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Short Communication
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# Need For Pharmacovigilance

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## Short Communication

The causes of the health damage due to drugs use are

i. Adulteration or inadequate production

ii. Misuse or abuse of drugs

iii. Human error such as prescription error or unknown interactions or contra-indications

iv. Inherent safety issues of drugs

Pharmacovigilance is the pharmacological science that deals with collection, detection, assessment, monitoring and prevention of adverse reactions with pharmaceutical products. With the advent of newer drugs by the day the monitoring of adverse drug reactions due to these drugs is absolutely essential. An adverse drug reaction is defined as an effect that is noxious and unintended and which occurs at doses used in man for the prophylaxis, diagnosis or therapy of disease or for the modification of physiological function (Table 1).

In a tertiary care hospital in France, in a study carried out, one out of every 30 urgent admissions of patients aged more than 65 years was adverse drug reaction- related. Nearly 50% of the adverse drug reactions are preventable. Pharmacovigilance is essential for the safety of patients and also for the rational use of medicines. The percentage of hospital admissions due to drug related events in some countries is about or more than 10%.The people involved in Adverse Drug Reaction reporting are the Physicians, Pharmacists, Pharmaceutical companies. Even patients are encouraged to report side effects. Pharmacovigilance will improve patient care, public health in relation to use of medicines, help in risk benefit assessment of medicines and will promote effective communication to health professionals and the public about drugs. Once the data about the adverse reaction is received there are four tasks to carry out which are Causality Assessment, Interpretation, Analysis and Actions. Adverse Drug Reactions could be Non-immunological, Immunological or miscellaneous like the Jarisch Herxheimer Reaction. There are several methods of Pharmacovigilance like Individual Case Safety Reports, Spontaneous Reporting, Cohort Event Monitoring Periodic Safety Update Reports, Longitudinal Electronic Patient Records and Record Linkage. We have The Naranjo Algorithm for Causality Assessment and the Hartwig and Seigels Scale for Severity assessment .The Hartwig and Seigel's Scale is:

**Mild ADRs** Are self-limiting and do not contribute to increase in hospital stay

**Moderate ADRs** Require therapeutic intervention or hospital admission or prolonged hospital

**Table 1:** The following drugs have been withdrawn from the market due to adverse reactions in the last few years.

| Drug | Year | Reason |
|---|---|---|
| Astemizole | 1999 | Cardiac arrhythmias |
| Grepafloxacin | 1999 | Cardiac repolarisation |
| Phenylporpanolamine | 2000 | Stroke |
| Rapacuronium | 2001 | Bronchospasm |
| Troglitazone | 2004 | Heart attack and stroke |
| Rofecoxib,Valdecoxib | 2004 | Myocardial infarction and stroke |
| Alatrafloxacin | 2006 | Liver toxicity |
| Gatifloxacin | 2006 | Risk of Dysglycaemia |
| Tegaserod | 2007 | Heart attack |
| Efa;lizumab | 2009 | Leukoencephalopathy |
| Propoxyphene | 2010 | Risk of heart attack |



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stay for at least one day.

**Severe ADRs** Life threatening, requiring intensive medical care or produce disability or lead to death.

A serious adverse event should be reported within 15 working days to the local Pharmacovigilance centre whereas if it is not serious it should be reported within 30 days.

**Application of Pharmacovigilance**

1. in national drug policy

2. in regulation of medicines

3. in clinical practice and

4. in disease control public health programs.

Thus there is a dire need for Pharmacovigilance as more and more drugs are being made available to treat various conditions.