Regulation of Medical Gases as Pharmaceutical Products

The Pharmacy and Poisons Board of Hong Kong (the “Board") is a statutory body established under the Pharmacy and Poisons Ordinance, Cap. 138 (the "Ordinance") to carry out the statutory functions as stipulated in the PPO and its subsidiary legislation. While the Ordinance is the principal legislation governing the regulation of pharmaceutical products in Hong Kong, the Drug Office of the Department of Health provides 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).

If you have any comments on the draft guidance notes, please send them to us on or before 19 January 2024 by any of the following means:

Mail: Suite 2002-05, 20/F,
AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong,
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Fax: 2803 4962

Email: pharmageneral@dh.gov.hk

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 of Drug Office at tel. no. 3974 4169.

Members of the trade are voluntary to supply their personal data when giving views on the consultation document. Any personal data provided on a submission will only be used for purpose of this consultation exercise.

The submissions and personal data collected may be transferred to the relevant Government bureaux, departments or agencies for purposes directly related to this consultation exercise. Parties receiving the data are bound by such purposes in their subsequent use of the data.

The names and views of individuals and organisations submitting their views in response to the consultation document ("senders") will be published for public viewing after the conclusion of this consultation exercise. The Department of Health may, either in discussion with others or in any subsequent report, whether privately or publicly, quote the senders and the views they submitted in response to the consultation document. We will respect the will of senders to remain anonymous and/or keep their views confidential in part or in whole, but if no such request is explicitly indicated, it will be assumed that the sender can be named and his / her views be published for public information.

Any senders providing personal data to the Department of Health in his submission will have the right to request access and make correction to such personal data. Data access or correction of personal data request should be made in writing to the focal point of contact specified above.

Drug Office

Department of Health

November 2023