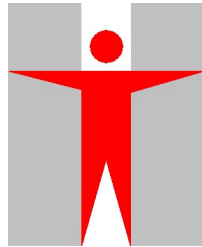


衛生署藥物辦公室
藥物評審及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG EVALUATION AND
PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
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本署檔號 Our Ref. : DH DO PRIE/1-55/1

電話 Tel. : (852) 3974 4175

圖文傳真 Fax : (852) 2803 4962

14 April 2026

Dear Sir / Madam,

**Reminder: Medical gases will be regulated as pharmaceutical products
starting from 14 June 2026**

Further to the letter issued by the Drug Office of the Department of Health on 17 June 2024 and 30 December 2025, please be reminded again that medical gases will be regulated as pharmaceutical products two months from now (starting from 14 June 2026). By that time, any company 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), so that they can operate the businesses lawfully. In addition, suppliers should only sell and supply medical gases that have been registered with the Pharmacy and Poisons Board of Hong Kong (the Board) to ensure that the products meet the required standards of safety, efficacy and quality.

The Board decided on 14 June 2024, that medical gases should be regulated 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 has 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,

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aspire to be an internationally renowned public health authority*

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 the relevant licences constitute criminal offences. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment upon conviction.

Relevant information on the regulation of medical gases and a list of registered medical gases can be found on 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).

If you wish to deal in trading of the medical gases, as pharmaceutical products since 14 June 2026, please ensure you obtained the relevant licence(s) and the products sold or supplied are registered. 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).

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