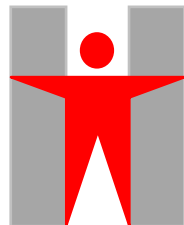


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THE GOVERNMENT OF THE HONG KONG  
SPECIAL ADMINISTRATIVE REGION  
DRUG OFFICE  
DEPARTMENT OF HEALTH  
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17 June 2024

Dear Sir/Madam,

### **Regulation of Medical Gases as Pharmaceutical Products**

The Drug Office of the Department of Health would like to inform you that the Pharmacy and Poisons Board of Hong Kong (the “Board”), a statutory body established under the Pharmacy and Poisons Ordinance (the “Ordinance”) (Cap. 138) has endorsed the regulation of medical gases as pharmaceutical products under the Ordinance with effect from 14 June 2026. The Department of Health is responsible for providing professional and executive support to the Board.

In September 2023, the Board agreed that medical gases should be regulated as pharmaceutical products under the Ordinance after taking into account the regulatory control of medical gases in other jurisdictions and the current situation in Hong Kong. In this connection, a public consultation had been conducted by the DH in November last year for collecting views and comments from the public and relevant stakeholders.

Noting that the overall responses were in support of the regulatory control of medical gases, the Board has decided at its meeting on 14 June 2024 to regulate medical gases as pharmaceutical products under the Ordinance by giving two years' preparatory time (i.e. from 14 June 2024 to 13 June 2026) for the trade to apply for relevant licences and registration of their products. The Board has also promulgated relevant Guidance Notes and details are available at the Board's website ([www.ppbhk.org.hk/eng/index.html](http://www.ppbhk.org.hk/eng/index.html)).

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aspire to be an internationally renowned public health authority*

When the new regulatory control takes effect, the medical gases, as pharmaceutical products, have to be registered with the Board before they can be legally sold or supplied in Hong Kong. In addition, traders of the pharmaceutical products must obtain relevant licence(s) from the Board before conducting manufacture, wholesale (including import and export) of pharmaceutical products and retail sales of pharmaceutical products containing poisons. According to the Ordinance, illegal possession or sale of unregistered pharmaceutical products or prescription drugs, and manufacture, wholesale of pharmaceutical products and retail sales of pharmaceutical products containing poisons 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 ([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.

Should you have any enquiries, please feel free to contact Ms. Jacqueline CHEUNG at 3974 4169 for product registration matters and Ms. Eunice HUNG at 3107 3497 for trader licensing matters.

Yours faithfully,



(C. CHEUNG)  
for Director of Health