

Pharmacovigilance to Ensure Safety, Efficacy and Quality of Medicines

World statistics show that 5-10% of the hospital admissions are attributed to adverse drug reactions and 0.3% of adverse reactions are fatal in nature.

Pharmacovigilance refers to all observational, post-approval scientific and data gathering activities relating to the detection, assessment and understanding of adverse events with the goals of identifying and preventing these events to the extent possible.

- ✍ Every patient who is taking a drug of any system of medicine is at a higher risk of developing Adverse Drug Reaction (ADR)
- ✍ ADR increases not only human sufferings but also healthcare cost
- ✍ Medical professionals who are suspicious of ADR and report the same to Pharmacovigilance centre, promote the safe use of drug
- ✍ All ADR - suspicions should be informed to the Pharmacovigilance Centre, Department of Pharmacology, PGIMER, Chandigarh.
- ✍ Spontaneous reporting will generate our own data in India and at the same time it will be shared with WHO and it will become inevitable part of global database maintained by WHO at Uppsala Monitoring Centre, Sweden.

Why Pharmacovigilance?

The World Health Organization (WHO) defines pharmacovigilance as the science and activity relating to the detection, assessment, understanding and prevention of ADR or any other drug related problem. The most important task of the WHO International Drug Monitoring is to identify "signals" of drug safety problems as early as possible. A signal is defined by WHO as "reporting information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously". The national Pharmacovigilance Centers, appointed by various governments in 104 countries are required to collect and compile the spontaneously reported cases of suspected adverse drug reactions (ADRs) and forward them to the WHO. The case reports recorded in a common format, are processed thereafter and stored in the ADR database, Vigibase. The centre, which provides a unique source of International ADR information, maintains over 3.1 million case records and they have a proven use in the early detection of signals.

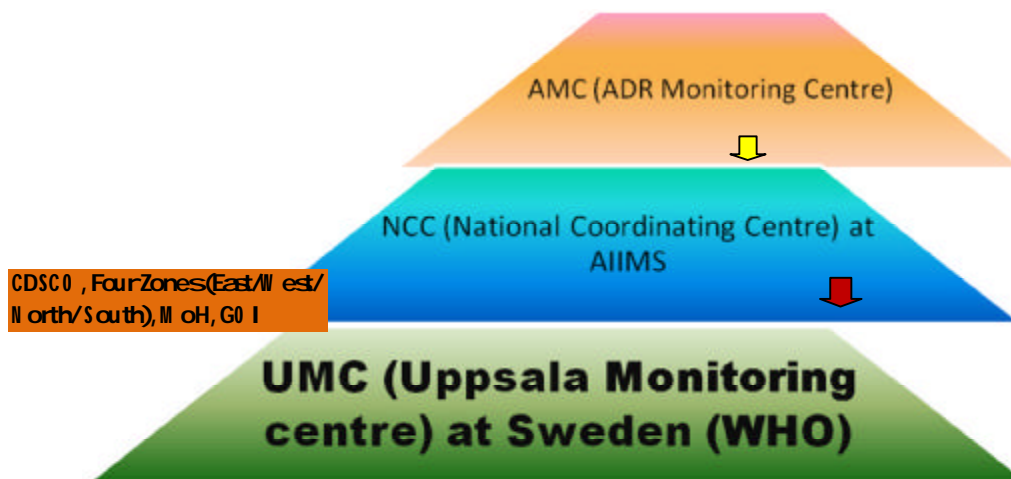
National Pharmacovigilance programme of India

Due to enormity of problem in India Central Drugs Standard Control Organization (CDSCO) has initiated a highly participative National Pharmacovigilance Programme to collate data, analyze it and use the inference to recommend regulatory interventions besides communicating the risks to healthcare professionals and the public. The milestones of the programme include:

- ✍ To monitor ADRs in Indian population.
- ✍ To create awareness amongst healthcare professionals about the importance of ADR reporting in India
- ✍ To monitor benefit-risk profile of medicines
- ✍ Communicate findings to all key stakeholders

- Generate independent, evidence based recommendations on the safety of medicines
- Support the CDSCO for formulating safety related regulatory decisions for medicines
- Create a national centre of excellence at par with global drug safety monitoring standards

The Programme is shaped as a three tier system :



It is envisaged that the AMC will collect their data and send them to the NCC, where it will be consolidated, analyzed and forwarded to the National Pharmacovigilance Advisory Committee which then makes appropriate recommendations to CDSCO, New Delhi for regulatory interventions. In parallel lines, NCC will submit the data to UMC to make it a part of global database, Vigibase.

PGIMER identified as AMC

PGIMER, Chandigarh being the tertiary care institute catering to the needs of most of the parts of north India has been identified as an AMC to collect the ADR and be a part of Pharmacovigilance Programme of India (PPI).

Pharmacovigilance at PGIMER

The Director and management of PGIMER have requested the support of the entire healthcare team to take part earnestly in this programme envisaged to ensure safe and rational use of medicine. Also, awareness programme has been organized by conducting the seminars amongst nurses, pharmacists and doctors of the institute and neighbouring hospitals in T, Chandigarh.

Spontaneous reporting: Principle- An undesirable medical event with drug exposure to be considered as suspected adverse drug reaction irrespective of its seriousness and severity. Spontaneous reporting of all the adverse events which may include suspected adverse drug reactions, lack of effect, dependence and abuse of allopathic medicines, traditional medicines and biological like vaccines have been started in a specific format.

The success of this programme calls for the proactive and dedicated participation of all the health care professionals including physicians, pharmacists and nurses in the Institute.

Programme Coordinators at PGIMER

Incharge: Dr. Bikash Medhi
Technical Associate: Mr. Rakesh Kumar

What needs to be reported?

Every ADR secondary to the use of any drug/ drugs should be reported to the Pharmacovigilance centre, Department of Pharmacology, Chandigarh. The reportable ADR may be known/expected or unknown/unexpected. Also, serious or non serious cases need to be reported to the pharmacovigilance centre. Conclusively, we can say that every adverse drug reaction secondary to any drug should be reported. ADR here is inclusive also of side effects of drug, extended pharmacological actions of the drug etc.

PGIMER Adverse Drug Reactions/Events Form :

ADR reporting form can be downloaded by clicking the link below :

<http://www.cdssn.in/pharmacovigilance.htm>

Downloaded ADR reporting form may be filled in and sent to:

Incharge of Pharmacovigilance Centre
Department of Pharmacology
Research block: B, Room No 4043, 4th floor
PGIMER, Chandigarh-160012

Contacting PGIMER Pharmacovigilance Centre

For more information, Contact us at

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ADVERSE EVENT

"Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment."(WHO)

ADVERSE DRUG REACTION(ADR)

"A response which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

SERIOUS ADVERSE DRUG REACTION

A serious adverse event or reaction is any untoward medical occurrence at any dose:

- ✗ results in death
- ✗ requires inpatient hospitalization or prolongation of existing hospitalization
- ✗ results in persistent or significant disability/incapacity
- ✗ is life-threatening
- ✗ causes congenital abnormality
- ✗ requires any intervention to prevent the occurrence of any of the above

SIDE EFFECT

Any unintended effect of a pharmaceutical product occurring at normal dosage which is related to the pharmacological properties of the drug.

SIGNAL

Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. The publication of a signal usually implies the need for some kind of review or action.

Frequently Asked questions (FAQ)

1. What is Pharmacovigilance?

According to WHO, Pharmacovigilance is the science and activities relating detection, assessment, understanding and prevention of adverse effects other drug-related problem.

2. What are the benefits of Pharmacovigilance programme?

Pharmacovigilance is becoming an important part of healthcare system as it deals with the patients' safety & efficacy of drug. Safe use of drug may be ensured by keeping watch over its safety profile amongst the patients consuming it.

3. *What kind of data will be managed in PV programme?*

Adverse drug reactions Reports pertaining to all drugs will be managed both in hard and soft copy at AMC and also in the vigibase, a database owned and managed by WHO.

4. *What is ADR?*

An effect or response of drugs which is noxious and unintended and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function." (WHO, 1972)

5. *Whether ADR and Adverse Event (AE) are the same?*

No, these term seem to be same but scientifically adverse event is defined as "any untoward medical occurrence that may present during treatment with a drug but which does not necessarily have a causal relationship with this treatment"(WHO) whereas in case of ADR, there must be a causal relationship between untoward medical occurrence and drug. Conclusively, we can say that every ADR is an AE but every AE not necessarily an ADR.

6. *What is the SERIOUS ADVERSE DRUG REACTION?*

A serious adverse event or reaction is any untoward effect of drugs, that at any dose which results into any of the given below:

- ✍ Death
- ✍ Inpatient hospitalization or prolongation of existing hospitalization
- ✍ Persistent or significant disability/incapacity
- ✍ Life-threatening condition
- ✍ Congenital abnormality
- ✍ Requirement of intervention to prevent permanent impairment/ damage

7. *What is unexpected adverse reaction?*

Occurrence of an adverse reaction, which is not consistent with labelling information or expected from characteristics of the drug regards to its nature or severity.

8. *What is the serious unexpected adverse drug reaction (SUADR)?*

A serious adverse drug reaction (SUADR) whose nature, severity or frequency is not identified previously in the risk information provided to the clinical investigator's brochure (CIB) or on the drug label.

9. *What is spontaneous reporting?*

This is the reporting by healthcare professionals (and in some countries, patients, relatives and others) "spontaneously" of their suspicion of an adverse reaction having occurred. The reporting might be directly to the regulatory authority or it could be made to company marketing the product.

10. *Where is the ADR reporting form available?*

Hard copy of blank ADR reporting form can be obtained from "Pharmacovigilance Centre, Department of Pharmacology, PGIMER, Chandigarh" and it can also be downloaded from the following link:

<http://www.cdsc.nic.in/pharmacovigilance.htm>

11. What would be the fate of so collected data through spontaneous reports?

ADR Reports collected at Pharmacovigilance centre will be analyzed for their causality assessment and validity and thereafter these reports will be entered into Vigiflow to channelize the reports to Vigibase which is a global database of ADR's which will help in signal generation.

12. What is periodic safety update reports (PSURs)?

After getting the approval of new drug, pharmaceutical companies are supposed to submit the safety reports of their product to the regulatory authority. This is called Periodic safety update report. This is a very important tool of pharmacovigilance to ascertain the safety of drug.



Spontaneous ADR Reporting Information

Pharmacovigilance centre, Department of Pharmacology,
4th Floor, Research Block: B, PGIMER, Chandigarh

Name:

Age/Sex:

Contact number:

Email:

Causative Drug information (name/dose/route):

Adverse Drug Reaction (ADR) occurred:

Treatment duration (Date of start and last dose used):

Other drug (s) used/or continued:

Detail of Reporter

Name:

Occupation:

Age/Sex:

For any query contact to:

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