



Newsletter to Trade

藥 商 通 訊

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This newsletter aims to strengthen communication with Pharmaceutical Traders, which include licensed manufacturers, wholesale dealers, retailers and holders of certificate of drug registration to enhance their knowledge on the regulatory requirements. It will be published every 6 months. For the latest news and information, please refer to the public announcements from the website of the Drug Office of the Department of Health (<http://www.drugoffice.gov.hk>).

Latest News

Updates on Registration of Pharmaceutical Products under "1+" Mechanism

The Chief Executive's 2025 Policy Address" on the "1+" Mechanism for New Drugs

"The Chief Executive's 2025 Policy Address" announced that the HKSAR Government will accelerate the reform of the regulatory system for drugs and medical devices. The Department of Health (DH) will continue to expedite the "1+" mechanism for new drugs by piloting the priority evaluation and approval of innovative drugs as recommended by the Hospital Authority for treatment of severe or rare diseases and to accelerate patients' use of the advanced treatments.

In addition, the DH will establish the Hong Kong Centre for Medical Products Regulation by the end of 2026, and will implement "primary evaluation" for new drug registration in phases beginning in 2026. These efforts will provide strong momentum for the development and market expansion of the healthcare industry in the HKSAR, the Chinese Mainland, and beyond.

The Department of Health's Briefing Seminar, Workshop for New Drug Applications and Pre-New Drug Applications Meetings under "1+" Mechanism for New Drugs

"The Chief Executive's 2024 Policy Address" announced that a consultation service for new drug applications ("NDAs") under the "1+" mechanism would be introduced to enhance the efficiency in processing relevant applications. The consultation service comprises three components, namely briefing seminars, workshops and pre-new drug

applications ("pre-NDA") meetings.

Briefing Seminar on "1+" Mechanism for New Drugs

The Department of Health ("DH") held eight briefing seminars on the "1+" mechanism for new drugs from March 2025 to February 2026, with an introduction of the requirements for registration of pharmaceutical products under this mechanism, as well as the workshops on good regulatory practices and pre-NDA meetings. The eight seminars were well received and were attended by 251 representatives from pharmaceutical and consultation companies inside or outside Hong Kong, as well as scientific research institutions.

In order to facilitate traders to understand the "1+" mechanism, the Drug Office has prepared a briefing video on "1+" Mechanism for Registration of Pharmaceutical Products. The DH aims to work with the pharmaceutical industry to achieve the goals of early consultation to enhance quality and efficiency throughout the process so that registration approval can be expedited, thereby bringing more good drugs for use in Hong Kong.

Workshop for New Drug Applications under the "1+" Mechanism

The Department of Health organized three Workshops for New Drug Applications under "1+" Mechanism on 16 June, 10 July and 27 November 2025, respectively. The workshop for provision of guidance and sharing of good practices and real-life experiences on submitting applications through the "1+" mechanism was significantly effective, attracted keen participation by over 330

representatives, primarily from the regulatory affairs departments of pharmaceutical and consultancy companies in Hong Kong. With the active participation from the industry, it is envisaged that the quality and efficiency for new applications submitted under "1+" mechanism will further be enhanced.

Pre-New Drug Application Meetings under the "1+" Mechanism

A [press release](#) was issued on 22 December 2025 to announce that potential applicants for new drugs registration through the "1+" mechanism may request for one-on-one pre-new drug application ("Pre-NDA") meetings with immediate effect. This service aims to further optimise the new drug registration approval process by working with the pharmaceutical industry to achieve the goals of early consultation and enhance the quality and efficiency throughout the process so that registration approval can be expedited, thereby bringing more treatment options for our patients in Hong Kong. It will consolidate Hong Kong's position as an international health and medical innovation hub.

A [letter](#) was also issued on 22 December 2025 to inform applicants for registration of pharmaceutical products and certificate holders of registered pharmaceutical products that the Department of Health ("DH") has launched the Pre-New Drug Application ("Pre-NDA") Meetings for applications for registration of pharmaceutical products containing new chemical or biological entities ("NCE products") with the Pharmacy and Poisons Board (the "Board") under the "1+" mechanism on 22 December 2025.

Companies intending to request Pre-NDA meetings with the Drug Office should refer to the "[Guidance on Pre-New Drug Application Meetings](#)" for details, complete the "Pre-New Drug Application Meeting Request Form" and lodge a meeting request to the Drug Office via the Pharmaceutical Registration System (PRS 2.0). Both documents are available in the "[Guidance for Industry](#)" section of the "1+" mechanism thematic webpage.

The Department of Health has organized 3 briefing sessions for the Pre-NDA Meetings under the "1+"

mechanism on 14, 16 and 21 January 2026 to introduce the Pre-NDA Meetings and provide guidance on the submission for meeting requests. The 3 briefing sessions were well received and were attended by 144 representatives from pharmaceutical and consultancy companies inside or outside Hong Kong, as well as scientific research institutions.

For the most current information on the briefing seminar, workshop of "1+" mechanism & Pre-New Drug Application Meetings, please refer to "Consultation service for New Drug Applications" at the following link:

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/onePlus_mechanism_for_Reg_PP_contain_New_Chem_Bio_Entities.html

New Drugs Approved under the "1+" Mechanism

The Hong Kong Special Administrative Region (HKSAR) has implemented the "1+" mechanism since 1 November 2023, in order to facilitate the registration of new drugs used for the treatment of life-threatening or severely debilitating diseases in Hong Kong. With effect from 1 November 2024, the "1+" mechanism has been extended to all new drugs, including all new chemical or biological entities and new indications, vaccines and advanced therapy products.

Since the implementation of the "1+" mechanism and as of February 2026, a total of 19 new drugs have been approved under this mechanism, bringing more treatment options for patients and facilitating the availability of more good drugs for use in Hong Kong. Seven of them have been listed in the Hospital Authority Drug Formulary. The HKSAR Government continues to strive to accelerate the introduction of innovative drugs and medical devices so that patients can gain early access to advanced diagnoses and treatments, while developing Hong Kong into an international health and medical innovation hub.

For the most current information on the list of new drugs approved under the "1+" Mechanism, please refer to "List of Pharmaceutical Products Registered Under "1+" Mechanism" at the following link:

https://www.drugoffice.gov.hk/eps/do/en/consumer/news_informations/relicList2.html?indextype=1PLUS

Latest News

Important Update: Successful Launch of the New Enlisting Interface in the Pharmaceuticals Licence Application and Movement Monitoring System (PLAMMS)

The Drug Office of the Department of Health ("DO") is pleased to announce that the new enlisting interface in the Pharmaceuticals Licence Application and Movement Monitoring System ("PLAMMS") has been successfully launched on 1 December 2025. This initiative marks a significant improvement in the processing time of enlisting applications of unregistered pharmaceutical products ("UPPs") imported for the purpose of re-export.

Key Highlights:

- *New Interface:* The PLAMMS enlisting interface has been updated with a more intuitive layout, streamlining the application process.
- *Standardized Questions:* The new interface includes a set of standardized questions to ensure that all required information is collected accurately and in a comprehensive manner.
- *Formal Declaration Requirement:* Applicants are required to make a formal declaration prior to submission, emphasizing the importance of compliance and accuracy in the data provided in the applications.
- *Rejection of Stagnant Applications:* Stagnant applications in which applicants didn't respond within 14 calendar days would be automatically rejected by the system,

ensuring efficient system operation.

- *Pilot Phase Implementation of Auto-Enlisting:* Seven companies were selected to participate in the pilot phase of the auto-enlisting mechanism. DO will continuously assess the performance of the selected companies, review the enlisting process and expand the number of eligible companies in due course.

Support Resources:

To assist users in adapting to the updated interface, the DO has released a new [User Guide](#) and [Application Guide for Drug Enlisting](#). These resources are available on the DO [website](#) and are designed to facilitate users navigate the enhancements effectively.

We are committed to supporting the growth of the e-commerce sector and enhancing the efficiency of importing for the purpose of re-export of UPPs in Hong Kong.

Recent law amendments published in Government Gazettes

Pharmacy and Poisons Regulations, Cap. 138 Sub. Leg. A

Amendments to Schedule 1, Schedule 3, and Part 1 of the Poisons List in Schedule 10 of the Pharmacy and Poisons Regulations published in the Gazette between September 2025 and February 2026 are listed below. Letters were also issued by the Drug Office to inform the concerned traders.

- Gazette 17/10/2025 No. 42 Vol. 29 (Letter to trade dated [17 October 2025](#))
- Gazette 30/01/2026 No. 5 Vol. 30 (Letter to trade dated [30 January 2026](#))

Regulation of Drugs

Regulatory requirements for traders

The Department of Health Continues to Step Up Enforcement Actions Against Illegal Use of Pharmacy Logo and Title

A [press release](#) was issued on 29 September 2025 to announce that the Department of Health ("DH") has stepped up inspections of Authorized Sellers of Poisons (ASPs), commonly known as pharmacies; Listed Sellers of Poisons, commonly known as medicine companies; and Retailers of Chinese Herbal Medicines in tourist areas to monitor their compliance with the laws and the relevant codes of practice.

Further, a [press release](#) was issued on 13 February 2026 to reaffirm that the DH would continue to step up inspections of Authorized Sellers of Poisons (ASPs), commonly known as pharmacies, and Listed Sellers of Poisons, commonly known as medicine companies, throughout Hong Kong, particularly in tourist areas, to monitor their compliance with the laws and the relevant codes of practice.

In 2025, approximately 9,600 inspections of these premises were conducted to combat illegal practices. The DH will continue to enhance enforcement actions against the illegal use of logos and titles of pharmacies and carry out follow-up investigations of suspected violations. These efforts aim to safeguard public health and enhance tourists' confidence in shopping in Hong Kong. The DH also reminded the public, including tourists, to verify the pharmacy logo when purchasing medicines

Refinement of Stop-clock Mechanism in Handling Applications for Certificate for Clinical Trial/Medicinal Test that Require Consideration by the Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong (the "Board") on 29 January 2026 to inform all holders of Certificate for Clinical Trial/Medicinal Test on the Pharmacy and

Poisons (Certification of Clinical Trial/Medicinal Test) Committee's ("the Committee") endorsement on the refinement of stop-clock mechanism in handling applications for Certificate for Clinical Trial/Medicinal Test for applications that require consideration by the Committee, with effect from 29 January 2026. Accordingly, the "[Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test](#)" has been updated and uploaded to the website of the Board and the Drug Office of the Department of Health.

For details, please refer to the [letter dated 29 January 2026](#) and the updated "[Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test](#)".

New Licensing Conditions for Wholesale Dealer Licence

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong (the "Board") on 4 February 2026 to inform all holders of Wholesale Dealer Licence ("WDL") on the implementation of new licensing conditions in relation to medical gases, which will take effect on 14 June 2026.

For details, please refer to the [letter dated 4 February 2026](#).

Regulatory requirements for Pharmaceutical Products

Refinement of the Requirements for Applications for Change of Registered Particulars Related to Indication, Dosage and Route of Administration

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong (the "Board") on 3 November 2025 to inform all certificate holders of registered pharmaceutical products on the Board's endorsement to refine the requirements for applications for change of registered particulars ("CORP") related to indication, dosage and route of administration of registered pharmaceutical products containing New Chemical or Biological Entities ("NCE products").

In accordance with the current "Guidance Notes on Change of Registered Particulars of Registered Pharmaceutical Products/Substances" ("CORP

Regulation of Drugs

Guidance Notes") promulgated by the Board, for any proposed changes in indication, dosage and route of administration which have not been previously approved for products registered in Hong Kong, applicants are required to provide documentary proof for registration approval of the products issued by the drug regulatory authorities in two or more of the listed reference countries. In order to further expedite access to expanded treatment options for patients, the Board has endorsed to refine the requirements for CORP applications related to indication, dosage and route of administration of registered NCE products, with effect from 29 November 2025.

Under the refined requirements, CORP applications for change of indication, dosage and route of administration for registered NCE products with documentary proof for registration approval in one of the listed reference countries (instead of two), may be accepted for evaluation on a case-by-case basis, subject to the fulfillment of specified criteria. For details, please refer to the [letter dated 3 November 2025](#).

Implementation of Risk Minimisation Measures for Lenalidomide

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong (the "Board") on 4 November 2025 to inform all applicants and certificate holders for registration of pharmaceutical products containing lenalidomide that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the "Committee") under the Board had decided at its meeting on 31 October 2025 that the certificate holders of registered pharmaceutical products containing lenalidomide are required to implement risk minimisation measures. This decision was made after considering the risk minimisation measures for lenalidomide in relation to the teratogenic risk

associated with lenalidomide, taking into account local situations and made reference to the measures imposed by the drug regulatory authorities of the European Union, the United Kingdom, and the United States. Certificate holders are also reminded that any modification to the risk minimisation measures shall be made with justification and that may be submitted to the Committee for consideration.

For details, please refer to the [letter dated 4 November 2025](#).

Reminder: Registration is Required Prior to the Sale of Medical Gases Starting From 14 June 2026

Further to the [letter](#) issued by the Drug Office of the Department of Health on 17 June 2024 regarding the regulation of medical gases as pharmaceutical products, a [letter to trade](#) and a [press release](#) were issued on 30 December 2025 to serve as a reminder to the trade that medical gases will be regulated as pharmaceutical products with effect from 14 June 2026.

When the new regulatory control takes effect, medical gases classified as pharmaceutical products must be registered with the Pharmacy and Poisons Board of Hong Kong (the "Board") before they can be legally sold or supplied in Hong Kong. In addition, traders involved in the manufacture, wholesale, or retail of medical gases must obtain the relevant drug dealer's licence(s) in accordance with the Pharmacy and Poisons Ordinance (Cap. 138) (the "Ordinance"). The industry is reminded to make early preparations to ensure compliance with the relevant regulatory requirements.

For details, please refer to the website of [the Board](#) and the [Drug Office](#) of the Department of Health.

News, information and education

Guidelines Related to Drug Registration and Clinical Trial/Medicinal Test

The "[Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test](#)" and the relevant content of the website was updated in January 2026

Compendium of Pharmaceutical Products 2025

The latest issue of the "Compendium of Pharmaceutical Products 2025" has been published on the websites of the [Drug Office](#) and

[the Pharmacy and Poisons Board](#), which could be downloaded for retention

New Arrangement for Drug Dispensing Service

With an aim to reduce medication wastage, ensure medication safety and appropriate use of public healthcare resources, the Department of Health (DH) has implemented the New Arrangement for Drug Dispensing Service with effect from 1 January 2026.

For details, please refer to the [website](#) of the Drug Office of the Department of Health.

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[https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical trade/other useful information/newsletter to trade.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical%20trade/other%20useful%20information/newsletter%20to%20trade.html)



Update on Drug Office’s website: You can now search the newly registered medicines in the past year at [https://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare providers?pageNoRequested=1](https://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare%20providers?pageNoRequested=1).



Details of ALL registered pharmaceutical products can still be found in the Drug Office website at [https://www.drugoffice.gov.hk/eps/do/en/healthcare providers/news informations/reListRPP index.html](https://www.drugoffice.gov.hk/eps/do/en/healthcare%20providers/news%20informations/reListRPP%20index.html).



A product containing any western drug ingredient must be registered under the Pharmacy and Poisons Ordinance before it can be sold in Hong Kong. Part 1 poisons should be sold at registered pharmacies under the supervision of registered pharmacists. Illegal sale or possession of Part 1 poisons and unregistered pharmaceutical products are offences under the Pharmacy and Poisons Ordinance (Cap. 138). The maximum penalty is a fine of \$100,000 and two years’ imprisonment for each offence. Antibiotics can only be supplied at registered pharmacies by registered pharmacists or under their supervision and upon a doctor’s prescription. They should only be used under the advice of a doctor. Illegal sale or possession of antibiotics are offences under the Antibiotics Ordinance (Cap. 137) and the maximum penalty is a \$50,000 fine and one year’s imprisonment for each offence.

Under the Import and Export Ordinance (Cap. 60), pharmaceutical products must be imported or exported under and in accordance with an import or export licence issued under the Import and Export Ordinance. Illegal import or export of pharmaceutical products are offences under the Import and Export Ordinance (Cap. 60) and the maximum penalty is a fine of \$500,000 and 2 years’ imprisonment.

Update on Drug Office’s website: You can now search the newly registered medicines in the past year at [http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare providers?pageNoRequested=1](http://www.drugoffice.gov.hk/eps/drug/newsNRM60/en/healthcare%20providers?pageNoRequested=1).

Details of ALL registered pharmaceutical products can still be found in the Drug Office website at [http://www.drugoffice.gov.hk/eps/do/en/healthcare providers/news informations/](http://www.drugoffice.gov.hk/eps/do/en/healthcare%20providers/news%20informations/)

Useful Contact

Drug Evaluation and Pharmacovigilance Division:

Drug Information and Import/Export Control Division:

Address: Suites 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong

Enquiry Phone No.: 3974 4175 (Drug Registration)
3974 4180 (Drug Import & Export)

Fax No.: 2803 4962

Licensing and Compliance Division:

- Retailers Regulatory Unit
- Wholesalers Regulatory Unit

Address: Room 2001-2002, 20/F, Dah Sing Financial Centre, 248 Queen's Road East, Wan Chai, Hong Kong

Enquiry Phone No.: - Wholesalers: 3107 2194
- Authorized Seller of Poisons: 3107 3477
- Listed Seller of Poisons: 3107 2196

Fax No.: 3107 0221

- Manufacturers Regulatory Unit

Address: Room 3817, Revenue Tower, 5 Gloucester Road, Wan Chai, Hong Kong

Enquiry Phone No.: 2594 7647

Fax No.: 3904 1225

Risk Management and Operations Division:

Address: Rooms 1804-06, 18/F, Wing On Kowloon Centre, 345 Nathan Road, Kowloon

Enquiry Phone No.: 3752 3524

Fax No.: 3752 3533