Pharmacovigilance

Day & Date:	Saturday, 7th May 2016
Time:	12:15 pm to 1:15 pm
Venue:	Convention Hall, Symbiosis International University, Lavale campus, Pune
Speaker:	Dr. Ganesh Uchit
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The master class was conducted by Dr. Ganesh Uchit on pharmacovigilance. The introduction was about how important drug safety is needed for the healthcare industry. There were a few examples provided to the delegates regarding the safety of any product. The important factor is that pharmacovigilance plays an important role in building the reputation of any organization. Any mishap becomes viral therefore safety is needed while producing a drug.

Detection, assessment, understanding and prevention of any adverse event or other medicine – related problem is known as pharmacovigilance. It is ideal to report any reaction to the drug. This is usually not practised in India and that is why there is under- reporting in India.
There was a case study presented regarding whether a drug has an **adverse effect** or not.
Types of ADR that were presented were:

- Serious ADR – Morbidity and fatality
- Severe ADR - Mild reaction
- Unexpected - Both positive or negative aspects are found , not found in labels

Why pharmacovigilance?
Because there are new drugs into the market, Pre marketing safety, whether the animal experiments are relevant or not and to understand if clinical trials are complete or not.

Establishment treatment like safety, cost, and efficacy are the interest of the community. Therefore with the pharmacovigilance practice we can understand whether the drug is safe or not ’

Facts about safety of medicines

- Approximately 5.3% of hospital admissions associated with ADRs
- Higher rates found in elderly patients who are likely to receive multiple medications
- Nearly 10;-20% of acute geriatric hospital admissions are related to ADRS
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ADR features in top ten causes of mortality but the eye opener here is that these are preventable. This is why pharmacovigilance needs to be implemented.

The next topic was **Perception of Risk**, intuitive estimate of Risk. This perception of risk with regards to ADRs is not consistent. Media plays an Important role – a two edged sword. Important of Choice – Risk communication is about choice – a shared decision making between both the patient and the doctor. Many factors which appear irrational will influence the choices of the patient.

The iceberg phenomena was dealt with respect to reported adverse events is the tip of the iceberg and bigger part consists of the events that went un-reported. Feedback & Publication rewards, Training and education and Awareness are the three key areas which help in induce good reporting practice. International organizations like WHO has a drug monitoring programme. The output of these programme is sending feedback to the respective countries. India is also a part of the programme.

The limitations of Clinical Study data was discussed. The factors were number of patients, duration, population, medication and illness, dose, conditions. We need to observe a large number of patients to find small adverse effects. That’s the reason it is been practised in the medical field.

India is said to have a good system right now regarding drug safety and the scope to develop more is found.

Pharmacovigilance Programme of India (PVPI) was launched in India 2010. Its goal was to ensure the benefits the use of the medicine such that it outweighs the side effects that any drug possess. These Programme is presented to the society in their respective language so that the reporting of any adverse effects can be reported.

Another complexity present in India is the multimodal practise like modern, medicine, Ayurveda etc. so the implementation of PV in not quite possible in all the practises. The session was concluded on how to widen the scope of pharmacovigilance. It included the reduction of medical errors and invading the herbal medicine domain so that their safety can be evaluated.

Pharmacovigilance should be an information tool for the patient to make their decision.