HHP Law Firm.

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BPOM's Regulation Requires Offshore Manufacturing Facilities to Comply With CPOB Fulfillment

For More Information:

Cahyani Endahayu
Partner
+62 21 2960 8515
cahyani.endahayu
@bakermckenzie.com

Reagen Mokodompit
Associate
+62 21 2960 8530
reagen.mokodompit
@bakermckenzie.com

Background

Drugs and Food Supervisory Agency (Badan Pengawas Obat dan Makanan or "**BPOM**") evaluates pharmaceutical manufacturing companies that apply for marketing authorizations for imported drugs ("**Applicant**") to ensure their compliance with the standards set out under the prevailing good manufacturing practice guidelines for drugs (*Cara Pembuatan Obat Yang Baik* or "**CPOB**").

CPOB guidelines are generally regulated under BPOM Regulation No. 34 of 2018 dated 7 December 2018 on Good Manufacturing Practice Guideline for Drugs ("**BPOM Regulation 34**"). BPOM issued BPOM Regulation No. 7 of 2019 dated 24 April 2019 on the Evaluation of the Fulfillment of CPOB Requirements on Manufacturing Facilities for Imported Drugs ("**BPOM Regulation 7**").

Content and Implications

BPOM Regulation 34 contains CPOB requirements that must be met by Applicants, while BPOM Regulation 7 focuses more on the requirements that are applicable to (and must be met by) the **offshore** Manufacturing Facility. Typically, 'Manufacturing Facilities' are owned by foreign pharmaceutical manufacturers (**read**: principals) that manufacture drugs outside of Indonesia and supply them into Indonesia through their appointed marketing authorization holder (i.e., Applicant) ("**Principal Manufacturer**").

**Note:*

- *Under BPOM Regulation 7, 'Manufacturing Facilities' are defined as facilities used in a series of activities to produce imported drugs, including: (i) production and (ii) quality control; starting from the procurement of basic materials and packaging materials, processing, packaging until the product is ready for distribution as finished drugs.*

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- *In general, all pharmaceutical manufacturing companies must comply with CPOB standards set out under BPOM Regulation 34 and obtain a CPOB certificate as proof of their compliance. In drugs registration (i.e., to obtain marketing authorization), BPOM would want to ensure that the Manufacturing Facility (and the manufacturer) of the registered drug has met with the CPOB standards - or at least has met with the relevant good manufacturing practice ("**GMP**") standards applicable in the offshore country where the Manufacturing Facility is located (for imported drugs).*

BPOM Regulation 7 introduces specific requirements for registration of imported drugs, in addition to the more general requirements on offshore imported drugs Manufacturing Facilities, which are previously governed under BPOM Regulation No. 24 of 2017 on Criteria and Procedures of Drug Registration ("**BPOM Regulation 24**").

With the issuance of BPOM Regulation 7, the Manufacturing Facility of the Principal Manufacturer must strictly be in compliance with the CPOB requirements. Gaining BPOM's approval on this compliance is part of the steps that an Applicant must go through to obtain a marketing authorization for imported drugs registration. Hence, BPOM Regulation 7 would only be relevant for imported drugs.

Given the above, naturally BPOM Regulation 7 could potentially prolong the marketing authorization application process for imported drugs (i.e., but on the other hand also give clarity on the process), specifically because of following:

(a) The time required to obtain marketing authorization approval of imported drugs registration may be longer than the time required before BPOM Regulation 7 was issued, considering that:

  (i) Additional documents may be required

  (ii) There are several layers of steps - they each potentially have long timeline

  (iii) In case BPOM's desktop assessment is not conclusive, a site visit may be carried out by BPOM officials to inspect the offshore Manufacturing Facility of the Principal Manufacturer (i.e., BPOM Regulation 7 even regulates on transportation and accommodation costs for the site inspection)

(b) As a comparison, BPOM Regulation 24 only requires the Applicant to present documents of the Principal Manufacturer to BPOM, but does not strictly require a site visit to the Manufacturing Facility of the

imported drugs to ensure CPOB compliance, which is typically located offshore. Based on BPOM Regulation 24, BPOM will conduct a site visit to the Manufacturing Facility of the imported drugs only if deemed necessary by BPOM (i.e., however, the timeline and method are unclear). On the other hand, BPOM Regulation 7 provides a specific guideline for the whole CPOB compliance assessment of offshore imported drugs Manufacturing Facilities, including the timeline and process for the site visit and when the site visit could be deemed as necessary.

Additional fees may be imposed to reimburse BPOM for the costs of the inspection of the Manufacturing Facility of the Principal Manufacturer.

Notable Provisions

We set out below some of the key provisions from BPOM Regulation 7 based on our review.

1. General Overview

Based on BPOM Regulation 7, the Manufacturing Facility of the Principal Manufacturer (i.e., in case of imported drugs) must comply with the CPOB requirements set out under BPOM Regulation 7 ("**Offshore CPOB Compliance**"), which is proven by BPOM's evaluation and approval of the same.

The Offshore CPOB Compliance is considered as part of the requirements that must be fulfilled in order for an Applicant to obtain a marketing authorization for imported drugs. The Offshore CPOB Compliance is also considered as part of the registration process to obtain the marketing authorization. In other words, it seems that the process in BPOM Regulation 7 will be an integral part of a marketing authorization registration process for imported drugs, and an Applicant cannot obtain the marketing authorization without securing BPOM's approval on the Offshore CPOB Compliance.

BPOM Regulation 7 does not specifically mention the exact timing of when the Applicant must apply for and obtain BPOM's approval on Offshore CPOB Compliance. However, from the way the regulation is drafted, it seems that the process can be done after the Applicant has submitted its application to become a holder of a marketing authorization for imported drugs (**read**: imported drugs registration).

2. BPOM's Evaluation on the Compliance of Offshore Manufacture Facility With CPOB Requirements

We set out below the general outline of the process to obtain BPOM's approval on the Offshore CPOB Compliance:

(a) Evaluation of imported drugs registration documents related to fulfillment of CPOB requirements

(b) Desktop Inspection

(c) Inspection of the Manufacturing Facility of the imported drugs (i.e., site inspection)

(d) Corrective Action and Preventive Action ("**CAPA**") evaluation as a result of inspection of the Manufacturing Facility of the imported drugs

**Notes*:

- *Desktop Inspection is an assessment of the implementation and fulfillment of CPOB requirement in the Manufacturing Facility of imported drugs, which is done through evaluation of the Principal Manufacturer's quality documents*
- *CAPA is an inspection result document which is submitted by the Applicant within the given time period.*

The Desktop Inspection and CAPA evaluation application are subject to fees, which is non-tax state revenue. This excludes transportation and accommodation fees for the BPOM officials to conduct the Inspection at the imported drugs Manufacturing Facility.

3. Re-Evaluation of CPOB Compliance

Principal Manufacturers of imported drugs that have already passed the Offshore CPOB Compliance could be re-evaluated by BPOM from time to time (i.e., BPOM will inspect their Manufacturing Facility) based on the following:

(a) surveillance based on a risk assessment

(b) alleged cases relating to quality, safety and efficacy of imported drugs

If the re-evaluation results in critical findings, the Applicants must submit the CAPA documents of their Principal Manufacturer to BPOM within 22 business days after the date of issuance of the result of the re-evaluation.

4. Effective Date and Transitional

BPOM Regulation 7 came into effect on 30 April 2019. Theoretically, Applicants are expected to comply with the requirements under BPOM Regulation 7 starting from 30 April 2019 onwards.

It is clear that new Applicants are bound to comply with BPOM Regulation 7. However, since there are no transitional provisions in BPOM Regulation 7, it remains to be seen how existing CPOB certificate holders would be affected.

www.hhp.co.id

HHP Law Firm
Pacific Century Place, Level 35
Sudirman Central Business District Lot. 10
Jl. Jenderal Sudirman Kav. 52-53
Jakarta 12190
Indonesia

Tel: +62 21 2960 8888
Fax: +62 21 2960 8999