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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

20 November 2023

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 decided to enhance the regulatory control of medical gases. The Department of Health is responsible for providing professional and executive support to the Board.

Recently, the Board has reviewed the current regulatory control of medical gases in Hong Kong. After a comprehensive review on the regulatory control of medical gases in the Mainland of China and overseas jurisdictions including Australia, Canada, the European Union, Singapore, the United Kingdom and the United States, the Board has endorsed the proposal to regulate medical gases as pharmaceutical products under the Ordinance in Hong Kong.

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 including oxygen, nitrogen, nitrous oxide, nitric oxide, carbon dioxide, helium, medical air and mixture of some of the above gases. The medical gas product covers the gas/gas mixtures and its primary packing including the container and the valve. These medical gases would be subject to the registration requirements and their manufacturers and wholesalers are also subject to licensing control under the Ordinance. Furthermore, sales control will be imposed in accordance with their intended use, i.e., nitrous oxide and nitric oxide to be regulated as prescription drugs, while other medical gases including oxygen, nitrogen, carbon dioxide, helium and medical air will not be classified or regulated as poisons under the Pharmacy and Poisons Regulations (Cap. 138A) and may be sold or distributed as over-the-counter medicines.

Please note that the enhanced regulatory control of medical gases as pharmaceutical products serves to impose registration requirements of medical gases as well as licensing requirements on the relevant traders in addition to the existing control of gases under other legislations, e.g., Dangerous Goods Ordinance (Cap. 295).

In this connection, the new guidance notes that cover the (i) registration requirements of medical gases as pharmaceutical products; and (ii) licensing requirements of manufacturers and wholesalers of medical gases; as well as (iii) the updated Guidance Notes on qualification, experience and training requirements for authorized persons and other key personnel of licensed manufacturers have been prepared, and are available on the website of Drug Office (www.drugoffice.gov.hk/eps/do/en/consumer/medical_gases.html).

The draft guidance documents are available for comments from 20 November 2023 to 19 January 2024. You are invited to send your views to the Drug Office of the Department of Health through email (pharmgeneral@dh.gov.hk), mail (Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong), or facsimile (2803 4962).

We shall consider the feedback from all relevant stakeholders before finalizing the guidance notes. The proposed regulatory control should take effect tentatively two years after endorsement of the finalized guidance notes by the Board to allow sufficient time for traders to make preparation to comply with the relevant registration/licensing requirements.

Should you have any enquiries, please feel free to contact Ms. Jocelyn CHU at tel. no. 3974 4169.

Yours faithfully,

(Y. F. YEUNG)
for Director of Health