PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局

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貴處檔號

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23th April 2026

Dear Sir/Madam,

Update of "Guidance Notes on Classification of Products as Pharmaceutical Products"

This letter serves to inform you that the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the "Committee") of the Pharmacy and Poisons Board of Hong Kong (the "Board") has, at its meeting held on 23 April 2026, endorsed the update of the "Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138)" (the "Guidance Notes"). The update makes explicit that products intended for human parenteral injection are regarded as pharmaceutical products and are therefore subject to the regulatory control of the Pharmacy and Poisons Ordinance, Cap. 138 ("PPO"). The updated Guidance Notes shall take effect immediately.

According to section 2 of the PPO, "pharmaceutical product" is defined as:
pharmaceutical product (藥劑製品) —

(a) means a substance or combination of substances that—
  (i) is presented as having properties for treating or preventing disease in human beings or animals; or
  (ii) may be used in or administered to human beings or animals with a view to—
    (A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or
    (B) making a medical diagnosis; and
(b) includes an advanced therapy product.

According to the Pharmacy and Poisons Regulations (PPR) (Cap. 138A) a subsidiary legislation of the PPO, pharmaceutical products must be registered with the Board before they can be sold, offered for sale or distributed or possessed for the purposes of sale, distribution or other use in Hong Kong.

The Committee has considered that products for human parenteral injection are high-risk products. Substances administered parenterally enter the systemic circulation directly and may exert pharmacological, immunological or metabolic actions. Such products bypass the body's natural defenses, thereby allowing microorganisms, pyrogens, or inappropriate substances direct access to the bloodstream or tissues. As such, products for human parenteral injections must be sterile and free from pyrogens; any failure to maintain sterility during manufacturing or handling poses immediate life-threatening risks, such as sepsis.

The Committee also make reference to other jurisdictions (such as Chinese Mainland, Europe, and United Kingdom) which their respective regulatory authorities generally regulate products intended for human parenteral injection under strict regulatory frameworks of medicines or medical devices.

In light of the above, the Committee confirmed that products intended for human parenteral injections are generally classified as pharmaceutical products, unless such products fall within other regulatory categories (e.g. medical devices) or otherwise considered on a case-by-case basis.

To ensure the trade is fully aware of the above, the Committee, has endorsed an update to the Guidance Notes, explicitly stating that, products intended for human parenteral injection are in general classified as pharmaceutical products. This update aims to provide clearer guidance to stakeholders, safeguard medication safety and public health, and ensure that products subject to regulation as pharmaceutical products must be registered with the Board before they can be sold or supplied in Hong Kong. Furthermore, the manufacturing, wholesaling, and retailing of pharmaceutical products are also subject to the relevant licensing requirements of the Board. For details about the updated Guidance Notes, please visit the website of the Drug Office of the Department of Health (https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/useful_guidelines_forms.html).

According to the PPO, illegal sale or possession of unregistered pharmaceutical products, is a criminal offence. The maximum penalty for each offence is a fine of $100,000 and two years' imprisonment upon conviction.

For enquiries, please contact the Drug Office at 3974 4175.

Yours faithfully,

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee

c.c. DH DO PRIE/7-15/3