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I. Background

The National Agency of Drug and Food Control (*Badan Pengawas Obat dan Makanan*/BPOM) has issued BPOM Regulation No. 4 of 2026 on the Implementation of Pharmacovigilance (**BPOM Reg. 4/2026**). This regulation was stipulated on 23 February 2026 and came into force on 26 February 2026.

BPOM Reg. 4/2026 was introduced to replace the prior pharmacovigilance framework because BPOM considered the previous rule no longer aligned with legal needs and scientific/technological developments. It also expressly serves as an implementing regulation under Government Regulation No. 28 of 2024 (implementing Law No. 17 of 2023 on Health)—specifically referencing the mandate in Article 410(1) of GR 28/2024. Marketing authorisation holders are required to align/adjust with BPOM Reg. 4/2026 within 12 months from promulgation of this regulation.

II. Key Changes Introduced by BPOM Reg. 4/2026

a. Clearer (and broader) pharmacovigilance scope across product lifecycle and real-world use

BPOM Reg. 4/2026 defines pharmacovigilance as end-to-end activities covering detection, assessment, understanding, communication, control, and prevention of adverse effects or other issues related to the use of products, including drugs, natural products, supplements, cosmetics, and quasi drugs.

For drugs specifically, the regulation expands the use-scenarios that must be monitored beyond “approved label” use, expressly covering:

- Use under approved marketing authorisation, including emergency use authorisation
- Off-label use, misuse/abuse, medication error, overdose, and lack of effectiveness

It also clarifies that pharmacovigilance is not limited to safety: it may include efficacy-related changes affecting the benefit-risk profile and quality aspects that impact safety and effectiveness.

b. Explicit reporting timelines and “nil reporting” obligation

BPOM Reg. 4/2026 introduces (or reaffirms with specificity) several operational timelines, for example (i) related to serious undesired event and drugs side effect reports within 15 calendar days from receipt of information, and (ii) related to non-serious undesired event and drugs side effect reports within 90 calendar days from receipt of information.

For post-marketing periodic safety reports, the regulation specifies a staged frequency:

- Every six months during the first two years after marketing authorisation
- Annually from years three to five.

III. Conclusions

Given the 12-month adjustment requirement, clients should treat BPOM Reg. 4/2026 as an immediate compliance programme trigger. BPOM evaluation outcomes can escalate from product information change requests to restrictions, freezing, revocation, and recalls (through separate recall rules). This increases business continuity and reputational risk. BPOM Reg. 4/2026 references detailed implementation guidance in *Lampiran* I–III, which should be reviewed alongside internal standard operating procedure (SOP) drafting and compliance design.

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