

**Report on  
On  
Drug Safety: Pharmacovigilance / Haemovigilance / Vaccine vigilance**

Date: 9<sup>th</sup> March 2019

Venue: Seminar Hall, JSS CoP, Ooty

Program Organized By:  
Dept. of Pharmacy Practice  
JSS College of Pharmacy  
Ooty

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One Day Workshop on Drug Safety was organized by the Dept. of Pharmacy Practice on 11<sup>th</sup> March 2019. About 100 participants participated in the program. This program is aimed to develop the understanding of the pharmacy students in drug safety and its regulatory requirements in India.

Pharmacovigilance (PV or PhV), also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products. As such, pharmacovigilance heavily focuses on adverse drug reactions, or ADRs, which are defined as any response to a drug which is noxious and unintended, including lack of efficacy. Medication errors such as overdose, and misuse and abuse of a drug as well as drug exposure during pregnancy and breastfeeding, are also of interest, even without an adverse event, because they may result in an adverse drug reaction.

Haemovigilance is now well-recognized as an integral part of quality management system in a blood programme. The goal of Haemovigilance is to identify and prevent occurrence/recurrence of transfusion related unwanted events, in order to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the blood transfusion chain from donors to recipients. Haemovigilance is an important tool not only to analyze blood transfusion incidents, but also to measure the effects of new processes or corrective actions at a national level. The avoidable transfusion related adverse events remain a serious cause of injury and death. This assessment of transfusion performance thus takes into consideration the safety of the product, the appropriateness of the clinical indication and the effectiveness of the transfusion process.

Vaccines pharmacovigilance is of utmost importance and necessary today, as millions of subjects are being immunized globally in the platinum era of vaccines with the introduction of 13 new vaccines in this century. New vaccines with safety profiles emanating from clinical trials on a small sample size would need active monitoring globally to assess newer reactions post-licensure. Vaccines differ from drugs as they are preventive while drugs are curative.

