(Unofficial translation)

Notification of Food and Drug Administration on Temporary Procedures for GMP Accreditation of Pharmaceutical Manufacturers During the Coronavirus (COVID-19) Pandemic

Due to the cancellation or suspension of pharmaceutical manufacturers by overseas public drug administration organizations responsible for the GMP inspection of pharmaceutical production of manufacturers located within and outside the country of their organizations because of an ongoing threat of (COVID-19) pandemic, the overseas drug administration organization have implemented a measure to extend the validity of the existing GMP certificate or GMP clearance letter until the inspection is resumed. Likewise, Thailand is under strict health protocols in response to the coronavirus (COVID-19) situation in the country.

Hereof, to ensure that the inspection process is compatible with the current healthcare challenge the country has been facing whilst maintaining the standard and speed of the process to be in conformity with the global practice, Food and Drug Administration issues temporary procedures for GMP accreditation of pharmaceutical manufacturers with the details as follows:

1. The existing GMP Certificates issued by Food and Drug Administration for overseas pharmaceutical manufacturers that expire before 31 December 2022 are considered valid until 31 December 2022.

2. The existing GMP Certificated issued by Food and Drug Administration for domestic pharmaceutical manufacturers that expire before 31 December 2022 are considered valid until 31 December 2022.

However, in case of high-risk pharmaceutical manufacturers, including manufacturers with multiple defects, manufacturers with inadequate quality of pharmaceuticals, or manufacturers requesting for their first inspection or expanding their pharmaceutical production line, a special GMP inspection can be carried out depending on reasons, necessity, and urgency of the case, in addition to the relevant policies of Food and Drug Administration.

3. For the overseas pharmaceutical manufacturers that have previously been inspected and received GMP certificates which expire after 31 December 2022, the manufacturers can request for a renewal of the GMP clearance letter as announced in the Announcement of Food and Drug Administration on Rules, Procedures, and Conditions for

Requesting, Issuance, and Renewal of GMP Clearance for Overseas Pharmaceutical Manufacturers issued on 31 March 2021.

4. According to the Announcement of Food and Drug Administration on Rules, Procedures, and Conditions for Requesting, Issuance, and Renewal of GMP Clearance for Overseas Pharmaceutical Manufacturers issued on 31 March 2021, the authorized importer can submit the GMP Certificate or the Certificate of Pharmaceutical Product that has not been notarized or legalized with specifying their reasons and necessity for using such documents. The authorized importer can certify the copy of overseas manufacturer GMP certificate for submission. In this regard, the official notarized and legalized overseas manufacturer GMP certificate must be later submitted as soon as possible, within 180 days from the issue date of the GMP certificate letter.

The authorized importer can submit the GMP inspection report and the GMP Certificate with the previous inspection of over three years with the endorsement of GMP certificate renewal or other evidence of the GMP certificate renewal or the extension of GMP inspection period issued by a local drug administration organization where the manufacturers are based, or the European Union organization for drug administration.

The validity of the certificate in this case depends on the result of risk assessment. However, the validity period must not be longer than three years and not exceed the expiration date of the GMP certificate/CPP submitted together with the request.

5. The procedures in this announcement shall be complied. Any measures or procedures on GMP accreditation of pharmaceutical manufacturers that are not in accordance with this announcement shall be disregarded.

6. This announcement is valid for one year from the issue date. The extension of the announcement is possible if necessary.

Henceforth.

Announced on 7 October 2021.

(Signed) Phisan Dankhum

(Mr. Phisan 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.