(Unofficial translation)

Notification of Food and Drug Administration
Re: Temporary Measures for GMP Certificate Consideration of Modern Drug Manufacturing Facilities During the Coronavirus Disease 2019 (COVID-19) Outbreak

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Whereas the foreign drug regulatory authorities responsible for GMP inspection of drug manufacturing facilities have cancelled or postponed their inspection of both domestic and foreign manufacturing facilities due to ongoing outbreak of the Coronavirus Disease 2019 (COVID-19) pandemic, and have implemented measures to allow previously issued GMP Certificate to remain valid until the next inspection round of drug manufacturing facilities.

For this reason, to ensure that current pharmaceutical product manufacturing regulations are suitable for the country's public health problems white being efficient, timely and consistent with international guidelines, the Food and Drug Administration hereby prescribes temporary measures for GMP Certificate consideration of modern drug manufacturing facilities as follows:

1. The GMP Certificates or GMP Clearance Letters previously issued by the Food and Drug Administration to foreign drug manufacturing facilities which will expire before 31 December 2023 shall remain valid until 31 December 2023.

ln case of doubt or plausible reason to believe that there is problem with the GMP standard of a foreign drug manufacturing facility to the extent that it may cause risk or harm to consumers, the Food and Drug Administration reserves the right to implement suitable measure(s) to guarantee compliance of said foreign manufacturing facility with the prescribed quality standard, such as conducting documentary inspection or on-site inspection of the drug manufacturing facility.

2. The GMP Certificates issued by the Food and Drug Administration to domestic modern drug manufacturing facilities which will expire before 31 December 2023 shall remain valid until 31 December 2023.

/Nevertheless…

Nevertheless, inspection of high-risk modern drug manufacturing facilities in special cases, such as the manufacturing facilities with several deficiencies or drug quality problems or where current drug manufacturing standards of these facilities may cause risk or harm to consumers or where licensees of modern drug manufacturing wish to undergo the first inspection or broaden their manufacturing category, can be carried out as deemed reasonable, of urgent necessity, and in compliance with the Food and Drug Administration's policies.

3. ln applying for the issuance or renewal of a GMP Clearance Letter of foreign drug manufacturing facilities, Licensees to import or order modern drugs into the Kingdom may proceed as follows:

3.1 Submit the GMP Certificate issued by a foreign drug regulatory authority that will expire after 31 December 2023 to supplement consideration on the renewal of GMP Certificate of the foreign modern drug manufacturing facility.

3.2 File an application for a documentary inspection for a renewal of the GMP Certificate issued by the Food and Drug Administration to foreign drug manufacturing facilities in the event that an on-site inspection of such facilities cannot be performed again within the prescribed period of time. After passing the documentary inspection, a GMP Clearance Letter will be issued to such facilities.

3.3 Copy of a GMP Certificate or a Certificate of Pharmaceutical Product issued by a foreign drug regulatory authority, which has not yet been notarized/legalized, can be submitted. However, licensees must provide the reason and necessity for doing so, self-certify such documents, and submit them with the application form. Licensees must, as soon as possible, submit a fully notarized/legalized copy of the documents within 180 days of the issue date of such GMP Certificate

3.4 GMP inspection Report and GMP Certificate of foreign drug manufacturing facilities, issued by a foreign drug regulatory authority with an inspection round less than three years, can be submitted. For GMP Certificate renewal application, the documents must be endorsed or evidence of a renewal or an extension of the GMP inspection round, as the case may be, issued by a foreign drug regulatory authority of the country in which the manufacturing Facility is located or by the EU drug regulatory authority, must be provided.

ln this case, the Certificate validity period shall be the same as the risk assessment validity period but shall not exceed three years and shall not be longer than expiration date of the GMP Certificate/CPP submitted with the application form.

/4. Any measures...

4. In the event of any conflict and inconsistency between the measures relating to GMP Certificate consideration of modern drug manufacturing facilities and the measures set forth in this Notification, the latter shall prevail.

5. This Notification shall be valid for one year as from its announcement date. ln case of necessity, the Notification may be renewed.

This Notification shall come into force from 7 October 2022 onward.

Announced on 30 September 2022.

(Signed) Phaisan Dankhum
(Mr.Phaisan Dankhum)

Secretary-General of Food and Drug Administration

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.