



# Adverse events Understanding & Reporting



**Synokem Pharmaceutical Ltd.  
and its subsidiaries**  
(Synokem Lifesciences Ltd., Nitin Lifesciences Ltd.  
& Kemsyn Lifesciences Pvt. Ltd.)

# Learning Objectives

- ▶ Definition of pharmacovigilance
- ▶ Definition of Adverse Event
- ▶ Importance of Adverse Event Reporting
- ▶ Responsibility of Synokem employees in AE Reporting
- ▶ Where to report ?
- ▶ What to report ?



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# What is Pharmacovigilance

Science and activities relating to the detection, collation, assessment, understanding and prevention of Adverse Event (AE) or any other drug related problem.



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# What is Adverse Event (AE)

**An adverse event is any undesirable experience, associated with the use of a medicine/drug in a patient, which may or may not be associated with the drug.**

## **Example...**

- Medication related side effects . Any symptoms/ sign (e.g. Vomiting, allergy etc.)
- Abnormal laboratory findings ( abnormal blood test report)
- Medication error ( inappropriate medication use)
- Failure of therapy (lack of effect of drug)
- Overdose (taking more than the recommended dose)
- Misuse/ abuse ( taking more than recommended dose of certain cough syrups to get high)



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# What is Serious Adverse Event

**Serious adverse event is any untoward medical occurrence which results in:**

- ▶ **Death**
- ▶ **Life-threatening condition**
- ▶ **Hospitalization (initial or prolonged)**
- ▶ **Disability (persistent or significant disability or incapacity)**
- ▶ **Birth defect (congenital anomaly)**
- ▶ **Other important medical events as decided by physician**



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# What to report ?

Following key information to be collected/reported to Synokem PV Team:

1. Patient information: **only patient's initials** (e.g. If patient's name is Amit Prakash ; initials will be AP)
2. Name of **suspected drug manufactured by Synokem/Nitin Lifesciences or Marketed by Kemsyn Lifesciences Pvt Ltd.**
3. Adverse event description in brief as informed by patient
4. Name of reporter (if reporter is other than patient himself)



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# Where to report/communicate adverse event?

If you become aware of any adverse event associated with the use of medicines manufactured by Synokem/Nitin Lifesciences

Report such event to the Synokem's Pharmacovigilance department

**Akash Pandey (Pharmacovigilance Officer In charge)**

Email: [pv@synokempharma.com](mailto:pv@synokempharma.com)

[pv@kemsynlifesciences.com](mailto:pv@kemsynlifesciences.com)

Helpline No. +918929055915



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# Why reporting of Adverse event is important ?

All adverse events are analyzed to determine the cause i.e. whether the adverse event has happened due to the inherent nature of the drug or it is unrelated to drug or there is a product quality related issue.

Once causality is established, new adverse events/adverse drug reaction are included in product label or prescribing leaflet for information of physicians/patients to ensure patient safety

Therefore, it is our responsibility to report all adverse events/adverse drug reaction, (which we become aware of) associated with use of drug products



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# Drugs Safety and Monitoring

Our Company > Drugs Safety



प्रतिकूल घटना को हिंदी में पढ़ने के लिए यहां क्लिक करें

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**THANK YOU!**



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