

Orientation on Pharmacovigilance for MSR

1. Meaning of Pharmacovigilance

Pharmacovigilance refers to the **science and activities related to the detection, assessment, understanding, and prevention of adverse effects of medicines.**

👉 In simple words:

“It is the system of monitoring drug safety after it is used by patients.”

2. Importance of Pharmacovigilance

Pharmacovigilance is important because it:

- Ensures **patient safety**
- Detects **side effects (adverse drug reactions)**
- Prevents harmful consequences
- Improves **quality and safe use of medicines**
- Helps in taking regulatory decisions (ban, warning, etc.)

👉 Key idea:

“A medicine is safe only when continuously monitored.”

3. Role of MSR in Pharmacovigilance

Medical Sales Representatives (MSRs) play an important role because they:

- Stay in **regular contact with doctors and pharmacists**
- Receive **feedback about medicines**
- Can identify and report **adverse drug reactions (ADRs)**

Responsibilities of MSR:

- Collect information about side effects
 - Report it to the company immediately
 - Follow company guidelines
 - Never ignore safety-related information
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4. Following Legal and Company Guidelines

MSRs must:

- Follow **company policies and procedures**
- Comply with **government regulations**

- Avoid making false or misleading claims
- Maintain **ethical standards**

👉 Pharmacovigilance is legally required in the pharmaceutical industry.

5. Common Terms in Pharmacovigilance

A. Adverse Drug Reaction (ADR)

- Harmful or unintended reaction to a medicine

B. Side Effect

- Known secondary effect of a drug

C. Serious Adverse Event (SAE)

- Severe reaction like:
 - Death
 - Hospitalization
 - Disability

D. Signal

- New or unexpected safety information about a drug

👉 Understanding these terms helps MSRs communicate properly.

6. Pharmacovigilance Regulatory Authorities

National Level (India)

- **Pharmacovigilance Programme of India (PvPI)**
- Coordinated by **Indian Pharmacopoeia Commission (IPC)**

International Level

- **World Health Organization (WHO)**
- **Uppsala Monitoring Centre (UMC)**

👉 These bodies monitor drug safety globally and nationally.

7. Reporting Process (Basic Understanding)

When an MSR receives information about a side effect:

1. Collect Information

- Patient details (basic)

- Drug name
- Reaction observed

2. Record Properly

- Write accurate and complete details

3. Report to Company

- Submit through official channels

4. Forward to Authorities

- Company sends data to regulatory bodies

👉 Important:

Timely and accurate reporting is critical

8. Case Processing (Basic Idea)

A pharmacovigilance case includes:

- Patient information
- Drug details
- Description of reaction
- Outcome

MSR is not responsible for full analysis but must:

- Provide **correct initial information**
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9. Ethical Aspects

MSRs must ensure:

- Patient **privacy and confidentiality**
- Honest reporting
- No hiding of negative information

👉 Ethics is crucial because:

Incorrect reporting can risk lives

10. Practical Example

A doctor tells an MSR that a patient experienced severe rash after using a medicine:

- MSR notes all details

- Reports to company immediately
- Company investigates and informs authorities

👉 This helps prevent similar cases in future.

11. Skills Required

- Observation skills
- Communication skills
- Attention to detail
- Ethical responsibility