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DEPARTMENT OF HEALTH
DRUG OFFICE
LICENSING AND COMPLIANCE DIVISION
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6 July 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

Further to the letter dated 1 April 2026 regarding the implementation of Good Distribution Practice (“GDP”) for pharmaceutical products in Hong Kong, the Pharmacy and Poisons Board of Hong Kong (“the Board”) had conducted a stakeholder consultation from 1 April 2026 to 31 May 2026 on the draft Guide to Good Distribution Practice for Pharmaceutical Products (“GDP Guide”), Guidance for Industry: Guide to Good Distribution Practice for Pharmaceutical Products (“Guidance for Industry”) and revised Code of Practice for Holder of Wholesale Dealer Licence (“revised COP”). It is noted that the implementation of GDP for pharmaceutical products are generally well accepted by the trade and some textual amendments on the draft guidance documents are received. Having considered the above, the Board has made appropriate revision and endorsed the finalised versions of the GDP Guide, Guidance for Industry and revised COP, together with the implementation timeline, at its meeting held on 18 June 2026.

The finalised documents are available on the GDP section of the Drug Office’s webpage for advance reference by the trade:

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/implementation_of_gdp.html

The implementation timeline is as follows:

- a) the GDP Guide and Guidance for Industry will be formally promulgated by the Board on 30 September 2026;
- b) for new applications for Wholesale Dealer Licence (“WDL”) and Manufacturer Licence (“ML”) received by the Drug Office on or after 30 September 2026, compliance with the GDP Guide will be imposed as one of the licensing requirements;
- c) for existing WDL holders and relevant ML holders engaged in wholesale dealings of pharmaceutical products, compliance with the GDP Guide will be

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imposed by way of licensing condition, upon licence renewal on or after 30 September 2028, thereby allowing a two-year preparatory period for the trade to make the necessary arrangements; and

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

Licence holders and prospective applicants are advised to note the above arrangement, and to make necessary preparations for compliance with the GDP requirements in accordance with the above implementation timeline.

Should you have any enquiries, please contact Mr Alex WONG of the Drug Office at Tel: 3107 3497.

Yours faithfully,



(YH WONG)
for Assistant Director (Drug)