

REPORT TO THE PHARMACOVIGILANCE TEAM

All employees must report medicine safety information | BPOM Regulation No. 4 of 2026 | SOP 02QA-002-036

WHAT MUST BE REPORTED?

- ▶ Adverse events / side effects (AE/ADR)
- ▶ Medical complaints from patients, family, or healthcare professionals
- ▶ Use during pregnancy or breastfeeding
- ▶ Overdose, abuse, misuse, off-label use
- ▶ Medication errors
- ▶ Lack of therapeutic efficacy
- ▶ Quality complaints suspected to affect safety
- ▶ Safety information from media / social media
- ▶ Any safety signal or issue from any source

REPORT CATEGORIES

SERIOUS — report on the same day

Death • Life-threatening • Hospitalisation / prolonged stay
Permanent disability • Congenital anomaly • Other medically important events

NON-SERIOUS — still report (unexpected cases to BPOM ≤90 days)

Non-medical / technical complaints → report to QA (not PV)

REPORTING FLOW TO THE PHARMACOVIGILANCE TEAM



HOW TO REPORT & MINIMUM DATA TO RECORD

CONTACT THE PHARMACOVIGILANCE TEAM

Office hours
Tel: (022) 6868800

After hours / holidays
Mobile: 0821-2262-3862

Or report directly to
QA Staff / PV Team Member / PV Responsible Person

MINIMUM DATA TO RECORD

1. Patient name / initials (if available)
2. Product name & batch number (if known)
3. Complaint / symptoms experienced
4. Start and end date of the event
5. Reporter name & contact details
6. Date information was received
7. Photo / sample (if relevant)

DO NOT

- Delay reporting of serious cases
- Keep safety information to yourself
- Decide on your own that “this does not need reporting”
- Delete or alter original data
- Share patient identity with unauthorised persons

DO

- Contact the PV Team immediately
- Record data as accurately as possible
- Hand over photos/samples if available
- Protect patient and reporter confidentiality
- Follow further instructions from the PV Team

PHARMACOVIGILANCE = PATIENT SAFETY

All employees of PT Solas Langgeng Sejahtera

REPORT

- Medicine side effects
- Medical complaints
- Pregnancy / breastfeeding
- Overdose / misuse
- Medication error
- Lack of efficacy
- Media safety issues

SERIOUS?

- Death
- Life-threatening
- Hospitalisation
- Permanent disability
- Congenital anomaly
- → Report SAME DAY

HOW

- 1. Record minimum data
- 2. Contact the PV Team
- 3. Hand over info/sample
- Tel (022) 6868800
- Mobile 0821-2262-3862
- Keep confidentiality