



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

Implementation of Phase 1 of Primary Evaluation for New Drug Registration

Revamping the Drug Registration Regime and Implementation of Phase 1 of Primary Evaluation

A [press release](#) was issued on 31 March 2026 to announce that the Department of Health ("the DH") has begun the phased implementation of "primary evaluation" for new drug registration on the same day. A [letter](#) was also issued by the Pharmacy and Poisons Board of Hong Kong ("the Board") on 31 March 2026 to inform pharmaceutical associations and stakeholders (including certificate holders of registered pharmaceutical products and applicants for registration of pharmaceutical products) of the Board's endorsement of the revamped drug registration regime and the publication of new and revised guidance notes for application for registration of pharmaceutical products, with a view to implementing phase 1 of primary evaluation, which has come into effect on 31 March 2026.

As mentioned in "The Chief Executive's 2025 Policy Address" that the Hong Kong Special Administrative Region ("HKSAR") Government would establish the Hong Kong Centre for Medical Products Regulation ("CMPR") in 2026 and begin the phased implementation of the "primary evaluation" mechanism for new drug registration in the same year. The HKSAR Government aims to achieve full coverage of all pharmaceutical products by 2030, which will enable Hong Kong to independently assess and approve the safety and efficacy of new drugs based on clinical data, with a view to expediting the introduction of innovative

medical products, thereby achieving the goal of making good drugs and medical devices available for use in Hong Kong for the benefit of patients.

On 26 June 2025, the DH announced the timetable for the establishment of CMPR by the end of 2026 and the roadmap towards adoption of primary evaluation in Hong Kong for pharmaceutical products. In accordance with the roadmap, the primary evaluation approach would be prudently implemented in four phases in the period between 2026 and 2030.

"Primary evaluation" is a regulatory process to approve applications for registration of new drugs which involves an independent assessment of primary data and information of all pre-clinical studies (i.e. animal testing), clinical studies, pharmacovigilance, manufacturing and quality control, etc. in order to fully ensure their safety, efficacy and quality before and after the drugs are placed in the market (i.e. throughout the product life-cycle). Registering new drugs under the "primary evaluation" mechanism facilitates immediate approval without relying and waiting for approval from non-local drug regulatory authorities, which further speeds up the introduction of new drugs and clinical applications. This will not only help speed up patients' access to breakthrough treatments but also boost medical R&D, testing and related industries in Hong Kong.

The DH has commenced the Phase 1 of primary evaluation for new drug registration on 31 March 2026, and the initial phase covers applications for registration of drug products containing locally registered chemical entities with extended applications (e.g. new indications, new strengths,

new posology, new dosage forms, etc.). For the purpose of conducting primary evaluation of applications for initial registration of pharmaceutical products, the Board has endorsed the revamped registration regime of pharmaceutical products, which includes the categorization of initial registration applications into six application categories and the formulation of three evaluation routes.

To reflect the revamped drug registration regime and requirements for primary evaluation, new sets of Guidance Notes are published and relevant Guidance Notes have been updated and uploaded to the website of the [Board](#) and the [Drug Office](#) of the Department of Health accordingly.

For details, please visit the DH's [dedicated website](#) and refer to the corresponding [letter](#) and [press release](#) dated 31 March 2026.

Briefing Seminar on Primary Evaluation for New Drug Registration

As mentioned in "The Chief Executive's 2025 Policy Address", the Hong Kong Special Administrative Region Government would establish the Hong Kong Centre for Medical Products Regulation in 2026 and begin the phased implementation of primary evaluation mechanism for new drug registration in the same year.

The Department of Health ("the DH") has begun the phased implementation of primary evaluation for new drug registration. The initial phase covers applications for the registration of drug products containing locally registered chemical entities with extended applications (e.g. new indications, new strengths, new posology, new dosage forms, etc.).

The DH held three briefing seminars on the revamp of drug registration regime and phase 1 of primary evaluation in April 2026. The six categories of initial registration applications established, the three evaluation routes formulated, and the corresponding new and revised guidance notes were elaborated during the sessions.

The three seminars were well-attended by 191 representatives from pharmaceutical and consultation companies inside or outside Hong Kong, as well as scientific research institutions. The Drug Office of the DH has also prepared a briefing video to facilitate traders to understand primary evaluation.

For details of information related to primary evaluation and the briefing video on "Revamping Drug Registration Regime and Phase 1 of Primary Evaluation", please visit the [dedicated website](#) in the Drug Office of the Department of Health.

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

Priority Review of New Drug Application Recommended by Hospital Authority under "1+" Mechanism

The Office for Introducing Innovative Drugs and Medical Devices ("the Office") was officially established on 8 June 2026 to identify and prioritise innovative drugs from the Chinese Mainland and overseas to address the patients' unmet medical needs and ensure accessibility by patients.

From 8 June 2026, the Department of Health ("DH") will expedite the approval process for innovative drugs recommended by the Office for Introducing Innovative Drugs and Medical Devices of Hospital Authority ("HA") under the "1+" mechanism via "Priority Review Pathway", thereby accelerating the approval of innovative drugs in Hong Kong. The initial phase covers cancer treatments, for which the evaluation time required for registration in Hong Kong will be shortened from a maximum of 150 working days under the "1+" mechanism to within 100 working days. This will enable patients to access advanced and effective clinical treatments more promptly.

To this end, the DH and HA jointly held a briefing seminar in June 2026. The seminar was well received and was attended by more than 110 representatives, primarily from the regulatory affairs departments of pharmaceutical and consultancy companies in Hong Kong.

For details, please visit the websites of the [Drug Office](#) of the Department of Health and the [Hospital Authority](#).

Seminar on Hong Kong Drug Registration Landscape

The Drug Office of the Department of Health joined the seminar of 'Advancing Hong Kong Drug Registration: Industry-Regulator Exchange on "1+" Mechanism', organized by the Greater Bay Area

International Clinical Trial Institute (GBAICTI) and co-organized by the Hong Kong Association of the Pharmaceutical Industry (HKAPI), the China Pharmaceutical Innovation and Research Development Association (PhIRDA), and the Hong Kong Science and Technology Parks Corporation (HKSTP) on 15 April 2026. The seminar facilitated in-depth exchanges with industry stakeholders on the drug regulatory developments and clinical trial advancement in the Greater Bay Area, and analyzed how new drugs are introduced to Hong Kong through the "1+" mechanism.

The seminar ended with a panel discussion featuring guests from the PhIRDA, HKAPI, HKSTP and two pharmaceutical companies in the Chinese Mainland, together with officers from the Drug Office, followed by a Q&A session. More than 150 participants attended the event, including representatives from over 30 companies in the Chinese Mainland.

Seminar on Hong Kong "1+" Mechanism for Registration of Pharmaceutical Products

The Drug Office of the Department of Health joined the seminar of 'Hong Kong "1+" Mechanism for Registration of Pharmaceutical Products' at Shenzhen, organized by the Guangdong Bio-Pharmaceutical Innovation Technology Association and co-organized by the Guangdong-Hong Kong-Macao Greater Bay Area Center for Drug Evaluation and Inspection of the National Medical Products Administration (GBACDEI), the Guangdong Provincial Medical Products Administration (GDMPA), the Guangdong Institute for Drug Control (GDIDC), and the Shenzhen Administration for Market Regulation (SZAMR) on 2 June 2026. The seminar facilitated in-depth exchanges with industry stakeholders in the Chinese Mainland, including various pharmaceutical companies in the Guangdong Province on the reform of drug registration regime in Hong Kong, "1+" mechanism for new drug registration and the procedures and requirements for inspecting Mainland manufacturers according to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Good Manufacturing Practice (GMP) Guide, and analyzed how new drugs from the Chinese Mainland are introduced to Hong Kong through the "1+" mechanism.

Over 90 participants attended the event, including representatives from 50 Mainland pharmaceutical companies. After the seminar, GBACDEI and the Drug Office personnel further communicated with pharmaceutical companies of the Guangdong Province regarding the specific requirements and application procedures of the "1+" mechanism. Several pharmaceutical companies have already submitted applications or expressed their intention to apply for registration of their products.

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

The Drug Office of the Department of Health (Drug Office) organized a workshop on new drug applications under the "1+" mechanism for the Pharmaceutical Distributors Association of Hong Kong (PDAHK) on 24 June 2026. Members and representatives of the China Pharmaceutical Innovation and Research Development Association (PhIRDA), the Hong Kong Productivity Council and the Hong Kong Trade Development Council were also present.

The workshop provided guidance on submitting applications through the "1+" mechanism for new drugs and its requirements, and shared good practices and common deficiencies encountered in submissions, aiming to enhance the efficiency of the application process. Recent regulatory updates were also highlighted.

More than 60 participants attended the event, including representatives from 40 companies in the Chinese Mainland and 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.

New Drugs Approved under the "1+" Mechanism

To pave the way for "primary evaluation", the Hong Kong Special Administrative Region (HKSAR) Government first implemented the "1+" drug approval mechanism on 1 November 2023, 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. New

drugs that are supported by local clinical data and recognised by local experts can apply for registration in Hong Kong by submitting evidence of approval from one reference drug regulatory authority (instead of two in the past).

Since the implementation of the "1+" mechanism and as of 31 August 2026, a total of 22 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 these drugs have been listed in the Hospital Authority (HA) Drug Formulary (HADF). Of these, six have even been listed under the "Special Drug" category of the HADF. If these drugs are prescribed under specified clinical applications, patients are only required to pay the standard fee (i.e. \$20 every four weeks). This significantly alleviates patients' financial burden and realizes the concept of "good drugs for use in Hong Kong".

The Department of Health (DH) has been promoting the "1+" mechanism through different channels and has so far received more than 910 enquiries from over 220 pharmaceutical companies, including those from overseas and the Chinese Mainland. Many companies have expressed interest in submitting applications for registration of their products, including advanced therapy products, under the extended "1+" mechanism. The DH has organised a pre-new drug application consultation service and held a number of briefing seminars and workshops. The DH has also rolled out pre-new drug application meetings to enhance the efficiency in processing relevant applications.

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

Implementation Plan of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 Guideline for Good Clinical Practice in Hong Kong

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong ("the Board") on 31 March 2026 to inform all holders/applicants of Certificate for Clinical Trial/Medicinal Test on the Board's endorsement of the implementation plan for the ICH E6(R3) Guideline for Good Clinical Practice ("ICH Guideline for GCP") as the Good Clinical Practice ("GCP") requirements for clinical trials to be conducted in Hong Kong.

In October 2023, the Board officially became an observer of the ICH. In June 2025, the Government announced the timetable for the establishment of the Hong Kong Centre for Medical Products Regulation ("CMPR"), which set out steps to prepare for Hong Kong's accession to the ICH as a regulatory member with the target of submitting application by Q2 2027. Implementation of ICH Tier 1 Guidelines, including ICH Guideline for GCP, are required before applying for the accession.

The ICH Guideline for GCP establishes an international standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting activities of clinical trials involving human participants. It outlines the responsibilities of sponsors, investigators, and other stakeholders to protect the rights, safety, and well-being of trial participants, while ensuring the integrity and credibility of clinical trial data. Considering the local situation and requirements, the implementation plan for ICH Guideline for GCP is summarised in the abovementioned [letter dated 31 March 2026](#).

For details of the implementation of ICH Guideline for GCP in Hong Kong, please refer to the updated [Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test](#) and [Guidance for Industry – Implementing ICH Guideline for Good Clinical Practice E6\(R3\) in Hong Kong](#).

Implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Q1 Guidelines on Stability

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong ("the Board") on 31 March 2026 to inform applicants for registration of pharmaceutical products and certificate holders of registered pharmaceutical products on the Board's endorsement of the implementation of ICH Q1 Guidelines in Hong Kong in the first quarter of 2026.

In June 2025, the Government announced the timetable for the establishment of the Hong Kong Centre for Medical Products Regulation, which sets out steps to prepare for Hong Kong's accession to the ICH as a regulatory member with the target of submitting application by Q2 2027. Implementation of ICH Tier 1 Guidelines, including ICH Q1 Guidelines on Stability, are one of the prerequisites to applying for the accession.

The ICH Q1 Guidelines establish the specific stability data requirements for registration applications concerning new molecular entities (defined as an active pharmaceutical substance that has not been previously approved in Hong Kong) and their associated drug products. This classification also includes new salts, esters, or noncovalent-bond derivatives of an existing drug, which are treated as new entities for stability testing purposes.

With effect from 31 March 2026, all initial applications for registration of the following product types must include evidence of demonstrating compliance with the stability requirements of the current ICH Q1 A-E guidelines:

- products containing new chemical or biological entity (NCE);
- products containing a new salt, ester or non-covalent-bond derivative of approved drug substance;
- products with a new dosage form.

Applications that do not meet this requirement will not be accepted for evaluation. For the updated

Guidance Notes and the ICH Q1A-E Guidelines, please visit the [website](#) of the Board.

The Department of Health Invited Representatives from GBA Center for Drug Evaluation and Inspection of National Medical Products Administration to Brief Local Pharmaceutical Industry on Latest Developments in Drug Regulation and Registration Evaluation in Chinese Mainland

The Department of Health (DH) invited senior reviewers from the Guangdong-Hong Kong-Macao Greater Bay Area (GBA) Center for Drug Evaluation and Inspection of the National Medical Products Administration (NMPA) to attend a forum called "New Chapter in Pharmaceutical Regulation: 2026 Drug Regulation and Review Trends Forum" on 5 June 2026 to provide the local pharmaceutical industry with a detailed overview of the latest developments and relevant regulatory requirements regarding drug regulation and registration evaluation in the Chinese Mainland. The forum aimed to help the local industry seize opportunities to expand into the Mainland market, while fostering drug innovation and collaboration within the GBA.

The forum was co-organised by the Hong Kong Institute of Biotechnology Limited and the Hong Kong Pharmaceutical Manufacturers Association Limited, with the DH as the supporting organisation. The forum featured a comprehensive programme, covering key drug regulatory legislation in the Chinese Mainland, drug registration procedures and application requirements, as well as quality and specification requirements. It helped local pharmaceutical manufacturers and agents to better understand the preparatory work required for drug registration in the Chinese Mainland, including the documents and information that need to be submitted.

Over 100 representatives from the local pharmaceutical sector attended the forum, including manufacturers and wholesalers. Participants generally considered that the content was practical and highly valuable. Not only did it provide a clear roadmap and timeline for drug registration in the Chinese Mainland, it also

significantly reduced the time and effort required for information collection and document preparation.

Prior to the forum, a delegation from the GBA Center for Drug Evaluation and Inspection met with the staff of the DH's Drug Office on 4 June 2026 to exchange views on practical experiences in drug evaluation and inspection in the Chinese Mainland. The DH staff also briefed the delegation on the initiatives of the Hong Kong Special Administrative Region (HKSAR) Government to develop Hong Kong into an international health and medical innovation hub; enhance the evaluation, approval and registration mechanism for drugs; implement a "primary evaluation" mechanism for new drugs; and establish the Hong Kong Centre for Medical Products Regulation by the end of 2026.

The DH has been actively promoting and enhancing Hong Kong's drug regulatory standards. The NMPA and its GBA Center for Drug Evaluation and Inspection have been providing staunch support for the HKSAR's pharmaceutical regulatory efforts. The DH expressed its sincere gratitude to the delegation.

Administrative Requirements for Institutional Review Board/Independent Ethics Committee (IRB/IEC) in Hong Kong

A [letter](#) was issued by the Pharmacy and Poisons Board of Hong Kong ("the Board") on 30 June 2026 to inform all holders/applicants of Certificate for Clinical Trial/Medicinal Test on the Board's endorsement of the "[Guidance for Institutional Review Board/Independent Ethics Committee: Requirements, responsibilities and Operations](#)" ("the Guidance") as the administrative requirements for Institutional Review Boards or Independent Ethics Committees (the "IRBs/IECs") operating in Hong Kong.

With the formal implementation of ICH E6(R3) Guideline for Good Clinical Practice ("ICH Guideline for GCP") in Hong Kong on 30 June 2026, clinical trials should be subject to independent review by an IRB/IEC, conducted in compliance with a protocol that has received prior IRB/IEC approval, and subject to periodic continuing review. To facilitate the clinical trial certification process, the Board has issued the

Guidance to provide direction to all IRBs/IECs established in Hong Kong, that are responsible for the independent ethics review and ongoing oversight of clinical trials involving pharmaceutical products for use in human subjects, and to set out the administrative arrangements for listing IRBs/IECs by the Board.

Please note that the following transitional arrangements for clinical trial certificate applications shall apply:

- From 2027 onwards, the Pharmacy and Poisons (Certification of Clinical Trial/Medicinal Test) Committee ("the Committee") will only approve applications for clinical trial certificates for interventional trials of investigational products intended for regulatory submission, with certification requirement of the trial must be approved by a Listed IRB/IEC.
- From 2028 onwards, the certification requirement will apply to all interventional clinical trials.

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

Establishment of the Expert Group on Pharmacovigilance

In view of the upcoming enhancement of the local drug registration regime, in particular the phased implementation of primary evaluation approach in Hong Kong, the Expert Group on Pharmacovigilance (EGPV) has been established under the Pharmacy and Poisons Board of Hong Kong on 1 August 2026 to strengthen the local pharmacovigilance and drug safety monitoring framework. Membership of the EGPV is composed of medical practitioner, pharmacist, pharmacologist and academia, and the Terms of Reference of the EGPV are found below:

- To review the benefit-risk profile of drugs available in Hong Kong and assess the impact of emerging drug safety information including the notifications and reports provided by the pharmaceutical industry, and advise the appropriate risk minimizing measures to allow safe use of the concerned drugs for consideration by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee ("the Registration Committee") and the Pharmacy and Poisons (Certification of Clinical Trial/ Medicinal

Test) Committee ("the CT Committee") of the Pharmacy and Poisons Board;

- To review and assess adverse drug reaction (ADR)/adverse event following immunisation (AEFI) reports of drugs and vaccines received and processed by the Department of Health (DH), with particular focus on selected serious or complicated cases, and advise/endorse the causality assessment and recommend any necessary regulatory or other follow up actions for consideration by the Registration Committee or the CT Committee;
- To advise and support the implementation of target post-approval interventions or studies for the continuous monitoring of drug safety when there is an impact to public health for consideration by the Registration Committee or the CT Committee;
- To advocate the DH drug safety monitoring system and promote ADR/AEFI reporting of drugs and vaccines by healthcare professionals and the pharmaceutical industry; and
- To advise, contribute and serve as editorial board for publications on drug safety or promotion of pharmacovigilance practice in Hong Kong.

For further details, please visit the website of the Pharmacy and Poisons Board at:

https://www.ppbhk.org.hk/eng/organization/expert_group_Pharmacovigilance.html

Revised Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements (Draft Version) for Consultation

The Pharmacy and Poisons Board of Hong Kong ("the Board") has been accepted as an observer of the ICH since October 2023, and has the ultimate goal of becoming an ICH regulatory member. The Drug Office of the Department of Health ("Drug Office") appreciate the industry's effort for the participation and valuable comment to the Task Force on Implementation of ICH Tier 1 and Preparation on Tier 2 Guideline Implementation all along.

In order to achieve the above goal, the Board has already implemented the ICH Tier 1 Guidelines including the Q7 Guideline (Good Manufacturing Practice Guideline for Active Pharmaceutical Ingredients), Q1 Guideline (Stability) and E6 Guideline (Good Clinical Practice), and has been planning the implementation of the various ICH Tier 2 Guidelines in Hong Kong, the latter includes the E2D(R1) Guideline (Post-Approval Safety Data: Definitions and Standards for Management and Reporting of Individual Case Safety Reports).

To prepare for this, Drug Office has revised the Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements to align with the E2D(R1) Guideline, and the Expert Group on Pharmacovigilance established under the Board advised in the latest meeting on 18 August 2026 to consult the industry regarding the aforesaid draft version of the revised guidance document.

On 27 August 2026, Drug Office has sent the revised Guidance for Pharmaceutical Industry – Adverse Drug Reaction Reporting Requirements (Version 2.0 - draft version) to the industry organisations, and invites their comments on the draft document on or before 30 September 2026.

Recent Law Amendments Published in Government Gazettes

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

The 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 1 March 2026 and 31 August 2026 are listed below. Letters were also issued by the Drug Office of the Department of Health to inform the concerned traders.

- Gazette 24/04/2026 No. 17 Vol. 30 (Letter to trade dated [24 April 2026](#))
- Gazette 03/07/2026 No. 27 Vol. 30 (Letter to trade dated [3 July 2026](#))

Regulation of Drugs

Regulatory requirements for traders

Implementation of Good Distribution Practice (GDP) for Pharmaceutical Products

Following a stakeholder consultation from April to May 2026, the Pharmacy and Poisons Board of Hong Kong endorsed the finalised Guide to Good Distribution Practice for Pharmaceutical Products ("GDP Guide"), Guidance for Industry: Guide to Good Distribution Practice for Pharmaceutical Products ("Guidance for Industry"), revised Code of Practice for Holder of Wholesale Dealer Licence ("revised COP") and implementation timeline on 18 June 2026.

The key implementation dates are:

- 30 September 2026: The GDP Guide and Guidance for Industry will be formally promulgated. Compliance with the GDP Guide will become a licensing requirement for new Wholesale Dealer Licence ("WDL") and Manufacturer Licence ("ML") applications received on or after this date.
- 30 September 2028: Existing WDL holders and relevant ML holders engaged in wholesale dealings of pharmaceutical products will be required to comply with the GDP Guide upon licence renewal. The revised COP will also take effect and be gazetted in due course.

The two-year preparatory period allows the trade to make the necessary arrangements. Licence holders and prospective applicants should review the documents and prepare for compliance. For details, please refer to the documents available on the Drug Office's GDP webpage:

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

The Department of Health Reminds Wholesale Dealer Licence Holders to Observe and Comply the Statutory Requirements for Handling Dangerous Drugs and Part 1 Poisons

The Department of Health ("DH") recently handled a case which involved the importation of Part I Dangerous Drugs by a holder of a Wholesale Dealer Licence ("WDL") and a Wholesale Dealer's Licence to Supply Dangerous Drugs ("WDLDD") which only authorised the licensee to supply Part II dangerous drugs under the Dangerous Drugs Ordinance, Cap. 134 ("DDO"). Furthermore, the relevant transaction records were not kept in the specified form prescribed under the Pharmacy and Poisons Regulations, Cap. 138A ("PPR").

Under the DDO, import, export, procuring, supply or dealing in or with, manufacture and possession of dangerous drugs must only be carried out under and in accordance with the DDO or any licence granted by the Director of Health thereunder. WDL holders in particular WDLDD holders should ensure that the substance handled falls within the scope of the relevant licence or authorisation. In particular, a WDLDD which only authorises the supply of Part II dangerous drugs does not authorise the licensee to deal in Part I dangerous drugs.

WDL holders are also reminded of the record-keeping requirements under the PPR. The PPR requires licensed wholesale dealers and licensed manufacturers to keep records of transactions in respect of Part 1 poisons and pharmaceutical products acquired or disposed of. Unless another system of recording has been approved by the Pharmacy and Poisons (Wholesale Licences) Committee, all records of transactions must be kept in the specified form.

Diazepam, for example, is subject to control as both a dangerous drug and a Part 1 poison. The DH reminds WDL holders and WDLDD holders to verify the classification of substances under the applicable legislations, and comply with the scope and conditions of their respective licences before engaging in any transaction involving controlled substances.

Failure to comply with the relevant statutory requirements, licence conditions or record-keeping requirements may result in enforcement and/or disciplinary actions where appropriate.

Regulation of Drugs

Regulatory requirements for Pharmaceutical Products

Reminder: Medical Gases will be Regulated as Pharmaceutical Products Starting from 14 June 2026

A [letter to trade](#) and a [press release](#) were issued on 14 April 2026 to serve as a reminder that medical gases would be regulated as pharmaceutical products starting from 14 June 2026. Further reminders were subsequently issued via a [press release](#) on 12 June 2026 and a [letter to trade](#) on 15 June 2026.

With effect from 14 June 2026, all companies that are 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") in order to operate lawfully. In addition, medical gases must be registered with the Pharmacy and Poisons Board of Hong Kong ("the Board") before they can be legally sold in Hong Kong, ensuring that the products meet the required standards of safety, efficacy and quality.

Drug retailers that only engage in the retail sale of medical gases that are not specified in the Poisons List under the Ordinance (such as medical oxygen), are not required to hold a retail licence.

The Board decided on 14 June 2024 to regulate medical gases as pharmaceutical products under the Ordinance. In addition, pharmaceutical products containing nitrous oxide (laughing gas) and nitric oxide should be regulated as prescription drugs. A two-year preparation period had been provided to the trade for obtaining the relevant licences and registering their related products.

The scope of the regulatory control of medical gases covers any gases or mixtures of gases in cylinders that fulfil definition of pharmaceutical product as stipulated under section 2 of the Ordinance, which may cover medical gases such as oxygen, nitrogen, nitrous oxide (laughing gas), nitric oxide, carbon dioxide, helium, medical air and mixture of some of the above gases.

A list of local licensed traders dealing with medical gases and a list of medical gases registered as

pharmaceutical products have been uploaded on the [website](#) of the Drug Office of the Department of Health.

For details, please visit the websites of the [Board](#) and the [Drug Office](#) of the Department of Health.

Update of "Guidance Notes on Classification of Products as Pharmaceutical Products"

A [letter to trade](#) was issued by the Pharmacy and Poisons Board of Hong Kong ("the Board") on 23 April 2026 to inform that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee ("the Committee") of the Board has endorsed an update to the "Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)" ("the Guidance Notes"). The update makes explicit that products intended for human parenteral injection are regarded as pharmaceutical products and are subject to the regulatory control of the Pharmacy and Poisons Ordinance, Cap. 138 ("PPO"). The updated Guidance Notes has come into effect on 23 April 2026.

The Committee has considered that products for human parenteral injection are high-risk products. The Committee has also referenced the regulatory approaches of other jurisdictions (such as Chinese Mainland, Europe, and United Kingdom) where authorities govern parenteral injection products under stringent medicine or medical device regulatory frameworks.

Accordingly, the Committee confirmed that products intended for human parenteral injections are generally classified as pharmaceutical products, unless such products fall within other regulatory categories (e.g. medical devices) or otherwise considered on a case-by-case basis.

The update aims to provide regulatory clarity to stakeholders, safeguard medication safety, and protect public health. Products classified as pharmaceutical products must obtain registration

Regulation of Drugs

with the Board prior to sale or distribution in Hong Kong. Additionally, the manufacture, wholesale, and retail of such products remain strictly subject to the Board's relevant licensing requirements.

For the full text of the updated Guidance Notes, please visit the websites 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 [Guidelines](#) related to drug registration and clinical trial/medicinal test, and the relevant content of the website have been updated between March to August 2026.

Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)

The [Guidance Notes](#) on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138) has been updated in April 2026.

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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, 38/F, Revenue Tower, 5 Gloucester Road, Wan Chai, Hong Kong

Enquiry Phone No.: 2594 7647

Fax No.: 3904 1225

Risk Management and Operations Division:

Address: Room 4105, 41/F, Revenue Tower, 5 Gloucester Road, Wan Chai, Hong Kong

Enquiry Phone No.: 3752 3524

Fax No.: 3752 3533