Hong Kong.

醫療氣體在生命救援上的應用日趨廣泛，於2019冠狀病毒病疫情期間尤甚。有鑑於此，管理局積極推動將醫療氣體規管為藥劑製品的措施。經2023年11月至2024年1月期間諮詢相關持份者並獲得他們的支持後，管理局決定由2026年6月14日起，在現行《藥劑業及毒藥條例》(第138章)下建立醫療氣體規管框架。為確保醫療氣體的質素、安全及供應，管理局於2024年6月向業界發布相關指南，詳細闡明醫療氣體製造商和批發商的註冊和發牌條件，以及製造商關鍵人員的資格和培訓最新要求。

於2024年6月1日推出的註冊藥劑師自願持續專業教育計劃，標誌着管理局工作的另一里程碑。這項計劃旨在鼓勵註冊藥劑師持續提升他們的專業知識和技能，以確保藥劑專業的最高水平。截至2024年年底，已有七間機構獲管理局認可為持續專業教育計劃管理機構，負責實施該計劃，並將計劃推廣予不同專業領域的藥劑師。

為進一步促進新藥劑或生物元素藥劑製品在本港註冊，管理局於2024年推出一系列措施優化「1+」機制。此機制容許新藥註冊申請者，在符合特定要求下，只須提交一個（而非兩個或以上）參考藥物監管機構的註冊許可，便可以在香港申請註冊。而自2024年5月1日起，「1+」機制實施「計時」機制，為處理新藥註冊申請設定150個工作日的目標時限，以提升藥品評審過程的透明度、一致性和效率。與此同時，管理局亦擴大藥劑製品註冊專家顧問諮詢組的組成，納入更多本地和國際專家，以涵蓋更廣博的專業知識，確保藥物申請的審評過程公正嚴謹。此外，除了用於治療嚴重或罕見疾病的藥品的註冊申請，「1+」機制的適用範圍由2024年11月1日起擴展至所有新藥。截至2024年年底，共九款獲得中國內地、美國或日本監管機構初步核准銷售的新藥按此機制成功在本港註冊，為本港病人提供更多治療選擇，並提升藥物的可及性。

In view of the Government's determination to leverage Hong Kong's medical strengths and developing Hong Kong into a health and medical innovation hub with different new initiatives in the pipeline, it is envisaged that the volume and complexity of the Board's registration and certification work would increase consistently and substantially. To bolster the Board's capacity and effectiveness in handling the regulatory processes, particularly in pharmaceutical product registration and clinical trial certification, the Board has restructured its former Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee by establishing two specialised committees in its place in December 2024, namely, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee, and the Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee.

We continue to strengthen our international engagement through active participation in global forums. Notably, the Board has been actively participating in the meetings of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") since 2023, with a view to becoming a regulatory member of ICH. This ongoing participation underscores our commitment to fostering regulatory enhancement and meaningful collaboration on the international stage.

The Board's achievements in 2024 outlined in the foregoing are a testament to the dedication and unwavering support of all Members of the Board as well as its committees and working groups. As we look ahead, we remain resolute in our dedication to preserving public health and safety, elevating pharmacy practice standards, and fostering collaboration between the pharmaceutical and healthcare professionals. Together, we will continue to strive for excellence in serving the people of Hong Kong.

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

為發揮香港的醫療優勢，推動香港發展成醫療創新樞紐，政府銳意推出多項相關措施。因此，管理局在註冊及認證方面的工作將更為繁重。為加強處理規管工作，特別是藥劑製品註冊和臨床試驗認證的能力和效能，管理局於2024年12月將藥劑業及毒藥(藥劑製品及物質註冊：臨床試驗及藥物測試證明書)委員會改組成兩個專責委員會，分別為藥劑業及毒藥(藥劑製品及物質註冊)委員會和藥劑業及毒藥(臨牀試驗及藥物測試證明書)委員會。

管理局繼續透過積極參與不同國際論壇，以加強對外聯繫。值得一提的是，自2023年起，管理局一直積極參與國際人用藥品註冊技術協調會[1]（下稱「ICH」）的會議，並致力爭取成為ICH監管機構成員。此舉不僅展現管理局致力優化監管制度的決心，亦突顯我們在國際層面上促進具意義協作的承擔。

管理局在2024年度取得的豐碩成果，端賴管理局全體成員及轄下各委員會與工作小組的克盡厥職和鼎力支持。展望未來，管理局將繼續恪盡職守，致力維護公眾健康與安全、提升藥劑業水平，並促進藥劑業和醫護專業人員的合作。我們將攜手並肩，精益求精，服務社會。

藥劑業及毒藥管理局主席
林文健醫生，JP

[1] 前譯為「國際醫藥法規協調會議」。

Introduction
引言

This annual report covers the calendar year 2024. 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.

這份年報載錄藥劑業及毒藥管理局(「管理局」)在二零二四年的工作。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(「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。

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

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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 CHING Ho-yan, Alex
(Legal Adviser)
程浩恩先生 (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 LAI Wing-him
黎榮謙醫生

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 2024 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 CHING Ho-yan, Alex (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 LAI Wing-him

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)。

在二零二四年十二月三十一日，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) 程浩恩先生（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) 黎榮謙醫生

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 eight 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。

管理局轄下設有八個委員會。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 eight committees are established under various provisions of the Pharmacy and Poisons Ordinance:

管理局根據《藥劑業及毒藥條例》內相關的條文成立了下述八個委員會，協助管理局執行職能：

(1) Examination Committee

(i) Membership as at 31 December 2024

Professor LEUNG Pak-heng, George (Chairman)
Mr CHAN Ling-fung, Frank, JP
Dr CHENG Wing-tak, Franco
Dr FUNG Ying
Mr LAM Fung-shing, Edwin
Dr LAM Tai-ning, Teddy
Dr LEE Wai-on
Professor NG Kwok-wai, Enders
Miss KWAN Sau-fan, Kim (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.

(1) 考試委員會

(i) 截至二零二四年十二月三十一日的成員名單

梁栢行教授 (主席)
陳凌峯先生，JP
鄭永德博士
封螢醫生
林豐盛先生
林泰寧博士
李偉安博士
吳國偉教授
關秀芬女士 (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 2024

Mr CHAN Ling-fung, Frank, JP (Chairman)
Mr CHAN Kam-chau
Mr CHENG Wai-chung
Mr KAN Kin-hang, Michael
Ms LI Ka-yan
Ms TAM Pui-ying, Peggy
Mr TING Wing-fai, MH
Mr NG Wai-kit, Grant (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 2024

Mr CHAN Ling-fung, Frank, JP (Chairman)
Mr CHAN King-che, Stephen
Mr CHAN Tai-fu
Ms HUI Mun-yee
Mr TSOI Chick-lai, Samson
Mr WONG Kei, Eric
Mr LAU Moon-tong, John (Secretary)

(2) 藥劑業及毒藥(列載毒藥銷售商)委員會

(i) 截至二零二四年十二月三十一日的成員名單

陳凌峯先生，JP (主席)
陳錦洲先生
鄭蔚聰先生
簡健恒先生
李嘉欣女士
譚佩英女士
丁志輝先生，MH
吳偉傑先生 (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) 截至二零二四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
許敏儀女士
蔡節禮先生
黃騏先生
劉滿堂先生 (秘書)

(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.

(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 2024

Mr CHAN Ling-fung, Frank, JP (Chairman)
Dr CHAN Sing-kwok, Theobald
Dr CHENG Chi-chung, Vincent
Dr CHOW Shing-fung, Aviva
Professor LEUNG Kam-tong
Professor LEUNG Shui-yee, Sharon
Dr LIU, Diana
Ms TSO Sau-ching
Ms YAP Woan-tyng, Tina
Mr YUNG Siu-lung, Stephen
Mr YIM Tsz-kok, Michael (Secretary)

(4) 藥劑業及毒藥(製造商牌照)委員會

(i) 截至二零二四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
梁錦堂教授
梁水意教授
劉寒青博士
曹秀青女士
葉婉婷女士
容兆龍先生
嚴子閣先生 (秘書)

(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.

(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) Committee^

(i) Membership as at 31 December 2024

Mr CHAN Ling-fung, Frank, JP (Chairman)
Ms CHAK Man-lee, Charlotta
Professor CHEUNG Yin-ting
Dr LEE Cheuk-kwong, MH
Dr LEE Ka-wing, Gavin
Ms LEUNG Shuk-mei
Dr NG Kwok-keung, JP
Professor TSE Wai-choi, Eric
Dr YEUNG Lee, Michelle
Ms YOUNG Wai-man, Grace
Mr YEUNG Yee-fai, Raphael (Secretary)

(ii) Functions

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) 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; and

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

^Note: The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee was dissolved and reformed as the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee on 20 December 2024.

(5) 藥劑業及毒藥(藥劑製品及物質註冊)委員會^

(i) 截至二零二四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
張彥婷教授
李卓廣醫生，MH
李家榮醫生
梁淑美女士
吳國強醫生，JP
謝偉財教授
楊莉獸醫
楊惠敏女士
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)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；及

(c) 審議有關更改藥劑製品或物質註冊詳情的申請。

^註: 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)委員會於2024年12月20日解散及改組為藥劑業及毒藥(藥劑製品及物質註冊)委員會。

(6) Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee*

(i) Membership as at 31 December 2024

Mr CHAN Ling-fung, Frank, JP (Chairman)
Miss CHAN Ho-yan
Mr CHOU Chi-hoi, Francis
Dr HO King-man
Mr KONG Chun-hon, Danny
Professor LEUNG Pak-heng, George
Dr PANG Wai-bing, Cecilia
Professor TAM, Sunny
Dr WONG Chun-kwan, Bonnie
Dr YOON Weng-li
Professor ZUO Zhong, Joan
Ms TSE Po-yiu, Blouie (Secretary)

(ii) Functions

The Pharmacy and Poisons (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 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

(b) 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.

*Note: The Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee was established on 20 December 2024 to take over the functions related to clinical trials and medicinal tests from the former Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee, which was dissolved on the same date.

(6) 藥劑業及毒藥(臨牀試驗及藥物測試證明書)委員會*

(i) 截至二零二四年十二月三十一日的成員名單

陳凌峯先生，JP (主席)
陳可欣女士
周智海先生
何景文醫生
江展航先生
梁栢行教授
彭慧冰博士
譚新榮教授
黃駿君醫生
袁永麗博士
左中教授
謝寶瑤女士 (秘書)

(ii) 職能

藥劑業及毒藥(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

(b) 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。

*註:藥劑業及毒藥(臨牀試驗及藥物測試證明書)委員會於2024年12月20日成立，以承接於同日解散的前藥劑業及毒藥(藥劑製品及物質註冊：臨床試驗及藥物測試證明書)委員會的臨床試驗及藥物測試相關職能。

(7) Poisons Committee

(i) Membership as at 31 December 2024

Dr LEE Wai-on (Chairman)
Mr CHAN Ling-fung, Frank, JP
Dr LAI Wing-him
Mr SUNG Ming-tat, Dick
Ms TAM Hi, Beverley
Professor WONG Chi-kei, Ian
Miss KWAN Sau-fan, Kim (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) 毒藥委員會

(i) 截至二零二四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
黎榮謙醫生
沈明達先生
譚起女士
黃志基教授
關秀芬女士 (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。

(8) Postgraduate Pharmacy Training and Development Committee

(i) Membership as at 31 December 2024

Professor ZUO Zhong, Joan (Chairman)
Mr CHAN Ling-fung, Frank, JP
Ms CHAN So-kuen, Sabrina
Mr CHAN Sze-tao, Lot
Dr CHENG Heung-kwan, Celine
Ms CHOY Sze-man, Connie
Dr FUNG Ying
Ms HUI Hoi-yun, Helen
Mr HUNG Chi-tat, Ray
Miss KWOK Wing-kai
Mr LO Cheuk-fei, Jeffrey
Mr SO Pak-yin, Stephen
Mr SUNG Ming-tat, Dick
Ms TAM Hi, Beverley
Ms TAM Yuen-ting, Eliza
Professor YOU Hoi-sze, Joyce
Miss KWAN Sau-fan, Kim (Secretary)

(8) 藥劑師持續進修及實習培訓委員會

(i) 截至二零二四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
陳素娟女士
陳詩濤先生
鄭香郡博士
蔡思敏女士
封螢醫生
許凱潤女士
洪志達先生
郭詠琪女士
盧卓飛先生
蘇栢賢先生
沈明達先生
譚起女士
譚宛婷女士
姚凱詩教授
關秀芬女士 (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) for locally trained applicant: holding a pharmacy degree awarded by the University of Hong Kong ("HKU") or the Chinese University of Hong Kong ("CUHK") after completion of a full time course of study at the university; or

(b) for non-locally trained applicant: having 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 that education.

(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 2024. A total of 30 applicants cumulatively passed all the three subjects in the year 2024.

The results of these two registration examinations are shown in **Table 1**. Figures for 2020 to 2024 are also included for comparison purpose.

(iii) Training

Applicants holding a pharmacy degree awarded by HKU or CUHK after completion of a full time course of study at the university 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) 本地培訓申請人：在香港大學或香港中文大學修畢全日制課程後，持有該大學所頒授的藥劑學學位；或

(b) 非本地培訓申請人：完成不少於三個完整學年的全日制藥劑學大專教育課程，或具備同等學歷，並通常於其完成教育課程的國家，已註冊為藥劑師或已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。

考試委員會在二零二四年六月及十二月舉辦了兩次註冊考試。同年累計有30人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，以及二零二零年至二零二四年的有關數字，以供比較。

(iii) 實習

在香港大學或香港中文大學修畢全日制課程後持有該大學所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。

Applicants holding a recognized 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.

(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 2024, there were 3 386 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 2020 to 2024 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 30 to 32 of this report.

Statistical data regarding disciplinary actions taken by the Board in respect of registered pharmacists in 2020 to 2024 are shown in **Tables 4, 5 and 6**.

持有其他地方頒授的認可藥劑學學位的申請人，其註冊前實習訓練及／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) 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。

管理局秘書亦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。

截至二零二四年十二月三十一日，香港共有3 386位註冊藥劑師。**表2及3**列出二零二零年至二零二四年有關藥劑師註冊的統計資料，以及新註冊、刪除註冊及重新註冊的分項數字。

(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30至32頁。

表4、5及6詳列管理局在二零二零年至二零二四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. 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 643 ASPs registered in Hong Kong as at the end of 2024. Statistical data regarding the total number of ASPs, applications for registration and renewal of registration of premises of ASPs in 2020 to 2024 are shown in **Tables 7 and 8**.

(2) 零售商（包括獲授權毒藥銷售商及列載毒藥銷售商）的發牌及規管工作

(i) 獲授權毒藥銷售商：發牌工作

獲授權毒藥銷售商一般稱為「藥房」("pharmacy"或"dispensary")，是獲授權銷售毒藥表內第1部毒藥的商號，惟銷售這些毒藥必須由註冊藥劑師監督或直接銷售。擬申請成為獲授權毒藥銷售商的商號，須向管理局申請將其進行毒藥零售業務的處所註冊。此外，獲授權毒藥銷售商亦會獲授權在註冊處所內零售毒藥表內第2部毒藥。如管理局信納該申請符合《藥劑業及毒藥條例》第13(4)條所列的條件，便批准有關申請，在繳付訂明費用後生效。

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

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

截至二零二四年年終，香港共有643名獲授權毒藥銷售商。**表7及8**詳列二零二零年至二零二四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, variation on the conditions relating to the registration of premises to disqualification from being an ASP for a specified period of time.

10 inquiries were held in 2024 and all of the ASPs concerned were found guilty of misconduct. Three ASPs were issued with written warnings whilst seven 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 six such interviews were held in 2024.

The number of inspections and test purchases conducted by pharmacist inspectors against ASPs in 2020 to 2024 is shown in **Table 9**.

Statistical data regarding disciplinary cases handled by the Board in respect of ASPs in 2020 to 2024 are given in **Tables 10, 11, 12 and 12A**.

(ii) 獲授權毒藥銷售商：紀律事宜

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

管理局會委出紀律委員會就任何不當行為展開研訊。銷售商如被裁定犯有不當行為，將會受到紀律制裁，由書面警告、更改處所註冊條件，以至在指定期間被取消銷售商資格。

在二零二四年，管理局舉行了十次紀律研訊，全部涉事的獲授權毒藥銷售商被裁定犯有不當行為。紀律委員會向其中三名獲授權毒藥銷售商發出書面警告，其餘七名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。管理局在二零二四年舉行了六次該類會面。

表9列出二零二零年至二零二四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詳列二零二零年至二零二四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 4 101 LSPs in Hong Kong as at the end of 2024. The number of licensed LSPs in 2020 to 2024 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 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/her case will be submitted to the Board for consideration. If the Board considers him/her not a fit and proper person to continue the retail business of Part 2 poisons, his/her 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 2020 to 2024 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。

截至二零二四年年終，香港共有4 101名列載毒藥銷售商。**表13**列出二零二零年至二零二四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會巡查列載毒藥銷售商的處所。但是，管理局不會因調查列載毒藥銷售商的經營手法而召開紀律研訊，這點與處理有關獲授權毒藥銷售商的紀律事宜的方法不同。假如有列載毒藥銷售商被裁定干犯任何《藥劑業及毒藥條例》、《抗生素條例》、《危險藥物條例》、《商品説明條例》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列出二零二零年至二零二四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 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.

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 1 032 holders of wholesale dealer licence in Hong Kong as at the end of 2024. Statistical data regarding the wholesale dealer licences and related disciplinary cases handled by the Board for 2020 to 2024 are shown in **Tables 18 and 19**.

(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。

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《商品説明條例》(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。

截至二零二四年年終，香港共有1 032名批發商牌照持有人。**表18及19**列出二零二零年至二零二四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) 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.

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.

(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。

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。

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 63 holders of a manufacturer's licence in Hong Kong as at the end of 2024, and all of them were required to comply with the PIC/S GMP Guide with effect from 1 October 2015. Among these 63 holders, 41 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 2020 to 2024 are given in **Tables 20 to 23** respectively.

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。

截至二零二四年年終，香港共有63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63名製造商牌照持有人當中，41名只獲授權從事藥劑製品外包裝操作。**表20至23**分別列出二零二零年至二零二四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 Board.

In considering an application for registration of a pharmaceutical product, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) 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 14 314 registered pharmaceutical products in Hong Kong as at the end of 2024. The number of registered pharmaceutical products as at the end of 2020 to 2024 is shown in **Table 24**.

(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管理局註冊。

在決定是否批准某一藥劑製品註冊時，藥劑業及毒藥(藥劑製品及物質註冊)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。

截至二零二四年年終，香港共有14 314種已註冊的藥劑製品。**表24**列出截至二零二零年至二零二四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 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:

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.

(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：

分類	銷售的限制
(a)第1部毒藥：附表10（即毒藥表）第1部所列毒藥	在註冊藥劑師監督下，由獲授權毒藥銷售商銷售。這類毒藥必須存放在上鎖的盛器內，而盛器則須存放在處所內顧客不准進入的地方。
(b) 附表1毒藥：同時列於附表10（即毒藥表）第1部及《藥劑業及毒藥規例》附表1的毒藥	在註冊藥劑師監督下，由獲授權毒藥銷售商銷售，並必須於出售前將銷售詳情記錄在毒藥冊中。
(c)附表3毒藥：同時列於附表10（即毒藥表）第1部及《藥劑業及毒藥規例》附表3的毒藥	須由註冊醫生、註冊牙醫或註冊獸醫處方授權，並在註冊藥劑師監督下，由獲授權毒藥銷售商銷售。
(d)第2部毒藥：附表10（即毒藥表）第2部所列毒藥	無須藥劑師監督，由列載毒藥銷售商或獲授權毒藥銷售商銷售。

Regulatory provisions in other related areas are contained in 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 2024 are shown in **Tables 25 to 28**.

《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説明
5	説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。立法會在二零二四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至28**。

(5) Certification of Clinical Trial/Medicinal Test

In accordance with regulation 36B of the Pharmacy and Poisons Regulations, a Certificate for Clinical Trial/Medicinal Test ("the Certificate") is required for the purpose of conducting a clinical trial on human beings or a medicinal test on animals.

The Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee is the statutory body to issue the Certificate. The Committee adopted the definition of "clinical trial" given in the International Council on Harmonisation Guideline for Good Clinical Practice which is defined as "any interventional investigation in human participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy".

In 2024, 273 Certificates were issued by the Committee. The number of Certificates issued from 2020 to 2024 is shown in **Table 29**.

(5) 臨牀試驗及藥物測試證明書

根據《藥劑業及毒藥規例》第36B條的規定，任何人對人類進行臨牀試驗或對動物進行藥物測試，必須事先申請臨牀試驗/藥物測試證明書(下稱「證明書」)。

藥劑業及毒藥(臨牀試驗及藥物測試證明書)委員會是簽發證明書的法定機構。委員會採用了國際人用藥品註冊技術協調會[#]《藥物臨牀試驗質量管理規範》就「臨牀試驗」所下的定義，把「臨牀試驗」界定為「任何在人類進行干預性的試驗，以發現或驗證試驗藥物的臨牀、藥理及/或其他藥效作用；及/或識別試驗藥物可會產生任何不良反應，及/或研究試驗藥物的吸收、分布、代謝和排泄情況，目的在於確定試驗藥物的安全程度及/或效能」。

委員會於二零二四年，共簽發273份證明書。**表29**列出由二零二零年至二零二四年委員會所簽發的證明書數目。

[#] 前譯為「國際醫藥法規協調會議」。

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 2024, 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 2024 included:

Mr CHEN Wen-ben, Benny
Ms CHEUNG Oi-ling
Mr HO Hon-fai
Mr KO Hok-yu
Ms KUNG Wai-yiu
Mr NG Pan-pan, Rex
Mr NG Yui-hong
Mr TAM Po-chun, Patrick
Mr WU Siu-lung

(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是紀律委員會在二零二四年十二月三十一日的主席。曾在二零二四年出任成員的註冊藥劑師包括：

陳文斌先生
張靄玲女士
何漢輝先生
高學漁先生
龔瑋珧女士
吳彬賓先生
吳裔康先生
談譜春先生
胡少龍先生

(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《商品説明條例》第7、7A或9條所訂罪行；

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

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

如研訊是就某註冊藥劑師或其僱員而進行，紀律委員會可在研訊完結時：

(a) 譴責該藥劑師；

(b) 向該藥劑師發出警告信；或

(c) 在紀律委員會指示的期間內，將該藥劑師的姓名從藥劑師名冊中刪除。

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

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

(b) any or all of the premises of that ASP be removed from the register of premises, either until the expiry of the certificate of registration issued to that 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 2024.

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。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；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。二零二四年，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 2024 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
Ms CHEN, Carina	Panel Member
Mr CHUNG Wing-fai	Panel Member
Mr LO Yin-cheung	Panel Member
Mr MAN Ka-ho	Panel Member
Mr PANG Hok-ming	Panel Member
Mr TAM Po-chun, Patrick	Panel Member
Mr YEUNG Chi-fat	Panel Member

(1) 成員

上訴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。

在二零二四年十二月三十一日，上訴審裁處的成員如下：

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
陳佩玉女士	小組委員
鍾榮輝先生	小組委員
盧彥璋先生	小組委員
文家豪先生	小組委員
彭鶴鳴先生	小組委員
談譜春先生	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.

One appeal was heard in 2024, which was lodged against the Board's decision of refusing the renewal of registration of premises of an authorized seller of poisons. The appeal was allowed by the Tribunal.

(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。

上訴審裁處於二零二四年審理了一宗就管理局拒絕某獲授權毒藥銷售商的處所註冊續期申請而提出的上訴。有關上訴獲判得直。

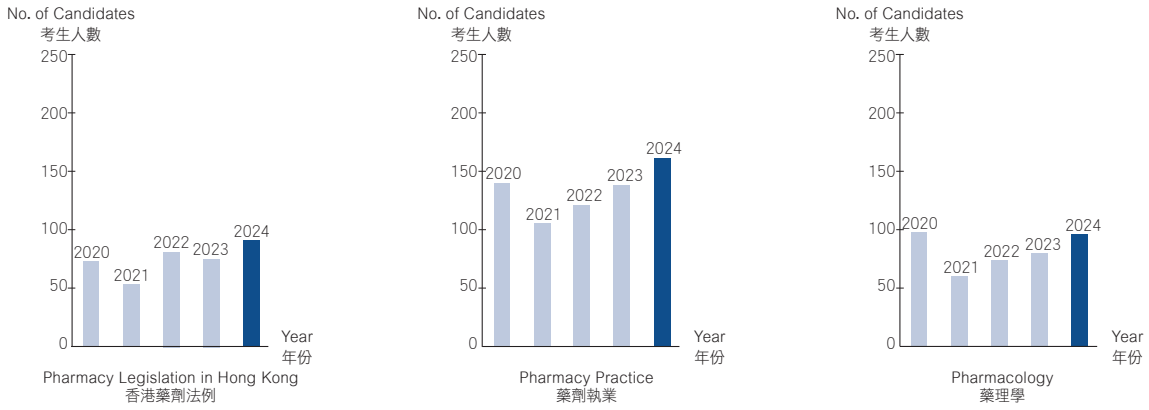
Statistical Tables and Charts
統計圖表

Table 表 1

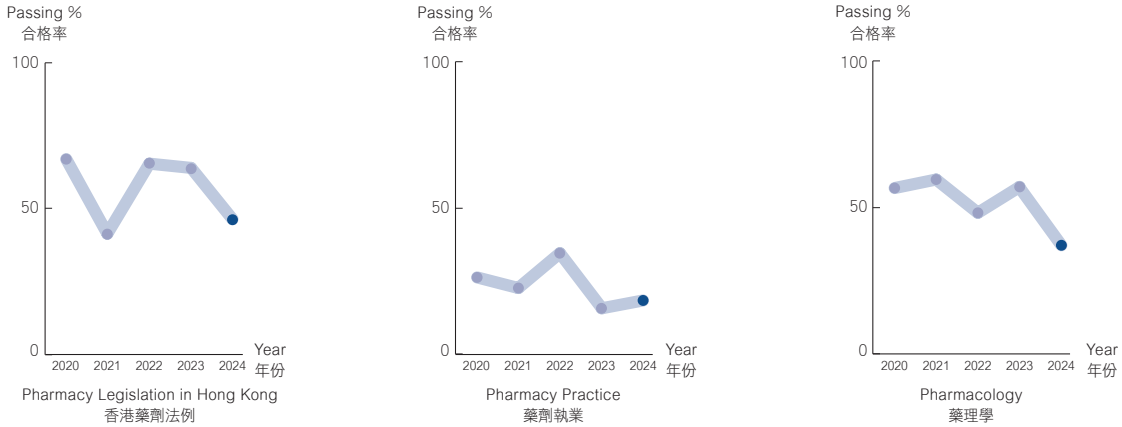
Results of the Registration Examinations
註冊考試成績

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
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
2024	91	42	46.2	161	30	18.6	96	36	37.5

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

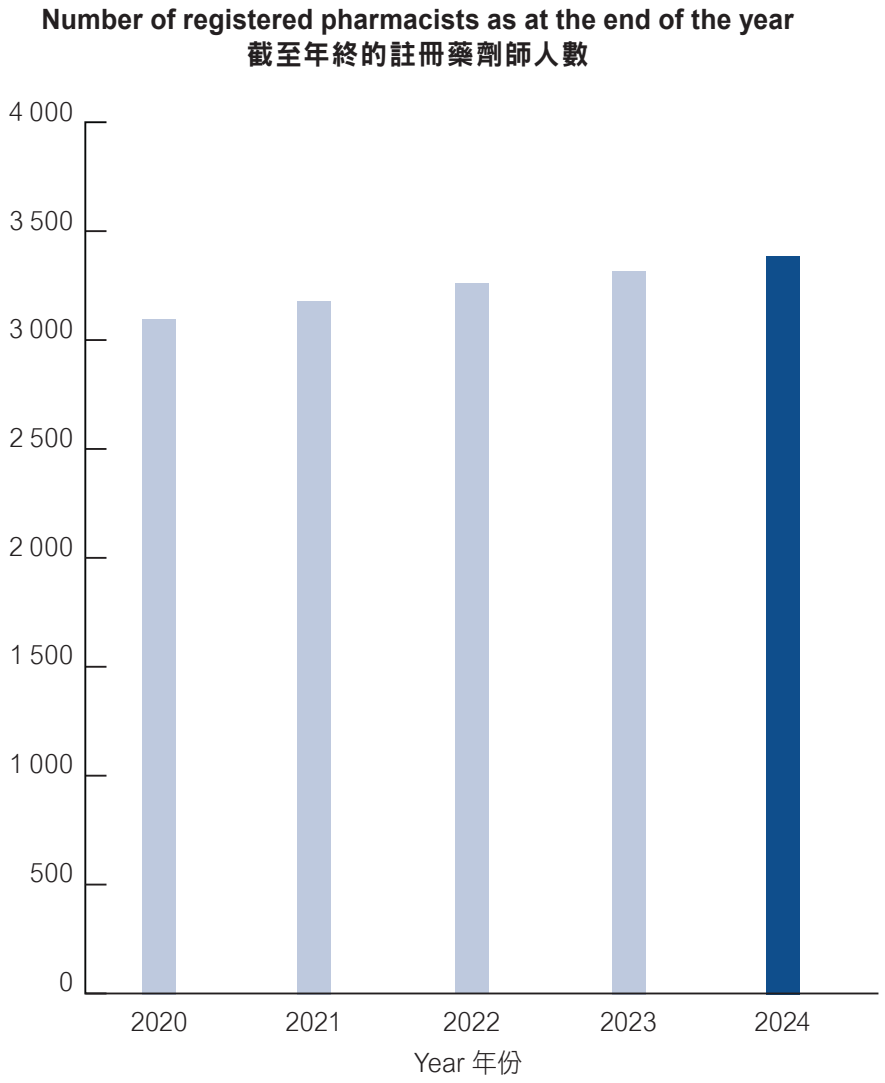


Statistical Tables and Charts
統計圖表

Table 表 2

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

Year 年份	2020	2021	2022	2023	2024
Number of registered pharmacists as at the end of the year 截至年終的註冊藥劑師人數	3 097	3 181	3 259	3 317	3 386



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	2020	2021	2022	2023	2024
Fresh registration (Non-local graduates) 新註冊(非本地畢業)	53	43	45	21	35
Fresh registration (Local graduates) 新註冊(本地畢業)	73	81	60	52	67
Removal from the register* 刪除註冊*	30	43	32	21	36
Re-registration 重新註冊	0	3	5	6	3
Net increase 淨增長	96	84	78	58	69

*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				
	2020	2021	2022	2023	2024
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)	0	0	1	0	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				
	2020	2021	2022	2023	2024
Charge dismissed 指控不成立	0	0	0	0	0
Guilty of the charge 指控成立	0	0	1	0	0
Directions of the Disciplinary Committee 紀律委員會的指示					
Censure 譴責	0	0	1	0	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				
	2020	2021	2022	2023	2024
(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	0	0	0	0	0
(3) Failing to keep proper record of antibiotics 沒有備存抗生素的適當記錄	0	0	1	0	0

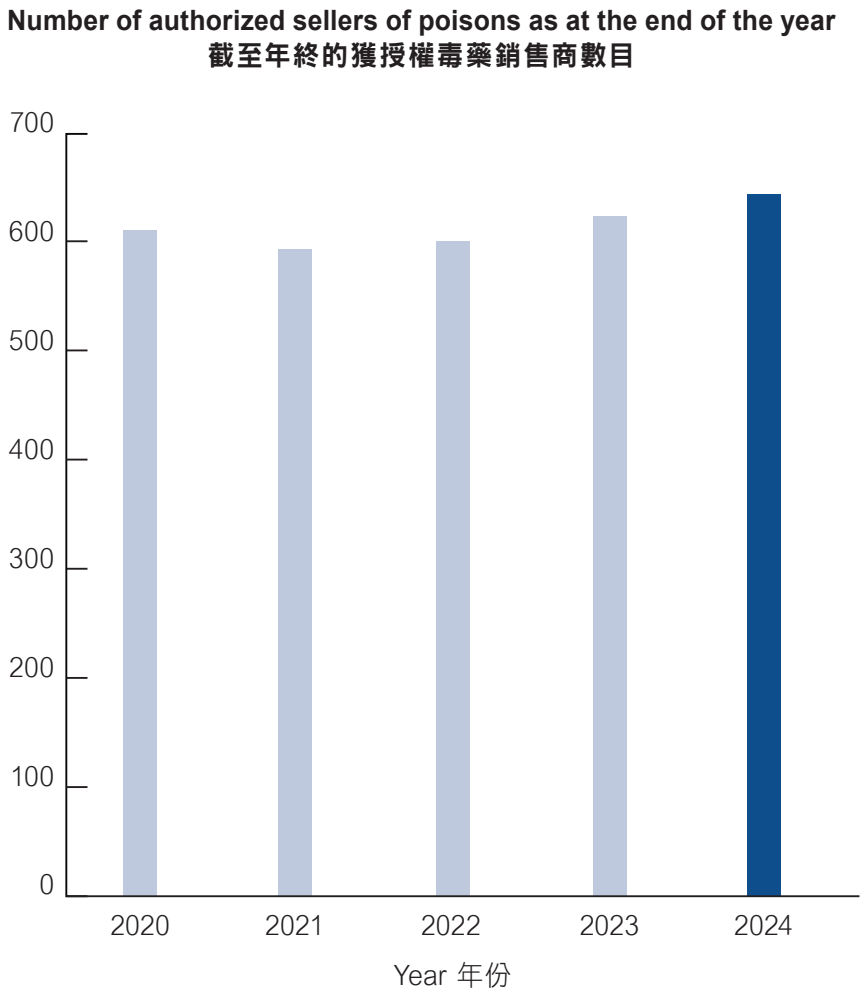
* Some cases involve multiple nature of offences

* 部份個案涉及多個罪行

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	2020	2021	2022	2023	2024
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	610	593	600	623	643



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	2020	2021	2022	2023	2024
Number of applications for registration of premises approved 接納處所註冊申請的數目	23	19	33	51	39
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	2	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	2020	2021	2022	2023	2024
Number of inspections conducted 巡查數目	1 060	1 213	1 250	1 242	1 284
Number of test purchases conducted 試買數目	2 664	6 033	5 615	5 156	5 339

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				
	2020	2021	2022	2023	2024
Formal disciplinary actions (i.e. Inquiry by Disciplinary Committee) 正式紀律行動 （即由紀律委員會進行紀律研訊）	4	7	5	5	10
Informal disciplinary actions (i.e. Verbal caution by representatives of the Board) 非正式紀律行動 （即由管理局代表給予口頭警告）	12	6	8	7	6
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	2	1	0	0	0
Total 總數	18	14	13	12	16

Statistical Tables and Charts
統計圖表

Table 表 11

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

Findings of the Disciplinary Committee 紀律委員會的裁決	**Number of cases 個案數目**				
	2020	**2021**	**2022**	**2023**	**2024**
Charge dismissed 指控不成立	0	0	0	0	0
Guilty of the charge 指控成立	4	7	5	5	10
Directions of the Disciplinary Committee 紀律委員會的指示					
Issue of written warning 發出書面警告	1	5	3	1	3
Disqualified from being an authorized seller of poisons for a period of time 取消銷售商資格一段時間	3	2	2	4	7

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)				
	2020	2021	2022	2023	2024
(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%)	1 (4.55%)	3 (16.67%)	0 (0%)	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	2 (20%)	4 (18.18%)	2 (11.11%)	1 (8.33%)	3 (11.11%)
(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	2 (20%)	4 (18.18%)	2 (11.11%)	1 (8.33%)	3 (11.11%)
(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	1 (10%)	8 (36.36%)	4 (22.21%)	0 (0%)	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%)	1 (8.33%)	2 (7.41%)
(6) Possession of unregistered pharmaceutical product(s) 管有未經註冊藥劑製品	2 (20%)	1 (4.55%)	1 (5.56%)	2 (16.68%)	4 (14.82%)
(7) Possession of substance(s) to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)	2 (7.41%)
(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%)	1 (3.70%)
(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	1 (10%)	0 (0%)	0 (0%)	1 (8.33%)	0 (0%)

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)				
	2020	2021	2022	2023	2024
(10) Failing to store poison(s) properly 沒有適當地貯存毒藥	1 (10%)	3 (13.63%)	3 (16.67%)	2 (16.68%)	3 (11.11%)
(11) Illegal sale of unregistered pharmaceutical product(s) 非法銷售未經註冊的藥劑製品	0 (0%)	0 (0%)	2 (11.11%)	1 (8.33%)	3 (11.11%)
(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%)	1 (4.55%)	1 (5.56%)	0 (0%)	0 (0%)
(13) Supplying / offering to supply false trade description goods 供應 / 要約供應應用虛假商品説明的貨品	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (7.41%)
(14) Selling goods to which a forged trade mark was applied 出售應用虛假商品説明的貨品	1 (10%)	0 (0%)	0 (0%)	1 (8.33%)	0 (0%)
(15) Trafficking in dangerous drug 販運危險藥物	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)	2 (7.41%)
(16) Failing to maintain proper record of dangerous drugs 沒有備存合適的危險藥物紀錄	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3.70%)
(17) Failing to maintain proper record of antibiotics 沒有備存合適的抗生素紀錄	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3.70%)

* 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 2024
2024 年有關獲授權毒藥銷售商的紀律研訊個案

Statistical Tables and Charts
統計圖表

Table 表 13

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

Year 年份	2020	2021	2022	2023	2024
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	4 187	4 170	4 151	4 143	4 101

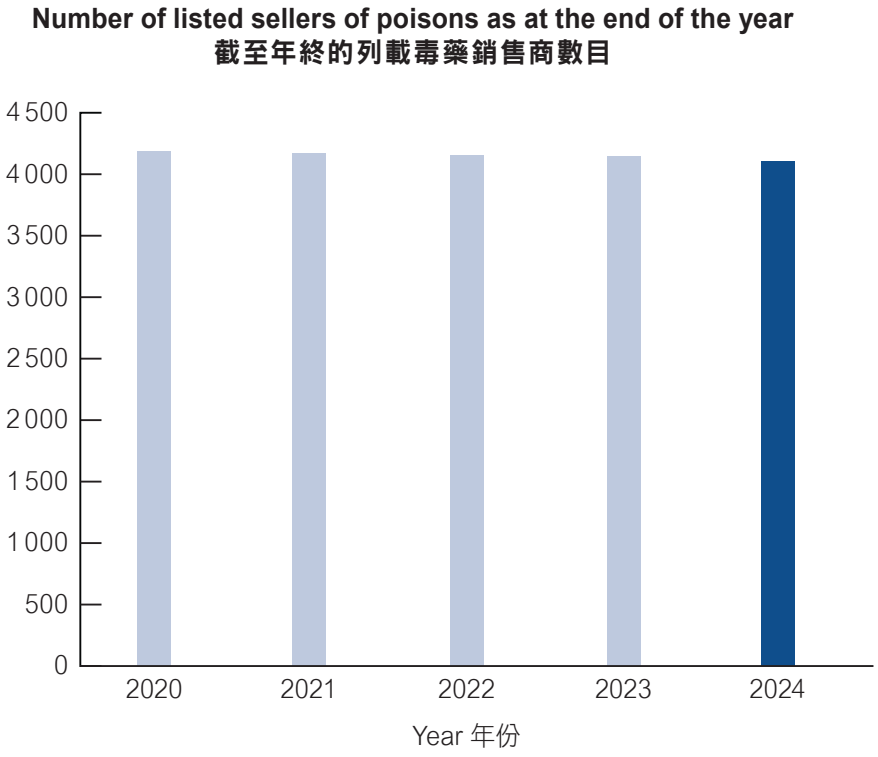


Table 表 14

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

Year 年份	2020	2021	2022	2023	2024
Number of applications approved 接納牌照申請數目	198	305	221	235	140
Number of applications rejected 拒絕牌照申請數目	0	0	0	0	0

Statistical Tables and Charts
統計圖表

Table 表 15

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

Year 年份	2020	2021	2022	2023	2024
Number of inspections conducted 巡查數目	3 268	6 975	8 385	8 348	8 326
Number of test purchases conducted 試買數目	2 144	1 984	1 948	2 412	2 461

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				
	2020	2021	2022	2023	2024
Removal from the list of listed sellers of poisons 從列載毒藥銷售商名單除名	0	0	0	1	0
Issue of written warning 發出書面警告	2	4	0	2	0
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	3	0	1	4	1
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	1	0	0	0	0
Total 總數	6	4	1	7	1

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)				
	2020	2021	2022	2023	2024
(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 (15.38%)	0 (0%)	0 (0%)	1 (8.33%)	0 (0%)
(2) Possession of Part 1 poison(s) 管有第1部毒藥	2 (15.38%)	2 (15.39%)	1 (50%)	2 (16.67%)	1 (33.34%)
(3) Possession of unregistered pharmaceutical product(s) 管有未經註冊藥劑製品	3 (23.10%)	1 (7.69%)	1 (50%)	3 (25%)	1 (33.33%)
(4) Possession of substance(s) to which the Antibiotics Ordinance applies 管有《抗生素條例》適用的物質	0 (0%)	0 (0%)	0 (0%)	2 (16.67%)	1 (33.33%)
(5) Possession of unregistered proprietary Chinese medicine 管有未經註冊的中成藥	0 (0%)	0 (0%)	0 (0%)	2 (16.67%)	0 (0%)
(6) Possession for sale or for any purpose of trade or manufacture goods to which a forged trade mark was applied 為售賣或任何商業或製造用途而管有應用偽造商標的貨品	2 (15.38%)	5 (38.46%)	0 (0%)	0 (0%)	0 (0%)
(7) Selling goods to which a forged trade mark was applied 售賣應用偽造商標的貨品	4 (30.76%)	5 (38.46%)	0 (0%)	1 (8.33%)	0 (0%)
(8) Sale of Part 1 poison(s) 銷售第1部毒藥	0 (0%)	0 (0%)	0 (0%)	1 (8.33%)	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 2024
2024年有關列載毒藥銷售商的紀律個案

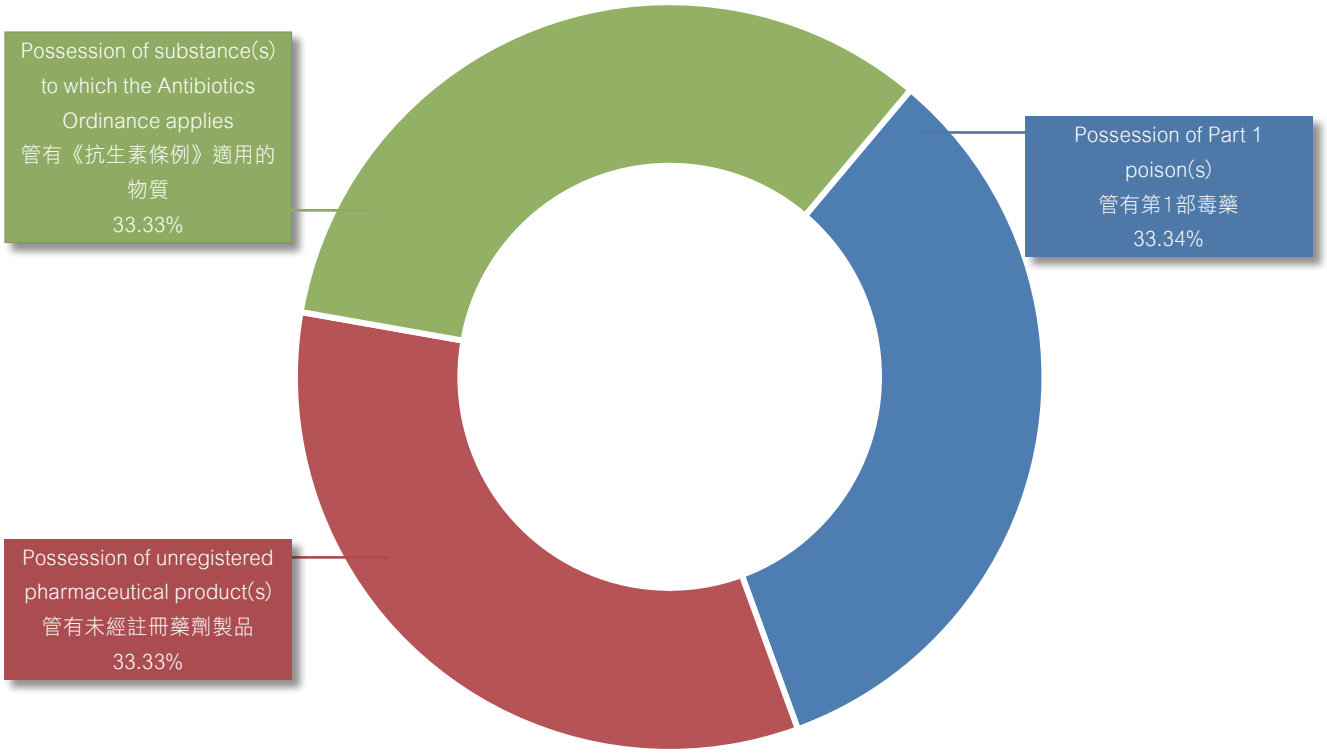


Table 表 18

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	2020	2021	2022	2023	2024
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	786	854	931	1 002	1 032
Number of wholesale dealer licences revoked/suspended 撤銷或吊銷批發商牌照的數目	1	2	0	0	0
Number of warning letters issued 發出警告信的數目	5	2	3	6	3

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 offences* 個案性質*	Number of counts (percentage) 次數 (百份比)				
	2020	2021	2022	2023	2024
(1) 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	1 (12.5%)	3 (42.84%)	0 (0%)	0 (0%)	0 (0%)
(2) 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%)	1 (16.67%)	0 (0%)
(3) 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	1 (12.5%)	1 (14.29%)	0 (0%)	0 (0%)	0 (0%)
(4) Illegal sale of unregistered pharmaceutical products 非法售賣未經註冊藥劑製品	1 (12.5%)	1 (14.29%)	3 (75%)	3 (50%)	2 (50%)
(5) 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	5 (62.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
(6) 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%)	1 (14.29%)	0 (0%)	0 (0%)	0 (0%)
(7) 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%)	1 (25%)	1 (16.66%)	1 (25%)
(8) 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%)	1 (14.29%)	0 (0%)	0 (0%)	0 (0%)
(9) Unlawful supply of Poisons 非法售賣毒藥	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (25%)
(10) 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%)	1 (16.66%)	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 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	2020	2021	2022	2023	2024
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	69	67	65	61	63
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	46	45	43	40	41
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	1	2	2	1

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

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。

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)				
	2020	2021	2022	2023	2024
(1) 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%)	1 (50%)	0 (0%)	1 (33.33%)	1 (100%)
(2) Contravention of the Good Manufacturing Practice Guide 違反生產質量管理規範指引	0 (0%)	1 (50%)	2 (100%)	2 (66.67%)	0 (0%)

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

Statistical Tables and Charts
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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	2020	2021	2022	2023	2024
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	149	153	153	149	152
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	94	93	93	87	88
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	6	10	10	12	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	3	0	1	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
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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

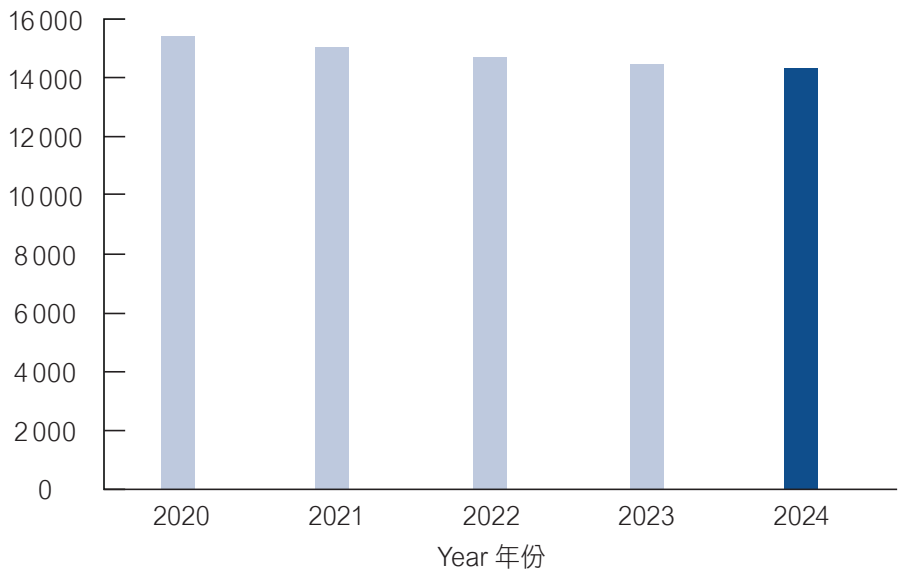
Nature of cases 個案性質	Number of counts (percentage) 次數 (百份比)				
	2020	2021	2022	2023	2024
Contravention of the Code of Practice for Licensed Manufacturers and Registered Authorized Persons or condition of the registration 違反《持牌製造商及註冊獲授權人執業守則》或註冊條件	0 (0%)	3 (100%)	0 (0%)	1 (100%)	1 (100%)

Table 表 24

Registration of Pharmaceutical Products
藥劑製品的註冊

Year 年份	2020	2021	2022	2023	2024
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	15 396	15 028	14 704	14 463	14 314

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 Schedule 1 to the Pharmacy and Poisons Regulations in 2024
2024年在《藥劑業及毒藥規例》附表1作出的修訂

New Substances Added 加入的新物質		
1.	Adagrasib; its salts	阿達雷塞；其鹽類
2.	Andexanet alfa	安地薩特α
3.	Asciminib; its salts	阿思尼布；其鹽類
4.	Atogepant	阿托吉泮
5.	Atropine; its salts; when contained in pharmaceutical products for human parenteral administration or pharmaceutical products intended to be used for slowing the progression of myopia	阿托品；其鹽類；但限於包含在供注射入人體的藥劑製品內者，或包含在擬用於減緩近視加深的藥劑製品內者
6.	Belumosudil; its salts	貝舒地爾；其鹽類
7.	Bexarotene; its salts	貝沙羅汀；其鹽類
8.	Capivasertib; its salts	卡匹色替；其鹽類
9.	Danicopan; its salts	達尼可泮；其鹽類
10.	Daridorexant; its salts	培普色替；其鹽類
11.	Delafloxacin; its salts; its esters; their salts	德拉沙星；其鹽類；其酯類；它們的鹽類
12.	Efanesoctocog alfa	艾凡凝血素Ⅷ-α
13.	Elacestrant; its salts	艾拉司群；其鹽類
14.	Eladocagene exuparvovec	艾哌依卡基
15.	Elapegademase	艾拉培加酶
16.	Elranatamab	埃納妥單抗
17.	Epcoritamab	艾可瑞妥單抗
18.	Etranacogene dezaparvovec	地哌艾可基
19.	Evocalcet; its salts; its esters; their salts	依伏卡塞；其鹽類；其酯類；它們的鹽類
20.	Fruquintinib; its salts	呋喹替尼；其鹽類
21.	Futibatinib; its salts	福巴替尼；其鹽類
22.	Gallium-68; its salts; when contained in pharmaceutical products	鎵-68；其鹽類；但限於包含在藥劑製品內者
23.	Germanium-68; its salts; when contained in pharmaceutical products	鍺-68；其鹽類；但限於包含在藥劑製品內者
24.	Glutathione; its salts; its derivatives; when contained in products for human parenteral administration	穀胱甘肽；其鹽類；其衍生物；但限於包含在供注射入人體的製品內者
25.	Hemin; its salts; its esters; their salts	Hemin；其鹽類；其酯類；它們的鹽類
26.	Iptacopan; its salts	伊普可泮；其鹽類

Table 表 25 (Cont'd) 續

New Substances Added 加入的新物質		
27.	Item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters", after "esters"— **Add** "; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following— 0.15 mg of Desogestrel; 3.00 mg of Drospirenone; 0.05 mg of Ethinyloestradiol; 0.10 mg of Gestodene; 0.25 mg of Levonorgestrel; 2.50 mg of Lynoestrenol; 0.05 mg of Mestranol; 1.00 mg of Norethisterone; 0.25 mg of Norgestimate; and 0.50 mg of Norgestrel"	"雄激素、雌激素與孕激素物質如下"項目，"具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類"分項，在"酯類"之後 —— **加入**"；但如包含在擬只作避孕用的某口服製劑內，而該製劑每劑含有不多於以下分量的物質，則屬例外 —— 0.10毫克孕二烯酮； 0.25毫克左炔諾孕酮； 0.15毫克去氧孕烯； 2.50毫克利奈孕酮； 0.05毫克炔雌醇； 0.50毫克炔諾孕酮； 1.00毫克炔諾酮； 3.00毫克屈螺酮； 0.05毫克的美雌醇；及 0.25毫克的諾孕酯"
28.	Item "Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item", after "tetrahydro"— **Add** "or hexahydro"	"大麻酚及其四氫衍生物；它們的3-烷基同系物；任何屬此項範圍內的物質的酯類或醚類"項目，在"四氫"之後 —— **加入**"或六氫"
29.	Labuvirtide	萊布韋肽
30.	Lecanemab	侖卡奈單抗
31.	Lenacapavir; its salts	來那帕韋；其鹽類
32.	Loncastuximab tesirine	替朗妥昔單抗
33.	Momelotinib; its salts	莫美替尼；其鹽類
34.	Naxitamab	那昔妥單抗
35.	Nirsevimab	尼塞韋單抗
36.	Oclacitinib; its salts	奧拉替尼；其鹽類
37.	Odevixibat; its salts; its esters; their salts	奧德昔巴特；其鹽類；其酯類；它們的鹽類
38.	Pegunigalsidase alfa	培古半乳糖苷酶α
39.	Perflubutane	全氟丁烷
40.	Repotrectinib; its salts	瑞普替尼；其鹽類
41.	Ritlecitinib; its salts	利特昔替尼；其鹽類
42.	Ropeginterferon alfa-2b	羅培干擾素α-2b
43.	Roxadustat; its salts	羅沙司他；其鹽類
44.	Savolitinib; its salts	賽沃替尼；其鹽類
45.	Sebelipase alfa	色貝脂酶α
46.	Solriamfetol; its salts	索安非托；其鹽類
47.	Somapacitan	帕西生長素
48.	Stiripentol; its salts	司替戊醇；其鹽類
49.	Surufatinib; its salts	索凡替尼；其鹽類
50.	Talquetamab	塔奎妥單抗
51.	Tirzepatide	替爾泊肽
52.	Tislelizumab	替雷利珠單抗
53.	Toripalimab	特瑞普利單抗

Statistical Tables and Charts
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Table 表 25 (Cont'd) 續

New Substances Added 加入的新物質		
54.	Tremelimumab	曲麥利尤單抗
55.	Treosulfan; its salts	曲奧舒凡；其鹽類
56.	Velmanase alfa	維馬酶α
57.	Vosoritide	伏索利肽
58.	Vutrisiran; its salts	夫曲賽侖；其鹽類
Others 其他		
1.	Chinese text, item"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯半胱氨酸"分項 —— **廢除** "醯" **代以** "酰"
2.	Chinese text, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯膽鹼"分項 —— **廢除** "醯" **代以** "酰"
3.	Chinese text, item"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚"— **Repeal** "對乙醯氨基酚" **Substitute** "對乙酰氨基酚(撲熱息痛)"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"對乙醯氨基酚"分項 —— **廢除** "對乙醯氨基酚" **代以** "對乙酰氨基酚(撲熱息痛)"
4.	Chinese text, item "蘆非醯胺；其鹽類"— **Repeal** "醯" **Substitute** "酰"	中文文本"蘆非醯胺；其鹽類"項目 —— **廢除** "醯" **代以** "酰"
5.	Item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"— **Repeal** sub-item "Atropine"	"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目 —— **廢除** "阿托品"分項
6.	Item relating to "Alkaloids"— **Repeal** the sub-item relating to "Nicotine" **Substitute** "Nicotine (except when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy); any compound containing the chemical structure of 3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution"	"生物鹼如下"的項目 —— **廢除**關乎"煙鹼(尼古丁)"的分項 **代以** "煙鹼(尼古丁)(但以下任何一項所包含者除外：(a)擬用於尼古丁替代療法而每片含有不多於4毫克尼古丁的口香糖或錠劑；或(b)擬用於尼古丁替代療法的外用貼片)；任何含有3-(1-甲基吡咯烷-2-基)吡啶的化學結構(在任何程度上被取代或沒有被取代者)的化合物"
7.	Item "Alkaloids, the following; their quaternary compounds; any salts, simple or complex, of any substance falling within the following", sub-item "Codeine, except substances containing not more than 0.1% of codeine"— **Repeal** "Codeine, except substances containing not more than 0.1% of codeine" **Substitute** "Codeine"	"生物鹼如下；它們的四級化合物；任何屬下列範圍內的物質的簡單或複雜鹽類"項目，"可待因，但含有不多於0.1%可待因的物質除外"分項 —— **廢除** "可待因，但含有不多於0.1%可待因的物質除外" **代以** "可待因"

Statistical Tables and Charts
統計圖表

Table 表 26

Amendments to Schedule 2 to the Pharmacy and Poisons Regulations in 2024
2024年在《藥劑業及毒藥規例》附表2作出的修訂

Others 其他		
1.	Item "Androgenic, oestrogenic and progestational substances, the following", sub-item relating to "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"— **Repeal** everything in column 2 **Substitute** "Multivitamin preparations (with or without minerals) containing not more than the following in each dosage form— 0.01 mg of Ethinyloestradiol; and 2.50 mg of Methyltestosterone"	"雄激素、雌激素與孕激素物質如下"項目，關乎"具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類"的分項 —— **廢除**在第2欄中的所有字句 **代以** "每劑型含有不多於以下分量的物質的多種維他命製劑(不論製劑含礦物質或不含礦物質) —— 2.50毫克的甲基睪酮；及 0.01毫克的炔雌醇"
2.	Item "Nicotine"— **Repeal** everything in column 2 **Substitute** "Tobacco in any conventional smoking product (as defined by section 2(1) of the Smoking (Public Health) Ordinance (Cap. 371))"	"煙鹼(尼古丁)"項目 —— **廢除**在第2欄中的所有字句 **代以** "傳統吸煙產品(《吸煙(公眾衞生)條例》(第371章)第2(1)條所界定者)中的煙草"

Statistical Tables and Charts
統計圖表

Table 表 27

Amendments to Schedule 3 to the Pharmacy and Poisons Regulations in 2024
2024年在《藥劑業及毒藥規例》附表3作出的修訂

New Substances Added 加入的新物質		
1.	Adagrasib; its salts	阿達雷塞；其鹽類
2.	Andexanet alfa	安地薩特α
3.	Asciminib; its salts	阿思尼布；其鹽類
4.	Atogepant	阿托吉泮
5.	Atropine; its salts; when contained in pharmaceutical products for human parenteral administration or pharmaceutical products intended to be used for slowing the progression of myopia	阿托品；其鹽類；但限於包含在供注射入人體的藥劑製品內者，或包含在擬用於減緩近視加深的藥劑製品內者
6.	Belumosudil; its salts	貝舒地爾；其鹽類
7.	Bexarotene; its salts	貝沙羅汀；其鹽類
8.	Capivasertib; its salts	卡匹色替；其鹽類
9.	Danicopan; its salts	達尼可泮；其鹽類
10.	Daridorexant; its salts	培普色替；其鹽類
11.	Delafloxacin; its salts; its esters; their salts	德拉沙星；其鹽類；其酯類；它們的鹽類
12.	Efanesoctocog alfa	艾凡凝血素Ⅷ-α
13.	Elacestrant; its salts	艾拉司群；其鹽類
14.	Eladocagene exuparvovec	艾哌依卡基
15.	Elapegademase	艾拉培加酶
16.	Elranatamab	埃納妥單抗
17.	Epcoritamab	艾可瑞妥單抗
18.	Etranacogene dezaparvovec	地哌艾可基
19.	Evocalcet; its salts; its esters; their salts	依伏卡塞；其鹽類；其酯類；它們的鹽類
20.	Fruquintinib; its salts	呋喹替尼；其鹽類
21.	Futibatinib; its salts	福巴替尼；其鹽類
22.	Gallium-68; its salts; when contained in pharmaceutical products	鎵-68；其鹽類；但限於包含在藥劑製品內者
23.	Germanium-68; its salts; when contained in pharmaceutical products	鍺-68；其鹽類；但限於包含在藥劑製品內者
24.	Glutathione; its salts; its derivatives; when contained in products for human parenteral administration	穀胱甘肽；其鹽類；其衍生物；但限於包含在供注射入人體的製品內者
25.	Hemin; its salts; its esters; their salts	Hemin；其鹽類；其酯類；它們的鹽類
26.	Iptacopan; its salts	伊普可泮；其鹽類
27.	After item "Cannabidiol; its salts; when contained in pharmaceutical products"— **Add** "Cannabinol and its tetrahydro or hexahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item"	在"大麻二酚；其鹽類；但限於包含在藥劑製品內者"項目之後 —— **加入** "大麻酚及其四氫或六氫衍生物；它們的3-烷基同系物；任何屬此項範圍內的物質的酯類或醚類"
28.	Labuvirtide	萊布韋肽
29.	Lecanemab	侖卡奈單抗
30.	Lenacapavir; its salts	來那帕韋；其鹽類
31.	Loncastuximab tesirine	替朗妥昔單抗

Table 表 27 (Cont'd) 續

New Substances Added 加入的新物質		
32.	Momelotinib; its salts	莫美替尼；其鹽類
33.	Naxitamab	那昔妥單抗
34.	Nirsevimab	尼塞韋單抗
35.	Oclacitinib; its salts	奧拉替尼；其鹽類
36.	Odevixibat; its salts; its esters; their salts	奧德昔巴特；其鹽類；其酯類；它們的鹽類
37.	Pegunigalsidase alfa	培古半乳糖苷酶α
38.	Perflubutane	全氟丁烷
39.	Repotrectinib; its salts	瑞普替尼；其鹽類
40.	Ritlecitinib; its salts	利特昔替尼；其鹽類
41.	Ropeginterferon alfa-2b	羅培干擾素α-2b
42.	Roxadustat; its salts	羅沙司他；其鹽類
43.	Savolitinib; its salts	賽沃替尼；其鹽類
44.	Sebelipase alfa	色貝脂酶α
45.	Solriamfetol; its salts	索安非托；其鹽類
46.	Somapacitan	帕西生長素
47.	Stiripentol; its salts	司替戊醇；其鹽類
48.	Surufatinib; its salts	索凡替尼；其鹽類
49.	Talquetamab	塔奎妥單抗
50.	Tirzepatide	替爾泊肽
51.	Tislelizumab	替雷利珠單抗
52.	Toripalimab	特瑞普利單抗
53.	Tremelimumab	曲麥利尤單抗
54.	Treosulfan; its salts	曲奧舒凡；其鹽類
55.	Velmanase alfa	維馬酶α
56.	Vosoritide	伏索利肽
57.	Vutrisiran; its salts	夫曲賽侖；其鹽類

Statistical Tables and Charts
統計圖表

Table 表 27 (Cont'd) 續

Others 其他		
1.	Item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters"— **Repeal** "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters" **Substitute** "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following— 0.15 mg of Desogestrel; 3.00 mg of Drospirenone; 0.05 mg of Ethinyloestradiol; 0.10 mg of Gestodene; 0.25 mg of Levonorgestrel; 2.50 mg of Lynoestrenol; 0.05 mg of Mestranol; 1.00 mg of Norethisterone; 0.25 mg of Norgestimate; and 0.50 mg of Norgestrel".	"雄激素、雌激素與孕激素物質如下"項目 —— **廢除** "具有雌激素作用的芪、二苄或萘的衍生物；它們的酯類 具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類" **代以** "具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類；但如包含在擬只作避孕用的某口服製劑內，而該製劑每劑含有不多於以下分量的物質，則屬例外 —— 0.10毫克的孕二烯酮； 0.25毫克的左炔諾孕酮； 0.15毫克的去氧孕烯； 2.50毫克的利奈孕酮； 0.05毫克的炔雌醇； 0.50毫克的炔諾孕酮； 1.00毫克的炔諾酮； 3.00毫克的屈螺酮； 0.05毫克的美雌醇；及 0.25毫克的諾孕酯 具有雌激素作用的芪、二苄或萘的衍生物；它們的酯類"
2.	Chinese text, item"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯半胱氨酸"分項 —— **廢除** "醯" **代以** "酰"
3.	Chinese text, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯膽鹼"分項 —— **廢除** "醯" **代以** "酰"
4.	Chinese text, item"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚"— **Repeal** "對乙醯氨基酚" **Substitute** "對乙酰氨基酚(撲熱息痛)"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"對乙醯氨基酚"分項 —— **廢除** "對乙醯氨基酚" **代以** "對乙酰氨基酚(撲熱息痛)"
5.	Chinese text, item "蘆非醯胺；其鹽類"— **Repeal** "醯" **Substitute** "酰"	中文文本"蘆非醯胺；其鹽類"項目 —— **廢除** "醯" **代以** "酰"
6.	Item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"— **Repeal** sub-item "Atropine"	"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目 —— **廢除** "阿托品"分項

Table 表 28

Amendments to Schedule 10 to the Pharmacy and Poisons Regulations in 2024
2024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.	Adagrasib; its salts	阿達雷塞；其鹽類
2.	Andexanet alfa	安地薩特α
3.	Asciminib; its salts	阿思尼布；其鹽類
4.	Atogepant	阿托吉泮
5.	Belumosudil; its salts	貝舒地爾；其鹽類
6.	Bexarotene; its salts	貝沙羅汀；其鹽類
7.	Capivasertib; its salts	卡匹色替；其鹽類
8.	Danicopan; its salts	達尼可泮；其鹽類
9.	Daridorexant; its salts	培普色替；其鹽類
10.	Delafloxacin; its salts; its esters; their salts	德拉沙星；其鹽類；其酯類；它們的鹽類
11.	Efanesoctocog alfa	艾凡凝血素Ⅷ-α
12.	Elacestrant; its salts	艾拉司群；其鹽類
13.	Eladocagene exuparvovec	艾哌依卡基
14.	Elapegademase	艾拉培加酶
15.	Elranatamab	埃納妥單抗
16.	Epcoritamab	艾可瑞妥單抗
17.	Etranacogene dezaparvovec	地哌艾可基
18.	Evocalcet; its salts; its esters; their salts	依伏卡塞；其鹽類；其酯類；它們的鹽類
19.	Fruquintinib; its salts	呋喹替尼；其鹽類
20.	Futibatinib; its salts	福巴替尼；其鹽類
21.	Gallium-68; its salts; when contained in pharmaceutical products	鎵-68；其鹽類；但限於包含在藥劑製品內者
22.	Germanium-68; its salts; when contained in pharmaceutical products	鍺-68；其鹽類；但限於包含在藥劑製品內者
23.	Glutathione; its salts; its derivatives; when contained in products for human parenteral administration	穀胱甘肽；其鹽類；其衍生物；但限於包含在供注射入人體的製品內者
24.	Hemin; its salts; its esters; their salts	Hemin；其鹽類；其酯類；它們的鹽類
25.	Iptacopan; its salts	伊普可泮；其鹽類

Table 表 28 (Cont'd) 續

New Substances Added 加入的新物質		
26.	Item "Androgenic, oestrogenic and progestational substances, the following", sub-item "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters", after "esters"— **Add** "; except when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following— 0.15 mg of Desogestrel; 3.00 mg of Drospirenone; 0.05 mg of Ethinyloestradiol; 0.10 mg of Gestodene; 0.25 mg of Levonorgestrel; 2.50 mg of Lynoestrenol; 0.05 mg of Mestranol; 1.00 mg of Norethisterone; 0.25 mg of Norgestimate; and 0.50 mg of Norgestrel"	"雄激素、雌激素與孕激素物質如下"項目，"具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類"分項，在"酯類"之後 —— **加入**"；但如包含在擬只作避孕用的某口服製劑內，而該製劑每劑含有不多於以下分量的物質，則屬例外 —— 0.15毫克的去氧孕烯； 0.10毫克的孕二烯酮； 0.25毫克的左炔諾孕酮； 2.50毫克的利奈孕酮； 3.00毫克的屈螺酮； 0.05毫克的炔雌醇； 0.50毫克的炔諾孕酮； 1.00毫克的炔諾酮； 0.05毫克的美雌醇；及 0.25毫克的諾孕酯"
27.	Item "Cannabinol and its tetrahydro derivatives; their 3-alkyl homologues; any ester or ether of any substance falling within this item", after "tetrahydro"— **Add** "or hexahydro"	"大麻酚及其四氫衍生物；它們的3-烷基同系物；任何屬此項範圍內的物質的酯類或醚類"項目，在"四氫"之後 —— **加入**"或六氫"
28.	After Item "Salicylamide; its salts; when contained in pharmaceutical products"— **Add** "Steroid compounds with androgenic or oestrogenic or progestational activity; their esters; when contained in a preparation intended to be taken orally for contraceptive purposes only and each dose of the preparation contains not more than the following— 0.15 mg of Desogestrel; 3.00 mg of Drospirenone; 0.05 mg of Ethinyloestradiol; 0.10 mg of Gestodene; 0.25 mg of Levonorgestrel; 2.50 mg of Lynoestrenol; 0.05 mg of Mestranol; 1.00 mg of Norethisterone; 0.25 mg of Norgestimate; and 0.50 mg of Norgestrel"	在"沒有列於本列表第1部的抗組胺物質；它們的鹽類；它們與任何其他物質的化合物"項目之後 —— **加入** "具有雄激素或雌激素或孕激素作用的類固醇化合物；它們的酯類；但限於包含在符合以下說明的製劑內者:製劑是擬只作避孕用的口服製劑，且每劑含有不多於以下分量的物質 —— 0.15毫克的去氧孕烯； 0.10毫克的孕二烯酮； 0.25毫克的左炔諾孕酮； 2.50毫克的利奈孕酮； 3.00毫克的屈螺酮； 0.05毫克的炔雌醇； 0.50毫克的炔諾孕酮； 1.00毫克的炔諾酮； 0.05毫克的美雌醇；及 0.25毫克的諾孕酯"
29.	Labuvirtide	萊布韋肽
30.	Lecanemab	侖卡奈單抗
31.	Lenacapavir; its salts	來那帕韋；其鹽類
32.	Loncastuximab tesirine	替朗妥昔單抗
33.	Momelotinib; its salts	莫美替尼；其鹽類
34.	Naxitamab	那昔妥單抗
35.	Nirsevimab	尼塞韋單抗
36.	Oclacitinib; its salts	奧拉替尼；其鹽類
37.	Odevixibat; its salts; its esters; their salts	奧德昔巴特；其鹽類；其酯類；它們的鹽類
38.	Pegunigalsidase alfa	培古半乳糖苷酶α
39.	Perflubutane	全氟丁烷

Table 表 28 (Cont'd) 續

New Substances Added 加入的新物質		
40.	Repotrectinib; its salts	瑞普替尼；其鹽類
41.	Ritlecitinib; its salts	利特昔替尼；其鹽類
42.	Ropeginterferon alfa-2b	羅培干擾素α-2b
43.	Roxadustat; its salts	羅沙司他；其鹽類
44.	Savolitinib; its salts	賽沃替尼；其鹽類
45.	Sebelipase alfa	色貝脂酶α
46.	Solriamfetol; its salts	索安非托；其鹽類
47.	Somapacitan	帕西生長素
48.	Stiripentol; its salts	司替戊醇；其鹽類
49.	Surufatinib; its salts	索凡替尼；其鹽類
50.	Talquetamab	塔奎妥單抗
51.	Tirzepatide	替爾泊肽
52.	Tislelizumab	替雷利珠單抗
53.	Toripalimab	特瑞普利單抗
54.	Tremelimumab	曲麥利尤單抗
55.	Treosulfan; its salts	曲奧舒凡；其鹽類
56.	Velmanase alfa	維馬酶α
57.	Vosoritide	伏索利肽
58.	Vutrisiran; its salts	夫曲賽侖；其鹽類

Statistical Tables and Charts
統計圖表

Table 表 28 (Cont'd) 續

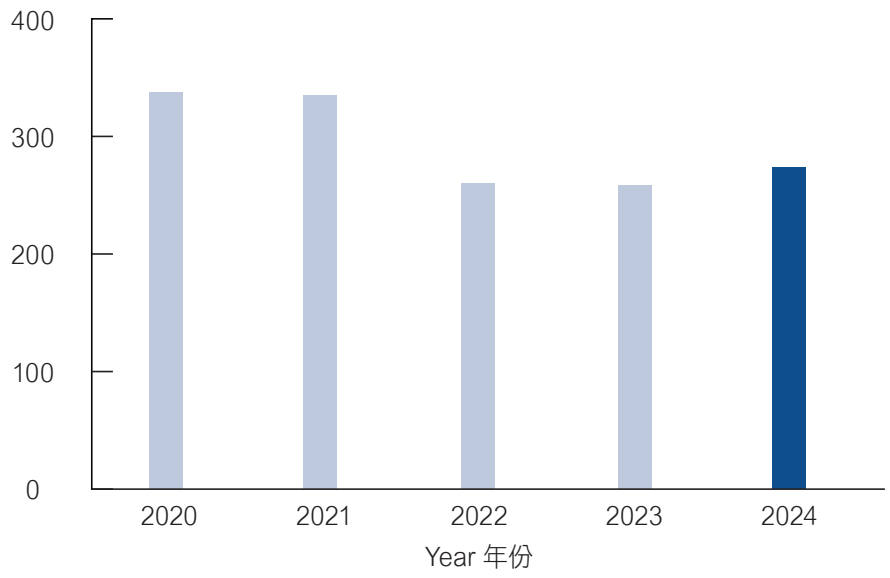
Others 其他		
1.	Chinese text, item"供注射入人體的藥劑製品，並包含 (作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯半胱氨酸"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯半胱氨酸"分項 —— **廢除** "醯" **代以** "酰"
2.	Chinese text, item "供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "乙醯膽鹼"— **Repeal** "醯" **Substitute** "酰"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"乙醯膽鹼"分項 —— **廢除** "醯" **代以** "酰"
3.	Chinese text, item"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外", sub-item "對乙醯氨基酚"— **Repeal** "對乙醯氨基酚" **Substitute** "對乙酰氨基酚(撲熱息痛)"	中文文本"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目，"對乙醯氨基酚"分項 —— **廢除** "對乙醯氨基酚" **代以** "對乙酰氨基酚(撲熱息痛)"
4.	Chinese text, item "蘆非醯胺；其鹽類"— **Repeal** "醯" **Substitute** "酰"	中文文本"蘆非醯胺；其鹽類"項目 —— **廢除** "醯" **代以** "酰"
5.	Chinese text, item "對乙酰氨基酚；其鹽類；但限於包含在藥劑製品內者", after "對乙酰氨基酚"— **Add** "(撲熱息痛)"	中文文本"對乙酰氨基酚；其鹽類；但限於包含在藥劑製品內者"項目，在"對乙酰氨基酚"之後 —— **加入** "(撲熱息痛)"
6.	Item "Pharmaceutical products for human parenteral administration containing the following or their salts, as active ingredients, except in mixture with insulin"— **Repeal** sub-item "Atropine"	"供注射入人體的藥劑製品，並包含(作為有效成分)以下物質或它們的鹽類，但在與胰島素的混合物內者除外"項目 —— **廢除**"阿托品"分項
7.	Item relating to "Alkaloids"— **Repeal** the sub-item relating to "Nicotine" **Substitute** "Nicotine (except when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy); any compound containing the chemical structure of 3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution"	"生物鹼如下"的項目 —— **廢除**關乎"煙鹼(尼古丁)"的分項 **代以** "煙鹼(尼古丁)(但以下任何一項所包含者除外:(a)擬用於尼古丁替代療法而每片含有不多於4毫克尼古丁的口香糖或錠劑；或(b)擬用於尼古丁替代療法的外用貼片)；任何含有3-(1-甲基吡咯烷-2-基)吡啶的化學結構(在任何程度上被取代或沒有被取代者)的化合物"
8.	Item relating to "Pharmaceutical products retailed in the form as supplied by the manufacturer", paragraph (e)— **Repeal** the sub-item relating to "Nicotine" **Substitute** "Nicotine (except when contained in (a) chewing gum or lozenges, intended to be used in nicotine replacement therapy and containing not more than 4 mg of Nicotine per piece; or (b) patches for external application, intended to be used in nicotine replacement therapy); any compound containing the chemical structure of 3-(1-methylpyrrolidin-2-yl)pyridine substituted to any degree or without substitution"	關乎"採用製造商供應的原裝零售的藥劑製品"的項目，(e)段 —— **廢除**關乎"煙鹼(尼古丁)"的分項 **代以** "煙鹼(尼古丁)(但以下任何一項所包含者除外:(a)擬用於尼古丁替代療法而每片含有不多於4毫克尼古丁的口香糖或錠劑；或(b)擬用於尼古丁替代療法的外用貼片)；任何含有3-(1-甲基吡咯烷-2-基)吡啶的化學結構(在任何程度上被取代或沒有被取代者)的化合物"

Table 表 29

Number of Certificates for Clinical Trial/ Medicinal Test issued as at the end of the year
截至年終簽發的臨牀試驗/藥物測試證明書數目

Year 年份	2020	2021	2022	2023	2024
Number of Certificates for Clinical Trial/Medicinal Test issued as at the end of the year 截至年終簽發的臨牀試驗/藥物測試證明書數目	336	334	260	258	273

Number of Certificates for Clinical Trial/Medicinal Test issued as at the end of the year
截至年終簽發的臨牀試驗/藥物測試證明書數目

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