International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

Pharmacovigilance: Past, Present Status, Future Perspective

Rajesh B. Jadhav[1], Vaishali R. Salunke[2]

[1, 2]Raosaheb Patil Danve College of Pharmacy, Badnapur, Dr. Babasaheb Ambedkar Technological University Lonere, Raigad, M.S., India

Abstract: ***Pharmacovigilance is a science which deals with identification, understanding, evaluation and prevention of adverse effect, experienced after the medicine. Particularly long-term and short-term adverse effect of medicine. The main issue is raised about the challenge due to the fact that Indian Helathcare professional have no comprehensive adverse drugs effect. Monitoring system are unaware of reporting system. The Uppsala monitoring centre, our nation has almost little commitment to the database. The main aim of Pharmacovigilance are to improve the care and safety of patient with regard to medicines and medical products and also contribution in the evaluation of medicines advantages, effectiveness, harm and danger to promise their efficient use, safe to promote indulgent education and clinical formation and there efficient, communication. The main aim of pharmacovigilance program are patient safety, patient care, and monitoring of negative of negative medication reaction. There is a need for additional clinical preliminary exam and clinical assessment in India to accurately practice pharmacovigilance. This review gives a systematic review of pharmacovigilance (PV) in India from its origin to its current scenario and also discuss the various strategies, proposal and prospects to build, maintain and implement a Pharmacovigilance system for India in coming year.***

Keyword: Pharmacovigilace, Adverse drugs effect, Uppsala monitoring centre, PvPI program, Central Drugs Standard Organization

1. Introduction

No drugs is safe! Any drugs, no matter how common its clinical uses have potential to cause harm. According to WHO Pharmacovigilance has been defined as the science and activities relating to the detection, assessment, understanding, & prevention of the adverse drugs reaction or any long terms and short terms medicine related problem. Pharmacovigilance the main goals are to enhance patient care and safety in connection to the use of medicine and all medical as well as Paramedical treatment and also improved public health & safety about the uses of medicine[1].

The Pharmacovigilance word comes from the combination of two Greek words i.e., 'Pharmakon' means "drugs"-The substance which prevent, diagnosis, and treatment of disease and 'Vigilance' means "Keep Watching"- to keep an eye on something it's mean to keep watching the Activity/ Effect of a drugs. It includes study of drugs, its adverse effect and unwanted effect after launching[2]. As such Pharmacovigilance heavily focuses on Adverse drugs Reaction or ADRs. Which are defined as any response to a drug that is noxious and unintended, including lack of efficacy[3-4]. Before a product is marketed, the experience of its safety and efficacy is limited by the patient number and duration of trials as well as by the highly controlled condition in which clinical trials one conducted[3].The diagrammatic representation of the Pharmacovigilance (Fig.1)

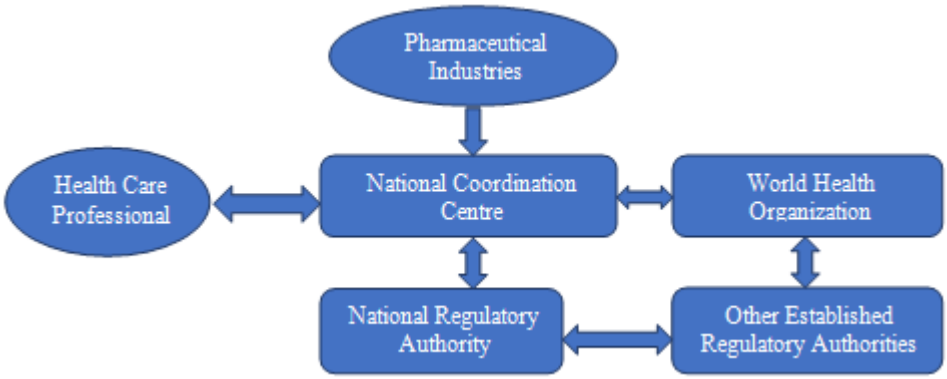

Figure 1: The diagrammatic representation of the Pharmacovigilance

Figure 2: The different pharmacovigilance service

History of Pharmacovigilance

Cloud Bernard, a great pharmacologist, stated that "Everything is poisonous, nothing is poisonous," It mean that it depends upon the dose of the drugs whether it will act as a medicine or poisons. That's why no any drug is safe or no drug is poisons.The history of pharmacovigilance stated 175 years ago. On Jan 29, 1848. When a young girl its name Hannah Greener from the north of England died after Receiving Chloroform as a anesthetic before removal of an infected toenail. Chloroform had discoveredby Sir James Simpson. Chloroform was a safer and powerful anesthetic, and he had initiate it in clinical practice. The causes of Hannah's death. Was examination to understand what happened to Hannah, but it was impossible to analyze what killed her, probably she died of pulmonary aspiration or a lethal arrhythmia[5].The US. Federal Food and Drugs Act was formed on June 30,1996, and it established that drugs must be pure and free of any contamination. Moreover, in 1911, this organization forbade false therapeutic indications of drugs[6].In 1937, there were 107 deaths in the USA, by reason of the use of sulfanilamide elixir, containing diethyl glycol as the solvent. This solvent was manufactory companies were not mindful about its toxicity at the time[7]. In 1938, Douthwaite supposed that acetylsalicylic (ASA) could cause melena[8].

In 1961, a big change of European Pharmacovigilance happened the tragedy of Thalidomide. Dr. McBride, an Australian doctor, wrote a letter to the editor of the Lancet Journal, in which he recommended a connection between congenital malformation of babies and thalidomide. Thalidomide was initial marketed within the late 1950s as a sedative and was used in the treatment of nausea in pregnant women. Inside some years of the widespread use of sedative-hypnotic in Europe, Australia, and Japan, about 10,000 kids were born with phocomelia, resulting in the ban of thalidomide in most countries in 1961. Some countries continued to supply access to thalidomide for a couple of years then forth Additionally to limb reduction anomalies, different effects later attributed to thalidomide involved congenital heart disease, malformations of the inside and outside ear, and ocular abnormalities.The sedative-hypnotic tragedy was averted within the United States as a result of the hold on its approval by Dr Frances Kelsey of the U.S. Food and Drug Administration, who was recognized by President John F. Kennedy as a recipient of the Gold Medal Award for Distinguished Civilian Service. Dr Kelsey's call to carry the approval of thalidomide was not because of the birth defects, that had not nevertheless been attributed to thalidomide, however as a result of her issues concerning peripheral neuropathy (sometimes irreversible) within the patient and therefore the potential effects a biologically active drug may have once treatment of pregnant ladies. The thalidomide tragedy conjointly brought into sharp focus the importance of rigorous and relevant testing of prescribed drugs before their introduction into the marketplace. Dr Kelsey was awarded associate degree unearned membership to the Society of Toxicology in celebration of its fiftieth day in 2011[9].

In the 1950s, scientists failed to apprehend that the results of a drug might be passed through the placental barrier and damage a vertebrate within the female internal reproductive organ, therefore the use of medications throughout physiological condition wasn't strictly controlled. And within the case of thalidomide, no tests were done involving pregnant women. As the drug was listed beneath such a large amount of totally different names in 49 countries, it

took 5 years for the affiliation between thalidomide taken by pregnant women and the impact on their children to be created. A UK Government warning wasn't issued till 1962. One reason why researchers and doctors were slow to form this affiliation was thanks to the big selection of changes to vertebrate development. Limbs, internal organs including the brain, eyesight and hearing might all be affected. Later, they found that the impact on development was joined to once throughout pregnancy the drug was taken, and effects only occurred between 20 and 37 days after conception. After that, thalidomide had no effect on the fetus. Another reason why it took so long to ascertain the link to thalidomide was that a number of the injury caused by the drug was terribly the same as bound genetic conditions that have effect the upper or lower limbs[10,11,12].

Sulfanilamide, is a medication used to treat streptococcal infections in tablet and powder form. Based on demand in the liquid dosage form of Sulfanilamide, the company prepared the Sulfanilamide elixir using diethylene glycol as solvent media. The Elixir Sulfanilamide was prescribed for patients with throat infections after a small laboratory test inclusive of taste, color, odor, and and not tested for its safety in any preclinical or clinical trials. Patients treated with Elixir Sulfanilamide for sore throat, many of them were children and produced severe poisoning effects. They were not well for about three weeks with symptoms such as severe abdominal pain, nausea, vomiting, stupor, dysuria, and convulsions. They suffered intense and unrelenting pain. At the time there was no known antidote or treatment, hence more than 100 people died[13].

Following are chronological sequences of how the network, which was initially a trial project in 10 nations with established national reporting procedures for ADRs, has grown dramatically as other nations around the world have evolved[14,15,16].

Year	Drugs	Toxicity
1937	Elixir Sulfanilamide	Mass poisoning
1950	Chloramphenicol	Aplastic Anemia
1961	Thalidomide	Phocomelia
1970	Clioquinol	SMON
1970	Diethylstilbestrol	Adenocarcinoma of the cervix
1975	Practolol	Oculo-mucocutaneous syndrome
1976	Zomepirac	Anaphylaxis
1978	Phenformin	Lactic acidosis
1980	Ticrynafen	Death from liver Disease
1982	Ticrynafen	Hepatitis
1990	Etretinate	Birth defect
1999	Astimizole	Arrhythmias
2004	Rofecoxib	Myocardial infarction
2007	Inhaled insuline	Long-term safety, high cost
2010	Rosiglitazone	Heart attacks
2011	Drotrcoginalfa	Prowess-shock study
2012	Rimonabant	Depression, risk of suicidal, tendencies seizures.
2012	Sibutramine	Heart related effect.

History of Pharmacovigilance in India

The concept of PV originated in the past because Vagbhatta, a specialist who to unfavorable reason, occasion and deferred ADRs to Ayurvedic Drug's around 500AD had warned that appropriately witnessed, improperly coordinated medicines are partially of a poison's substance in the hour of Charaka Samhita in 700 BC Since the first attempt was made in 1989, there have been countless reports of adverse drug reactions (ADRs) from the Indian subcontinent throughout the history of modern medicine, but there has never been a systematic effort to track ADRs . After that, many reports of ADRs from India area unit found within the history of modern medicine but there was no systematic efforts of ADR monitoring since the primary try was created in 1989 [17,18,19,20].

In 1986, Pharmacovigilance started in India. A formal Adverse Drugs Reaction(ADR) monitoring system was initiated with 12 regional centers,each covering a population of 50 million. Indian joined the WHO ADR monitoring program in Uppsala, Sweden, ten years after the event. In 2004-08, India had started National Pharmacovigilance Program which was performing under 2 Zonal, 5-regional and 24 peripheral Regions. The Uppsala monitoring Centre (UMC) was established to maintain a global data set of reports of suspected ADR's. In India, for the monitoring of Adverse Drugs Reaction (ADR's) there were six main centers identified, namely in New Delhi, Lucknow, Chandigarh, Mumbai, Pondicherry, and Kolkata. However, only a National Pharmacovigilance Centre in the Department of Pharmacology, All India Institute of Medical Science (AIIMS), New Delhi[21,22]. And two WHO-monitored centers in Mumbai KEM Hospital and Jawahar Lal Nehru Hospital (JLN Emergency Clinic) were active among these six centers, and as result, unrestricted announcing of ADR's was inadequate[17,23].The above six mentioned centers monitor the Adverse Drugs Reactions. (ADR's) of the drugs available in market for sell on OTC counter[24]. This effort was ineffective and then second time from the Ist of January2005, the WHO sponsored and World Bank- funded National Pharmacovigilance Program for India was established[25].

A National Pharmacovigilance Program (PvPI) identified in January 2005. This program to protect the health of patients with an enhanced drugs security program is being launched by the Central Drugs Standard Control Organization (CDSCO), the Health Services Directorate under The Ministry for Health & Family Welfare, the Government of India in collaboration with Indian Pharmacopeia Commission[26]. The programme is coordinated as a National Coordinating Centre (NCC) by the Ghaziabad Indian Pharmacopeia Board. The Indian government launched the Indian Pharmacovigilance Program (PvPI) on July 14, 2010, as the National Coordinating Centre for the Monitoring of Adverse Drugs Reaction (ADRs), New Delhi. In 2010 this programme established 22 ADR monitoring centers, including All India Institute of Medical Science (AIIMS), New Delhi[27]. The National Coordination Centre was relocated on 15 April, 2011 to the IPC, Ghaziabad, to ensure the more successful implementation of this programme.

Aim of Pharmacovigilance

The major aim of pharmacovigilance have been Improve patient care and safety in relation to the use of medicines and all medical & para medical interventions. Another main aim of pharmacovigilance is human medicines and these can readily be adapted for veterinary medicines[28,29].

1) Early detection of hitherto unknown adverse reaction and improvement, interaction of patient care and safety.
2) Detection of increasing frequency of known adverse reactions.
3) Estimation of quantitative aspects of benefits/risk analysis and dissemination of information needed to improve drug prescribing and regulation.
4) Identification of risk factors and possible mechanisms underlying adverse reactions.
5) Identification of subgroup of patients at particular risk of adverse drugs reaction (ADRs). Ex. Relating to species, age, bread, gender, physiological status and underlying disease.
6) Continued monitoring of the safety of a product in each species for which it is authorized to ensure that the risks and benefits remain acceptable . This should include prolongation of monitoring to new indications and new species.
7) Comparation the adverse drug's reaction profile with those of products in the same therapeutic class, both within and across species.
8) Detection of inappropriate prescription and administration with respect to the letter, administration by specific groups ex. public or farmer, may need to be monitored.
9) Detection of drug-drug interaction. This is particularly important for new drugs that are taken co-administered with established product or even other drugs.
10) Further investigation of a drug on product pharmacological, toxicological or microbiological properties in order to understand, where possible the mechanism underlying adverse drug reaction.
11) Adverse effects of veterinary medicinal products on the environment and on organisms in the environment.
12) The violation of permitted residue limits of veterinary medicines in food of animal origin such as meat, milk and honey.
13) Legislation and guidelines governing the requirements of pharmacovigilance[30].

Adverse Drug Reaction

According to world health organization (WHO), an ADR can be defined as any response of a drugs which noxious and unintended, that occurs at doses used in humans for the prophylaxis, therapy and diagnosis of disease, or for the modification of physiologic function purposely excludes therapeutic failures, drug abuse, overdose, noncompliance, and medication errors[31]. Through, it is difficult to recognize the causative agent related with the medicinal preparation generally contain more than ingredients[32]. All drugs are efficient of producing adverse drug's reaction (ADRs) and whenever a drug is given a risk is taken.[33] An adverse effect, which occurs as overstate of the desired therapeutic effect, form a part of ADR, however, side effectis generally related to the therapeutic activities of a drugs which may be beneficial ae well harmful.[34]Therefore, it may be suggested that an ADR is a harmful reaction or unwanted reaction that is followed by the administration of a medicinal product or a combination of drugs under normal condition of use. The various types of Adverse Drugs Reaction (ADRs) as follows[38,39,40,41,42].

Type of ADRs	Characteristics	Example
Type-A Augumented	• Dose related • Related to pharmacological action of drugs. • Predictable from know pharmacology.	• Hypoglycemia due to Insulin • Anticoagulant due to Bleeding • Nitrates due to Headache • Beta blocker due to Bradycardia
Type-B Bizarre	• Non dose related • Uncommon • Non relation to pharmacological action & the drugs.	• Penicillin induced urticaria • Anti-convulsant hypersensitivity syndrome reaction.
Type-C Chronic	• Uncommon • Long terms exposure of drugs	• NSAIDS induced renal failure & GI effects • Osteoporosis with oral steroids • Colonic dysfunction due to laxative
Type-D Delayed	• Prolonged exposure to a drug.	• Teratogenic effect with anticonvulsant or lisinopril. • Tardive dyskinesis caused by antipsychotic medication.
Type-E End of treatment	• They are related with withdrawal of the medication	• Withdrawal with benzidiazepine
Type-E Failure of treatment	• Surprising failure in therapy triggered by drugs interactions (no response)	• Resistance to Antimicrobial.

ADRs and AE Reporting

The ADRs and AE Reporting is the most commonly associated with pharmacovigilance and consumes a considerable amount of resource of government agencies or drug regulatory authorities or drugs safety department. in pharmaceutical organization[24]. In Adverse Event(AE) reporting includes the receipt, data maintaining, triage, distribution, reporting of AE data[38,39]. The foundation of AE reports may include solicited reports from post-marketing or clinical studies, spontaneous reports from healthcare professionals or patients or other intermediaries, report form literature source, reporting is a regulatory requirement in most countries, This report from the media including website and media and also report reported to drugs regulatory authorities[43]. For pharmaceutical companies AE reporting also provides data that play an important in assessing the risk benefit profile of a given drugs. The following are several elements of Adverse Event (AE) reporting.

1) An identifiable patient.
2) An identifiable report.
3) A suspect drug.
4) An adverse event.

Current Scenario of Pharmacovigilance in India

India is a huge country and there are a drug brand more than 6,000 licensed drugs manufactures and over 60,000 branded formulations. India ranks as the fourth largest producer of pharmaceuticals manufacturer in the world and emerging as a hub for clinical trials. Various new drugs are being introduced in the country, so there is a huge need to improve the pharmacovigilance system to protect the Indian population from probable harm that may be caused by some of the new drugs[44]. In the past, India's regulatory agencies and pharmaceutical drug companies based their safety valuations on experiences derived from long-term drug use in the Western markets and there was no real urgency for the government to found a strong pharmacovigilance system of its own. In present years, however, the lag between when a drug is placed in the market and its subsequent availability in India has decreased significantly so that the much needed longer-term safety data is no longer available. In adding, India-based drugs companies have increased their capacity to develop and launch new drugs through their own research efforts and this has heightened the importance of developing adequate internal pharmacovigilance standard to detected drugs events[45]. Examinations in all pharmaceutical companies operating in India all pharmaceutical companies should be trained to maintain and submit to the DCGI the Summary of Pharmacovigilance System document operating within the company, which would serveas the base for future pharmacovigilance examination. The Ministry of Health and Family Welfare (MHW), Medical council of India (MCI), the Indian Council of Medical Research (ICMR), the Pharmacy Council, the Nursing Council, the Dental Council, Consumer Associations, Pharmaceutical Companies, Nongovernmental Organization (NGOs), and Patient Groups Should be invited to a high-level discussion to inform them of the plans the Drugs Control General of India (DCGI) has to enhance and develop a strong system. Add qualified scientific and medical evaluators for pharmacovigilance to the DCGI office strengthen it official working in the DCGI's pharmacovigilance department as well as at the regional, peripheral, and zonal centers should get intensive training in all facets of pharmacovigilance. Training session should be organized twice a year for the this to be continuous activity. The creation of a single, uniform adverse event reporting from for the whole nation[46,47,48].

A single countrywide specific adverse event reporting form needs to be designed should not only be used by the National Pharmacovigilance Centers, but also by all registered hospitals (Private as well as government), teaching hospital. Drug Information Centers and pharmacist throughout the country. It should also be made available to all primary healthcare centers (PHCs) in rural areas and all practicing general practitioners and physician. Creating a clinical trial and post-marketing database. Adverse Drugs Reactions for signal detection and access to all relevant data from various stakeholders' full complete data should be made available to the DCGI and to the various stakeholders from the date of first registration of the clinical trial in the India. The clinical trial in the India. This data should comply with consolidated standards of reporting trails guidelines including general benefit-risk profile of the product. Current standards of safety reporting as outlined in Schedule and information about all adverse drugs effects (ADRs) and adverse events (AEs) per study arm should be thoroughly included as well as detailed depiction of cases with earlier unknow adverse events (AEs) adverse drug effects (ADRs) and the reasons for study withdrawals, for drugs already in the market, type and frequency of all adverse events (serious and non-serious) should be submitted in periodic safety update reports (PSURs) and added to the summary of product characteristics (SPCs). List of all marketed new drugs indications by maintaining a standard database for every pharmaceutical company a list should be maintained by the pharmaceutical companies and regulatory authorities for all new drugs indication in the database. All new problems need to be put under heightened surveillance. Pharmaceutical companies in these circumstances should have meetings set up with Drugs Controller General of India (DCGI). To outline their risk management plan (RMP) for the safety issues in question and describe how they would put effective strategies in place to mitigate the Education and training of pharmacist, nurses, medical student in the area of pharmacovigilance.Nurses and pharmacist should also be trained in pharmacovigilance so that pharmacist is able to identify adverse drug reaction (ADRs) and develop a culture of reporting ADRs in the future. A training schedule and awareness program (both by distance education and face-to-face learning) covering all aspects of pharmacovigilance[49].

These are planned for pharmaceutical companies with a focus on research and development (R&D), mostly those engaged in new drug development, as well as for the pharmacist, medical community, and chemist-druggist trader, as well as patients, to be vigilant in spotting ADRs and reporting them to the Indian regulatory agencies, who will them investigate and take prompt corrective action. As Information technology (IT) new options for national and international collaboration that can improve post-marketing monitoring programmes and promote medication safety have emerged. These collaborations can be made with pharmacovigilance groups to improve drugs safety. A visual of an international partnership to create a uniform post-marketing surveillance database is the Uppsala Monitoring Center (UMC). The method depends on national drugs monitoring institutes in 80 different nations exchanging data on adverse drug reaction. Through the internet, the data is quickly and securely sent, saved, and retrived[50, 51].

2. Future Prospects

As future prospects increase, Pharmacovigilance systems capable to detect new adverse drugs effects (ADRs) and taking regulatory actions are needed to protect public health. Little prominence has been put into creating information that can assist a healthcare professional or a patient in the decision-making process. The get- together and communication of this information is an important goal of PV information about the safety of drugs active surveillance is necessary. When develop new method for active post-marketing surveillance, one has to keep in mind that the important to collect accurate and total complete data on every Serious reported event. Spontaneous reporting is a useful tool in generating signals, but the relatively low number of reports received for the specific association makes it less useful in identifying patient features and risk

factors Pharmacovigilance methods must also be able to describe which patients are at risk of developing an adverse drugs effect (ADRs). As a source of information, the pharmacovigilance approach would be consistent with the growing patient involvement in drug safety[52].

The Pharmacovigilance play a role in detecting individual risk factors for the occurrence of certain adverse drugs effects. In the future, pharmacovigilance has to focus on the patients as a source of information in addition to the more traditional groups, such as the health professionals. The DCGI should act quickly to improve pharmacovigilance so as to participate Good pharmacovigilance practice (GPP) into the procedures and processes to help ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance. An appropriately working pharmacovigilance system is essential if medicines are to be used wisely. It will benefit regulatory authorities, healthcare professional, pharmaceutical companies and the consumers. The pharmaceutical companies help to monitor their medicines for risk. Post-marketing pharmacovigilance is presently a inspirational and laborious process, not only industry-wide, but also for regulatory agencies[53]. The main aim of the Pharmacovigilance is to receive the documentation, information of the work and knowledge online while giving priority to the new and important safety issues. The less priority of nonserious events than serious events but important in comparing the change in health, although they are also screened normally in present time, Glaxo Smith Klie has created a powerful new approach to Pharmacovigilance , case-based PV methods, integrating traditional, disproportionally and data visualization tools. These tools exist within a system agenda that facilitates in-stream review, tracking of safety issues and information management. This more innovative tool and the procedures will help to advance pharmacovigilance by improving efficacy and providing new analytical capabilities. The main approach may be adopted by pharmaceutical companies for prompt analysis and detection of adverse drugs effects Communication and Transparency would strengthen consumer reporting, which are positive steps towards involving consumers more in pharmacovigilance[54,55].

3. Strategies and Proposol: The way forward in India

The discipline of PV has achieved an amazing progress in the recent decade since its opening. In recent years, significant attempts have been made to revolutionize existing pharmacovigilance system to satisfy future expectations. As the possibilities for the future improve, pharmacovigilance system to satisfy future expectations. As the possibilities for the future improve, pharmacovigilance system must be capable of detecting new adverse drugs effects and taking regulatory steps to protect public health. It is critical to design and implement system for evaluating and monitoring the safety of medication in clinical use to avoid or limit harm to patitents and promote public health. However, there are just too many pressing challenges hurting the healthcare system these days. Web-based sales and globalization, information, broader safety concerns, monitoring of established products, public health versus pharmaceutical industry economic growth, developing and emerging drugs, attitudes and perceptions to benefit and harm, outcomes and impact, and other related issues are some of the major challenges. It is more critical than ever to rise knowledge of pharmacovigilance and communicate this information from diagnosis to signal to control overall adverse medication responses, which has become one of pharmacovigilance primary aims[56,57,58].

The collection and dissemination of this data is a key objective for pharmacovigilance. It's important to know the safety of medication active surveillance. When creating new active post-marketing monitoring technique, it's critical to bear in mind how critical it is to gather comprehensive and correct information on every Serious reported occurrence. However, due to the relatively small number of reports obtained for a given relationship, spontaneous reporting is less effective at detecting patient features and risk factors. Pharmacovigilance techniques must also be able to identify whether patients are susceptible to experiencing a negative medication response (ADRs). The pharmacovigilance strategy would be in line with the rising patient participation in medication safety as a source of knowledge[17]. A well-functioning pharmacovigilance system is crucial if medications are to be used safety. All stakeholders, with regulatory agencies, healthcare professionals, pharmaceutical corporation, and consumers, will benefit from it. It helppharmaceutical business create and implement comprehensive threat management plans to safeguard their medication in perilous circumstance and continually monitor their products for threats.

The capability of the following suggestions as follows:

1) Building and maintaining a strong pharmacovigilance system.
2) Verifiable dialogues with various groups of the workforce.
3) Strengthening of the DCGI office with ready pharmacovigilance logical and clinical assessors.
4) Establishing a single, universally accepted, country-explicit, hostile event announcement structure.
5) Training and instruction in the field of pharmacovigilance for medical students, pharmacists, and nurses.

The pharmacovigilance may contribute to certain risk factors that result in the incidence of some adverse drug effects. Pharmacovigilance must concentrate on using people as a source of information in addition to more conventional groups like health professionals. To implement Good Pharmacovigilance Practice (GPP) into the tactics and cycles to assist ensure administration consistency, upgrade clinical preliminary security, and enhance post-advertising observation, the DCGI should take action quickly to improve Pharmacovigilance[59].

4. Conclusion

India has 6,24,000 beds across 15,000 hospitals and more than 500000 certified doctors. India ranks as the fourth largest producer of pharmaceuticals manufacturer in the world. The nation has made a name for itself as a prominent center for clinical trials. Its growing in significances as a global center for clinical trials. With the introduced of a new

drugs molecule a strong pharmacovigilance structure is required in our country to guard the inhabitants from the impending harm and adverse effects. Pharmacovigilance plays an important role of convention the challenges posed by the ever-rising range and effectiveness of medicines. But the pharmacovigilance system in our country is till need development. In India performs at a pharmacovigilance rate of less than 1% compared to a global average of 5%. This is due to a lack of preparation and general ignorance of the topic. In India pharmacovigilance (PV) system has increased awareness in people regarding adverse drugs effect (ADRs) reporting. The issues of underreporting are resolving due to available reporting facilities like toll free number, mail, message, adverse drug effects from in vernacular language. The number of multinational companies have started the outsourcing of pharmacovigilance activity in India which is making the good pharmacovigilance culture. The various university have incorporated pharmacovigilance courses in their curriculum as elective subject or compulsory. Till government need to focus on the enhancement and awareness. Pharmacovigilance is comes under drugs safety reporting and post-marketing surveillance.

In this pharmacovigilance we can report the adverse drug events (AE) for efficacy of the drug product. Drug safety associate can investigate the report and case to the drug regulatory affairs. Various pharmaceutical companies across the world will maintain this pharmacovigilance (PV) reports. The pharmacovigilance department is key for maintaining the drug safety.

In India is now considered to be a hub for clinical research. The drug control general of India (DCGI) has shown its commitment to ensure safe use of drugs by beginning the National Pharmacovigilance Program. More clinical trials are now being conducted in India and business process outsourcing (BPOs) based in India are now undertaking pharmacovigilance projects from multinational corporations (MNCs). Consumer groups, Healthcare professionals, nongovernment organization (NGOs) and hospitals should appreciate that there is now a system in place to collect and analyze adverse event data. They should start reporting adverse events (AE) and participate in the National Pharmacovigilance Program (NPP) to help ensure that people in India receive safe drugs. Which the help and proper co-ordination of all stakeholders, we can definitely build a world class pharmacovigilance system in India.

References

[1] Rajkumar soni, Bikrant kesari, 2014 A review on Pharmacovigilance in P.237.
[2] Garima Dhingra, Sonia Tanwar, Devender sharma, Shwata Parihar, A review of pharmacovigilance, 2022, P 7-8.
[3] Singh, n., Singh, s.p. And tandan, n., 2015. Current problems and future prospective of pharmacovigilance in India.
[4] EFERENCE 1) Kumar, A., 2011. Past, present, and future of pharmacovigilance in India. Systematic Reviews in Pharmacy, 2(1), p.55.
[5] Routledge P. 150 years of pharmacovigilance. Lancet. 1998;351:1200–1.
[6] Commission on Anaesthetics. Lancet. 1893; i:629–38.
[7] Woolf AD. The Haitian diethylene glycol poisoning tragedy: a dark wood revisited. JAMA. 1998;279:1215–6.
[8] Douthwaite AH. Some recent advances in medical diagnosis and treatment. Br Med J. 1938;1:1143.
[9] https://academic.oup.com/toxsci/article/122/1/1/1672454.
[10] McBride WG. Thalidomide and congenital abnormalities. Lancet. 1961; ii:1358.
[11] Lenz W, Knapp K. Foetal malformations due to Thalidomide. German Med. 1962;7:253–8.
[12] Kajii T, Kida M, Takahashi K. The efect of thalidomide intake during 113 human pregnancies. Teratology. 1973;8:163–6.
[13] R.S.Satoskar, Nirmala N.Rege, Raakhi K. Tripathi and S.D. Bhandarkar. Textbook of Pharmacology and Pharmacotherapeutics, 25th Edition. Elsevier co-published with popular prakashan.
[14] World Health Organization. The importance of pharmacovigilance – safety monitoring of medicinal products. World Health Organization, Geneva, 2002.
[15] Ghosh Rupanwita, Bhatia M.S. and Bhattacharya S.K., "Pharmacovigilance: Master Key to Drug Safety Monitoring and its Status in India", Delhi Psychiatry Journal, 15, October 2012, 412-415.
[16] Kulkarni M.D., Baig M.S., Chandaliya K.C., Doifode S.M., Razvi S.U., Sidhu N.S., "Knowledge, Attitude and Practice of Pharmacovigilance among Prescribers of Government Medical College and Hospital, Aurangabad (Maharashtra), international journal of pharmacology and therapeutics, 3, 2013, 10-18.
[17] Mall, S.K., Dipa, P., Goswami, S., Singh, P. and Singh, R.P., 2022. Pharmacovigilance program in India (PvPI): History, Current scenario, future aspects, and role in COVID19. Asian Journal of Research in Pharmaceutical Sciences, 12(3), pp.205-209.
[18] Sawarkar, A., Sharma, R.K., Gautam, V., Shramankar, K. and Dinodia, N., 2019. Pharmacovigilance: Present status and future perspectives. The pharma innovation journal, 8(8), pp.84-92.
[19] Satyanarayana, B.V., Reddy, D.N., Nagabhushanam, M.V. and Chamarthi, S.K., 2020. A comparative study of regulatory issues on pharmacovigilance in us, Europe and India: a review.
[20] Kalaiselvan v, et al . "Pharmacovigilance programme of India Recent development and future perspectives." Indian Journal of Pharmacology 48.6 (2016) 624-628.
[21] Vora Mukesh kumar B., Paliwal Narendra P., Doshi Vikas G., Barvaliya Manish J. and Tripathi C.B., "Knowledge of Adverse Drug Reactions and Pharmacovigilance Activity among The Undergraduate Medical Students of Gujarat", International Journal of Pharmaceutical Sciences and Research (IJPSR), 3, 27 April, 2012, 1511-1515.
[22] Kothari Miral, Sadaria Priti and Dave Nehal, "Data mining in pharmacovigilance – to reduce Adverse Drug Effects (ADRs)", International Journal of Computer Applications & Information Technology, II, January 2013, 01-04.
[23] Gohil Kashmira, J., 2019. Pharmacovigilance and techniques: focus 2020.
[24] Reddy V.Lokesh, Pasha S.K. Javeed, Dr. Rathinavelu Mohanraj and Dr. Reddy YP, "Assessment of

Knowledge, Attitude and Perception of Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting among the Pharmacy Students in South India", IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS), 9, Mar-Apr. 2014, 34-43.
[25] Shuka SS, Gidwani Bina, Pandey R, Rao SP, Singh V and Vyas Amber, "Importance of Pharmacovigilance in Indian Pharmaceutical Industry", Asian Journal of Research in Pharmaceutical Science, 2, 2012, 04-08.
[26] Edwards IR. The management of adverse drug reactions: from diagnosis to signal. Thérapie, 2001, 56:727-733.
[27] Kalaiselvan, V., Srivastava, S., Singh, A., & Gupta, S. K. (2019). Pharmacovigilance in India: present scenario and future challenges. Drug safety, 42(3), 339-346.
[28] WHO, Pharmacovigilance: ensuring the safe use of medicines, Geneva: WHO 2004.
[29] Stephens K. Pharmacovigilance future prospective. Journal of Pharmacovigilance. 2000; 2:23-29
[30] Gildeeva GN, Yurkov VI. Pharmacovigilance in Russia: Challenges, Prospects and Current State of Affairs. Journal of Pharmacovigilance. 2016; 4:206-209.
[31] Word Health Organization. International drug monitoring: the role of the hospital. Geneva, Switzerland: word health organization;1966. technical report series no.425.
[32] Maiti Bodhisattwa, Nagori B.P., Singh Rambir, Kumar Pragati and Upadhyay Nishant, "Recent Trends in Herbal Drugs: A Review", International Journal of Drug Research and Technology, 1, 2011, 17-25.
[33] Kulkarni M.D., Baig M.S., Chandaliya K.C., Doifode S.M., Razvi S.U., Sidhu N.S., "Knowledge, Attitude and Practice of Pharmacovigilance among Prescribers of Government Medical College and Hospital, Aurangabad (Maharashtra), international journal of pharmacology and therapeutics, 3, 2013, 10-18.
[34] Nebeker JR, Barach P, Samore MH. Clarifying adverse drug events: a clinican's guide to terminology, documentation, and reporting. An Intern. Med 2004; 140: 795-801.
[35] S Amarnath, S Jaikumar, S Basalingappa, M Thulasimani and S Ramaswamy, "Pharmacovigilance for Health Care Professional Students", Research Journal of Pharmaceutical, Biological and Chemical Sciences (RJPBCS), 4, January-March 2013, 1204-1217.
[36] Beijir HJ, de Blaey CJ. Hospitalisations caused by adverse drug reactions (ADR): ameta- analysis of observation studies. Pharmworld Sci 2002; 34: 1373-1379.
[37] Rohilla Ankur, Kumar Vipin, Sharma Mohit Kumar, Dahiya Amarjeet and Kushnoor Ashok, "Pharmacovigilance: Needs and Objectives", Journal of Advanced Pharmacy Education & Research, 2, Oct-Dec 2012, 201-205.
[38] Bennett PN, Brown MJ. Clinical Pharmacology. Tenth edition. Churchill Livingstone, Edinburgh, 2008.
[39] Walker R, Whittlesea C. Clinical pharmacy and therapeutics, 4th edn, Churchill Livingstone, Edinburgh 2007.
[40] Clinical pharmacology and therapeutics-edited by Roger and Walker (3 rd edition).pg no-(21-43) Biopharmaceutics and pharmacokinetics-Brahmankar. pg no-(224-234).
[41] Dr. Ramesh KG, Dr. Parloop AB, Dr. Mahesh DB. Elements of clinical pharmacy, 4th edn:2008-2009, B.S. Shah prakashan; page no-109-114.
[42] Clemerson J, Payne K. Pharmacogenetics current applications. Hospital Pharmacist 2008; 15: 167-173.
[43] Patel Avani, Giles D, Thomas Vidhya, Gurubasavarajaswamy P.M. and Patel Riddhi, "Pharmacovigilance: A Review", International Journal of Pharmaceutical & Biological Archives, 2, 24 Oct 2011.
[44] Yerramilli A, Veerla S, Chintala E, Guduguntla M, Velivelli P. A Pharmacovigilance Study Using Tracer Techniques. Advances in Pharmacoepidemiolology Drug Safety. 2014; 3:165-167.
[45] Mishra H, Kumar V. Pharmacovigilance: Current Scenario in a Tertiary Care Teaching Medical College in North India. Journal of Pharmacovigilanc. 2013; 1:108- 109.
[46] Bavdekar, S.B. and Karande, S., 2006. National pharmacovigilance program. Indian pediatrics, 43(1), p.27.
[47] Rajanandh, M.G. and Chamundeeswari, D., 2017. Need of pharmacovigilance in AYUSH drugs. J Pharmacovigilance, 5, p.e166.
[48] Prakasam, A., Nidamanuri, A. and Kumar, S., 2012. Knowledge, perception, and practice of pharmacovigilance among community pharmacists in South India. Pharmacy Practice, 10(4), p.222.
[49] Elhassan GO. Clinical Perspectives towards patient safety. Journal of Pharmacovigilance. 2015; 3:129-132.
[50] Gromek, K., Drumond, N. and Simas, P., 2015. Pharmacovigilance of herbal medicines. International Journal of Risk & Safety in Medicine, 27(2), pp.55-65.
[51] Mandal, S.C. and Mandal, M., 2017. Evolution of pharmacovigilance program: Present status in India. Pharma times, 49(5), pp.31-6.
[52] Flower DR. Pharmacovigilance, drug repositioning and virtual screening. Journal of Pharmacovigilance. 2013; 1:103-104.
[53] Ghewari P, Salunke S, Bhatiya N, Killedar S. Strategies and current scenario of pharmacovigilance in India. Journal of Pharmacovigilance. 2014; 1:122-134.
[54] Borja-Oliveira CR. Alcohol-Medication interactions: The Acetaldehyde Syndrome. Journal Pharmacovigilance. 2015; 2:145-147.
[55] Kalaiselvan V, Prasad T, Bisht A, Singh S, Singh GN. adverse drug reactions reporting culture in pharmacovigilance programme of India. Indian Journal of Medical Research. 2014; 5:114-117
[56] Suke, S.G., Kosta, P. and Negi, H., 2015. Role of pharmacovigilance in India: An overview. Online journal of public health informatics, 7(2).
[57] Talbot, J.C.C. and Nilsson, B.S., 1998. Pharmacovigilance in the pharmaceutical industry. British journal of clinical pharmacology, 45(5), p.427.
[58] Rahman, S.Z. and Singhal, K.C., 2002. Problems in pharmacovigilance of medicinal products of herbal

origin and means to minimize them. Uppsala reports, 17(Suppl), pp.1-4

[59] Pharmacovigilance, J., 2014. Journal of Pharmacovigilance.