PwC Indonesia Legal Alert

June 2026 / No. 63

BPOM Regulation No. 5 of 2026 on the Supervision of the Management of Drugs and Medicinal Substances

I. Background

The Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan*/**BPOM**) has issued BPOM Regulation No. 5 of 2026 on the Supervision of the Management of Drugs and Medical Substances in Pharmacy Services Facilities and Other Facilities (**BPOM Reg. 5/2026**). The regulation was stipulated on 13 March 2026 and became force on 6 April 2026.

BPOM Reg. 5/2026 was issued to ensure better protection of public health by strengthening supervision over the management of drugs and medicinal substances, in response to developments in the legal framework under Law No. 17 of 2023 on Health and its implementing regulation Government Regulation No. 28 of 2024.

II. Key changes introduced under BPOM Reg. 5/2026

Compared to BPOM Reg. 24/2021, BPOM Reg. 5/2026 introduces several materials shifts in scope and regulatory approach, including the following key changes:

a. Broader scope of supervision

BPOM Reg. 5/2026 expands and clarifies supervision not only over pharmacy services facilities, but also over other facilities involved in the management of drugs and medicinal substances. This reflects BPOM's intention to cover non-traditional or non-pharmacy settings where drugs may be managed, stored, or handled, as contemplated under the new health regulatory framework.

b. Integration with the new health regulatory framework

The regulation explicitly implements Article 417(4) of Government Regulation No. 28 of 2024, which serves as the main implementing regulation of Law No. 17 of 2023 on Health. This alignment signals a shift towards a more integrated supervision regime across healthcare providers and facilities.

c. Refined focus on drug and medicinal substance management

Unlike BPOM Reg. 24/2021, which also regulated narcotics, psychotropics, and pharmaceutical precursors, BPOM Reg. 5/2026 refocuses supervision specifically on drugs and medicinal substances. Supervision of other controlled substances is expected to be governed under separate or sector-specific instruments.

d. Strengthened supervisory authority

BPOM Reg. 5/2026 reinforces BPOM's authority over post-distribution supervision, including oversight on compliance with safety, efficacy/benefit, and quality standards throughout the management lifecycle of drugs and medicinal substances.

III. Key implications for businesses

BPOM Reg. 5/2026 has direct implications for a wide range of stakeholders in the pharmaceutical and healthcare value chain, including:

- Pharmacy service providers and healthcare facilities managing drugs and medicinal substances
- Hospitals, clinics, and other healthcare facilities that store, distribute, or administer drugs
- Business actors involved in downstream handling and storage of drugs, even if not operating as licensed pharmacies
- Pharmaceutical companies and distributors, particularly in relation to post-market control and downstream compliance

The broadened scope means that facilities previously outside BPOM's routine pharmaceutical supervision may now fall under regulatory scrutiny, increasing compliance exposure.

IV. Conclusions

BPOM Reg. 5/2026 marks a significant recalibration of BPOM's supervisory regime over drug and medicinal substance management, shifting towards broader coverage and closer integration with Indonesia's new health law framework. Stakeholders are encouraged to proactively assess their compliance posture to mitigate regulatory, operational, and reputational risks.

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