Need for Study

3. NEED FOR STUDY

India is a vast country and there is surfeit of drug brands with more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India has more than half a million qualified doctors and 15,000 hospitals having bed strength of about 6,24,000. It is the fourth largest producer of pharmaceuticals and emerging as an important clinical trial hub in the world [118]. Many new drugs are being introduced in our country; therefore, there is a need for a vibrant pharmacovigilance system in the country to protect the population from the potential harm that may be caused by some of these new drugs.

As per the National Pharmacovigilance programme, the effectiveness of a national PMS programme is directly dependent on the active participation of HCPs and patients as they are in the best position to report any suspected ADRs observed in their everyday patient care. Moreover, hospitals need to develop an effective way to identify such events that do cause harm to patients.

Furthermore, the identification of drug safety issues in patients with complex diseases and extensive comorbidities is therefore particularly challenging. Dialysis patients those with ESRD and often other comorbidities such as diabetes, hypertension, and cardiovascular disease - are a population with significant treatment challenges. Patients undergoes dialysis using dialyzers vis-a-bis receive a range of pharmaceutical agents as part of dialysis itself (e.g., HD solutions) [75]. Many of the pharmaceutical agents used to treat these patients have been developed in populations without these complications and, therefore, an extensive knowledge of potential problems and contraindications in the dialysis population is lacking. It is

important that the nephrology community understands the concept of pharmacovigilance. Health care professionals and providers, pharmaceutical companies, global regulatory agencies, and the patients themselves all play unique and critical roles in this process. Thus, it is important to conduct the safety surveillance of ADRs in patients on haemodialysis and thereby improving the existing pharmacovigilance practices.