Information for healthcare professionals

1. Terms and Definitions:-

1.1 Pharmacovigilance (PV) is the science & activities which is related to the detection, assessment, understanding & prevention of adverse event (AE)/Adverse drug reaction (ADR) or any other medicine/vaccine related problems.

- It is used to ensure safety of medicine/vaccine & its uses throughout the lifecycle.
- Basically it's an arm of patient care.

1.2 The aim of pharmacovigilance

Detect & assess new information related to risk and benefits of medicine/vaccine. Early detection from identified risks as defined by regulation and safety guidelines.

1.3 Biological products/Vaccine

Biological products/ Vaccine can be composed of sugars, proteins, or nucleic acids or a combination of these substances. They may also be living entities, such as cells and tissues. Biologics are made from a variety of natural resources- human, animals and microorganisms. It is used for the prevention or treatment of diseases.

1.4 Adverse drug Reaction- A response which is noxious and unintended occurs at doses having a casual relationship with dose administered, used in human for diagnosis and modification of physiological function.

1.5Adverse Event- Any untoward response which is present during treatment with vaccine/medicine does not necessarily have casual relationship with dose administered.

1.6 Serious Adverse drug Reaction- An untoward medical occurrence at any dose that leads to Results in death, Life threatening, Results in permanent disability/damage, Requires hospitalization.

1.7 Suspected Serious Adverse Reaction- A medical occurrence which is serious, have consistency with the domestic labeling & characteristic vaccine/medicine.

1.8 Unexpected Serious Adverse Reaction- A medical occurrence which is serious, have no any consistency with the domestic labeling & characteristic vaccine/medicine

2. Minimum Criteria for Valid Case

- An Identifiable Reporter

- An Identifiable Patient
- A Suspect Product
- An Adverse Drug Event

3. Responsibility of Pharmacovigilance Department in Bio-Med

- Timely Collection of Data
- Data Entry
- Case processing
- Data Analysis
- Submission of report
- Response

4. People Involves During Safety Data Reporting

Healthcare professionals-	**Non-healthcare professionals-**
Clinicians	Patient
Marketing Executive	Relative
Doctor/Nurses	Friend etc

5. The legal procedure for Pharmacovigilance In Bio-Med

- Active Pharmacovigilance
- Passive Pharmacovigilance

Active Pharmacovigilance-

Active pharmacovigilance is the follow-up of patients treated/vaccinated with medicinal/biological product through risk management plan.

Channels of reporting AEFI: It is essential that the medical executives identify and report all serious and non – serious adverse events.

All the serious events shall be reported within 24 hours of events.

All side effects are firstly monitored for about 7 days & at the end of the day they are reported by medical executive after the collection of information. If anyone has suffering/suffered from side effect then they can submit the report with the help of our online format submission procedure and the help of telephonic communication. These are some side effects related to the medicine/vaccine, Pain, Pruritus/ Itching, Fever, Redness, Headache.

If there is no any serious or non serious Events or reaction are not observed the report shall be submitted monthly through marketing executive according to their location's survey.

Passive Pharmacovigilance-

Passive Pharmacovigilance is a spontaneous report plays an important role in the identification of safety signals once the drug is marketed.

If any spontaneous report is observed by the Health care professionals or consumers, Pharmacist, Health care community member the report can be submitted to us by our 24 hour telephone Number or through email mentioned on our website.