



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

Your Ref. :
貴處檔號
Our Ref. :
本局檔號
Tel. No. :
電話
Fax No. :
圖文傳真

3107 3497

3107 0221

Drug Office
Department of Health
Rm. 2001-2002, 20/F., Dah Sing Financial Centre,
248 Queen's Road East,
Wan Chai, Hong Kong.
香港灣仔皇后大道東248號
大新金融中心20樓2001-2002室
衛生署藥物辦公室

30 September 2026

To: Licensed Wholesale Dealers
Licensed Pharmaceutical Manufacturers
Licensed Pharmaceutical Manufacturers (Secondary Packaging)

Dear Sir / Madam,

Implementation of Good Distribution Practice (GDP) for Pharmaceutical Products

This letter serves to inform you that today, **30 September 2026**, the Pharmacy and Poisons Board of Hong Kong (“the Board”) implements the Guide to Good Distribution Practice for Pharmaceutical Products (“GDP Guide”) and the Guidance for Industry: Guide to Good Distribution Practice for Pharmaceutical Products (“Guidance for Industry”).

The Board has reviewed the implementation of GDP for pharmaceutical products in the Chinese Mainland and other overseas jurisdictions. Having regard to the above, the Board endorsed to require licensed manufacturers and licensed wholesale dealers to implement GDP in Hong Kong by adopting the Pharmaceutical Inspection Co-operation Scheme Guide to Good Distribution Practice through the imposition of additional licensing condition. This is intended to strengthen regulatory control of the pharmaceutical supply chain, align Hong Kong’s regulatory regime with international standards and practices, and ensure that pharmaceutical products are consistently stored, transported and handled under suitable conditions throughout the distribution chain to safeguard their quality, integrity and public health.

On 18 June 2026, the Board has endorsed the finalised GDP Guide, Guidance for Industry and revised Code of Practice for Holder of Wholesale Dealer Licence (“revised COP”), after taking into consideration of the feedback collected during a two-month stakeholder consultation from 1 April to 31 May 2026 together with the following implementation timetable:

With effect from **30 September 2026**, **applicants** for new Wholesale Dealer Licence (“WDL”) and Manufacturer Licence (“ML”) must comply with the GDP Guide as a licensing requirement. This applies to new applications received by the Drug Office of the Department of Health on or after that date.

For **existing** WDL holders and relevant ML holders engaged in the wholesale dealing of pharmaceutical products, compliance with the GDP Guide will be imposed by way of a licensing

condition **upon licence renewal** on or after **30 September 2028**, thereby allowing the trade a two-year preparatory period to make the necessary arrangements.

Since 6 July 2026, the endorsed GDP Guide and Guidance for Industry have been available on the Drug Office's website for advance reference and preparation. The Drug Office has also informed the trade of the implementation timetable through letters dated 6 July and 7 September 2026.

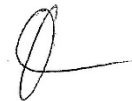
The revised COP will also take effect on 30 September 2028 and will be gazetted in due course in accordance with section 4B(5) of the Pharmacy and Poisons Ordinance (Cap. 138).

The GDP Guide and Guidance for Industry are available on the Board's website:
https://www.ppbhk.org.hk/eng/implementation_of_gdp.html

Licence holders and prospective applicants should read these documents together and make timely preparations to meet the applicable GDP requirements in accordance with the above timetable.

Should you have any enquiries, please contact the Drug Office at tel. no. 3107 3497.

Yours faithfully,



(Y. H. WONG)

Secretary, Pharmacy and Poisons
(Wholesale Licences) Committee