

衛生署藥物辦公室  
藥物評審及警戒科  
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DEPARTMENT OF HEALTH  
DRUG OFFICE  
DRUG EVALUATION AND  
PHARMACOVIGILANCE DIVISION  
Suites 2002-05, 20/F, AIA Kowloon Tower,  
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30 December 2025

Dear Sir / Madam,

**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 dated 17 June 2024 regarding the regulation of medical gases as pharmaceutical products, please be reminded that **starting from 14 June 2026**, medical gases will be regulated as pharmaceutical products. From that time, 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 in Hong Kong. In addition, traders involved in the manufacture, wholesale, or retail of medical gases must obtain relevant drug dealer's licence(s) in accordance with the Pharmacy and Poisons Ordinance (Cap. 138) (the Ordinance). The industry should make early preparations to ensure compliance with the relevant regulatory requirements.

The Board had decided in June 2024 that medical gases should be regulated as pharmaceutical products under the regulatory framework of 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 has been provided for the trade to apply for relevant licences and registration of their 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

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as oxygen, nitrogen, nitrous oxide (laughing gas), nitric oxide, carbon dioxide, helium, medical air and mixture of some of the above gases.

According to the Ordinance, illegal possession or sale of unregistered pharmaceutical products or prescription drugs, and manufacture or wholesale of pharmaceutical products without relevant licences are criminal offences. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment upon conviction.

For relevant information on the regulation of medical gases, please visit the website of the Drug Office of the Department of Health ([http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical\\_trade/medical\\_gases\\_regulation.html](http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/medical_gases_regulation.html)).

If you wish to deal in trading of the medical gases, as pharmaceutical products, please apply for relevant licence(s) and register your products as soon as possible. For details on applying for the relevant licences and product registration, please visit the website of the Drug Office of the Department of Health ([https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical\\_trade/guidelines\\_for\\_ms/useful\\_guidelines\\_forms.html](https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_for_ms/useful_guidelines_forms.html)).

Should you have any enquiries, please feel free to contact Ms. Tracy WONG at 3974 4169 for product registration matters and Mr. Alex WONG at 3107 3497 for trader licensing matters.

Yours faithfully,



(C. CHEUNG)

for Director of Health