



Notification of the Procedures for Submission of Applications and GDP Inspection for the Year 2569 (2026)¹

Authority: Drug Division, Food and Drug Administration, Ministry of Public Health, Nonthaburi 11000.

Document number: 1009/1096

Promulgation Date: 6 December, 2025

To: Holders of licenses to import or order modern drugs into the Kingdom

Whereas the Ministry of Public Health has issued the Notification on the Criteria, Procedures, and Conditions for the Distribution of Modern Drugs (Good Distribution Practice; GDP), by virtue of the authority under Ministerial Regulation No. 16 (B.E. 2525) issued under the Drug Act B.E. 2510, as amended by Ministerial Regulation No. 30 (B.E. 2563) issued under the Drug Act B.E. 2510; and whereas such Notification requires that license holders who import or order modern drugs into the Kingdom and fall under the conditions for inspection shall conduct drug distribution in accordance with the said criteria, and upon passing the inspection shall receive a Certificate of Good Distribution Practice (GDP Certificate) for Modern Drugs from the Food and Drug Administration.

In this regard, the Drug Division, Food and Drug Administration, hereby informs the procedures for submission of applications and inspection for GDP certification of premises importing or ordering modern drugs for the year 2569 (2026), as follows:

License holders may verify the list of licensees included in the annual GDP inspection plan for Fiscal Year 2569 via the website:

<https://drug.fda.moph.go.th/gdp-audit>

Officers shall send a written notification of the GDP inspection to the license holder, specifying the details of the inspection date and the schedule for submission of supporting documents through the SKYNET system.

After officers have reviewed the supporting documents submitted by the license holder, the officers shall send a written notification of the GDP Inspection Agenda to the license holder.

¹Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law



In cases where the license holder submits an inspection request and supporting documents through the SKYNET system prior to receiving the written notification of the GDP inspection, officers shall reject the application in all cases.

The preparation of the list of license holders included in the annual GDP inspection plan is based on the conditions for GDP inspection as prescribed in the Ministerial Regulation, namely: the license holder possesses a valid drug registration and has already imported such registered drug into the Kingdom.

In cases where a license holder does not appear in the annual inspection plan but wishes to request an inspection, the license holder shall submit a written notification expressing the intention to request GDP inspection to the Drug Division. Upon consideration by the officers, the result of the consideration shall be notified to the license holder accordingly.

Please be informed accordingly.

Yours sincerely,

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