

Implementation of Good Distribution Practice (GDP) for 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 perform statutory functions under the Ordinance 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 support to the Board.

Recently, the Board reviewed the implementation of Good Distribution Practice (“GDP”) for pharmaceutical products in the Chinese Mainland and other overseas jurisdictions, including Australia, Canada, the European Union, Japan, Singapore, South Korea, the United Kingdom and the United States. Having regard to the above, the Board endorsed to require licensed manufacturers (“ML”) and licensed wholesale dealers (“WDL”) 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. Tentatively start off with new applicants in Q3 2026 as licensing requirements and extend to relevant existing licencees in Q3 2028. 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.

In this connection, the following draft documents for implementation of GDP have been drafted/ revised and uploaded to the website of the Board (https://www.ppbhk.org.hk/eng/implementation_of_gdp.html):

1. Guide to Good Distribution Practice for Pharmaceutical Products (“GDP Guide”);
2. Guidance for Industry: Guide to Good Distribution Practice for Pharmaceutical Products (“Guidance for Industry”); and
3. Revised Code of Practice for Holder of Wholesale Dealer Licence (“WDL COP”).

We shall consider the feedback received from stakeholders before finalising the above documents for submission to the Board for consideration.

The implementation of GDP is tentatively by phases. The Board tentatively promulgate the finalize GDP Guide, the Guidance for Industry and revised WDL COP in Q3 2026. Upon promulgation, the compliance with the GDP Guide will be the licensing requirements of new applicants for a ML or a WDL, and the relevant licensees will be required to comply with the GDP Guide as a licensing condition. Existing holders of a ML or a WDL will be required to comply with the GDP Guide two years after the promulgation of the GDP Guide as a licensing condition upon renewal of their licences.

In addition, the revised WDL COP is applicable to WDL holders only and its effective date will be published in the Gazette. It is tentatively take effect two years after the promulgation of the GDP Guide by the Board. Upon commencement, all WDL holders (whether new applicants or upon licence renewal) will be required to comply with the GDP Guide and its compliance as a licensing condition, and the revised WDL COP.

If the public have any comments on the above draft documents, please send them to us **on or before 31 May 2026** by any of the following means:

Mail: Drug Office
Department of Health
Room 2001-2002,
20/F, Dah Sing Financial Centre,
248 Queen's Road East,
Wan Chai, Hong Kong

Fax: 3107 0221

Email: gdp_consultation@dh.gov.hk

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 the purpose of this consultation exercise.

The submissions and personal data collected may be transferred to 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”) may 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 submissions will have the right to request access to and correction of such personal data. Data access or correction requests should be made in writing to the contact point specified above.

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

Drug Office
Department of Health

April 2026