



Client Alert

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New Drug Management Regulations

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New Drug Management Regulations

In March 2026, the Indonesian Drug and Food Supervisory Agency (*Badan Pengawas Obat dan Makanan* - "BPOM") issued Regulation of BPOM No. 5 of 2026 regarding the Supervision of the Management of Drug and Drug Substance at Pharmaceutical Service Facility and Other Facility ("**RB POM 5/2026**"), which came into effect on 6 April 2026.

By the enactment of RB POM 5/2026, the previous regulation, i.e., Regulation of BPOM No. 24 of 2021 regarding the Supervision of the Management of Drug, Drug Substance, Narcotic, Psychotropic, and Pharmaceutical Precursor at Pharmaceutical Service Facility ("**RB POM 24/2021**"), is revoked and declared no longer valid.

RB POM 5/2026 amends several provisions previously regulated under RB POM 24/2021, including those relating to the parties that may conduct drug management activity, the classification of drug, as well as the supervision and authority provisions in drug management.

The following are several key points regarding RB POM 5/2026:

1. Adjustment to the Scope of Drug

Previously, RB POM 24/2021 only covered provisions on the management of drug, drug substance, narcotic, psychotropic, and pharmaceutical precursor. RB POM 5/2026 now expands and classifies the scope of drug management as follows:

- a. drug that may be obtained with a prescription, which include narcotic, psychotropic, and prescription-only/potent drug (*obat keras*); and/or
- b. drug that may be obtained without a prescription, which include limited over-the-counter drug (*obat bebas terbatas*) and over-the-counter drug (*obat bebas*).

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2. Adjustment to Drug Management Provisions

Previously, RBPOM 24/2021 provided that drug management could only be conducted at pharmaceutical service facility, namely pharmacy, hospital pharmacy installation, and public health centers (*pusat kesehatan masyarakat* - "puskesmas"). Under RBPOM 5/2026, drug management may be conducted by:

- a. Pharmaceutical service facility (*fasilitas pelayanan kefarmasian*), consisting of hospital pharmacy installation, puskesmas, pharmacy installation, clinic pharmacy installation, and pharmacy.

Drug management at pharmaceutical service facility is conducted in the form of procurement (*pengadaan*), receipt (*penerimaan*), storing (*penyimpanan*), dispensing (*penyerahan*), returning (*pengembalian*), destruction (*pemusnahan*), reporting (*pelaporan*), and compounding (*peracikan*). Pharmaceutical service facility other than hospital pharmacy installation is prohibited from conducting drug production activity.

- b. Other facility (*fasilitas lain*), consisting of drugstore, hypermarket, supermarket, and minimarket.

Drug management at other facility is conducted in the same forms as drug management at pharmaceutical service facility, except for compounding activity. Also, other facility may only manage over-the-counter drug and limited over-the-counter drug.

In addition, other facility is prohibited from conducting:

- i. the management of narcotic, psychotropic, drug substance, and/or prescription-only/potent drug; and/or
- ii. compounding and repackaging (*pengemasan ulang*) activities for drug, narcotic, psychotropic, and/or pharmaceutical precursor.

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3. Person in Charge

RB POM 5/2026 provides that each drug management activity must have a person in charge, subject to the following provisions:

a. Pharmaceutical Service Facility

All drug management activities at pharmaceutical service facility are under the responsibility of the pharmacist (*apoteker*) in charge, who may be assisted by other pharmaceutical personnel. The pharmacist in charge and such other pharmaceutical personnel must hold a valid practice license.

b. Other Facility in the Form of Drugstore

All drug management activities at other facility in the form of drugstore are under the responsibility of pharmaceutical vocational personnel (*tenaga vokasi farmasi*). Such pharmaceutical vocational personnel must hold a valid practice license.

c. Other Facility in the Form of Hypermarket, Supermarket, and Minimarket

All drug management activities at other facility in the form of hypermarket, supermarket, and minimarket are under the responsibility of health support or auxiliary personnel (*tenaga pendukung atau penunjang kesehatan*). Such health support or auxiliary personnel must hold a training certificate related to drug management activities.

4. Sanction

RB POM 5/2026 regulates the imposition of sanctions for violations of the provisions stipulated therein, including any failure or non-compliance by pharmaceutical service facilities and other facilities to appoint the appropriate person in charge.

Such sanctions are administrative sanctions, in the form of warnings, stern warnings, and/or temporary suspension of activities, imposed by the Head of BPOM. In addition, the Head of BPOM may also submit a recommendation to the ministry/institution issuing the business license for the revocation of the business license of the relevant pharmaceutical service facility or other facility.

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Takeaways

RB POM 5/2026 introduces an important change by expanding the parties that may conduct drug management activities. In addition to pharmaceutical service facility, other facility such as drugstore, hypermarket, supermarket, and minimarket may now also conduct drug management activities, provided that such activities are limited to over-the-counter drug and limited over-the-counter drug.

In light of this change, retail businesses that manage or intend to manage drug should ensure that their business activities comply with the restrictions on the types of drug, forms of management activities, and requirements for the person in charge as regulated under RB POM 5/2026.

This Client Alert is provided for general information purposes only and does not constitute legal advice. Please contact us should you require further information or assistance regarding drug management regulations or related matters.

For further information regarding the above Client Alert and future updates, please contact our counselors at:

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