BioGecko

Vol 12 Issue 03 2023
ISSN NO: 2230-5807

A COMPREHENSIVE STUDY ON THE PHARMACOVIGILANCE SYSTEMS IN INDIA

Dr. Amrita Sarkar
Associate Professor, Community Medicine, TomoRiba Institute of Health and Medical Sciences (TRIHMS), India.
Dr. Murugesan Sannasi
Associate Professor, Nanju Maruthuvam (Siddha Toxicology), National Institute of Siddha, India.

Dr. Richa Verma
Department of Periodontics, PGIDS, Rohtak, India

Dr. Himani Kaushik
Department of Pedodontics, PGIDS, ROHTAK, India

ABSTRACT
Pharmacovigilance (PV) refers to the method as well as science of observing the medicinal safety to minimise risks and enhance advantages of medicines. The main element of a pharmacovigilance system is an information gathering process that can be actively followed by proper reporting. Pharmacovigilance process is completed by detection, ICSRs, assessment, drug safety and prevention of negative effects. Therefore, the robust PV system requires Standard Operating Procedure (SOPs), safety database and a trained qualified incharge. The aim of this paper is to determine the pharmacovigilance system following in India. Therefore, all the data available in secondary resources are collected for conducting this study. Both quantitative and qualitative data from different resources are collected for completing this study in an effective manner. As per the findings, in the year 2010, Pharmacovigilance Programme of India (PvPI) was established by the Ministry of Health and Family Welfare (MoHFW). According to the Drugs and Cosmetics Act 1945, MoHFW takes the responsibility to reduce the medicine risks in India. There are 3 main kinds of pharmacovigilance activities; these are drug abuse, drug safety, and adverse monitoring effects. Additionally, Kinapse, GVK, MSD Merck, Syneos Health are some top Indian companies that are following the best practices of pharmacovigilance in India. Hence, this study reveals that all vaccines and medicines undergo proper and rigorous testing for efficacy and safety by clinical trials. After these crucial medical tests, the drugs are authorised for public use in India.

Keywords: Pharmacovigilance, India, Ministry of Health and Family Welfare (MoHFW), Standard Operating Procedure, Drug Safety

INTRODUCTION
The activities for understanding as well as preventing the negative effects of drugs are known as pharmacovigilance process. According to "National Pharmacovigilance Centre" there are 99 peripheral and 5 intermediary centres in India that are functioning. Pharmacovigilance is necessary for monitoring medication safety as well as post marketing surveillance of safety. This is important for monitoring medication safety in India. Therefore, a lot of clinical trials are performed for analysing medication safety in India. Hence the aim of this paper is to analyse the hazards in relation with varieties of pharmaceutical products with reducing the risk of harm that may affect the health of patients. However, the benefit-risk ratio will be analysed in this paper by following proper monitoring methods. The decision making method on using multiple methods can be analysed through following approaches.
The main aim of pharmacovigilance is to maintain a proper monitoring system that ensures a safety issue and also implement proper approaches for reducing risk. In addition to this, installing a method of rapid decision making as

well as triggering activities in immediate safety concerns is possible through pharmacovigilance process. Improving safety and care to the patients in terms of medicine use is possible through following these approaches. Thus, services which support medical activities like radiography, first aid, nursing can be completed effectively by following proper interventions. Public health services can be improved through following these approaches in relation to medicine use. Hence, an assessment of risk, benefits as well as effectiveness of medicines is possible through adopting pharmacovigilance methods. Hence, an accessibility of knowledge regarding medicinal safety is possible through following the approach of pharmacovigilance. Thus, promoting education, understanding as well as training for pharmacovigilance is essential for providing proper care to the patients. In this regard, effective communication to the public through pharmacovigilance is possible by adopting these methods[1].

The main tasks of pharmacovigilance are as follows;

- Assessing the potential and known risk of every method before creating a marketing plan for collecting data is a crucial part. In addition to this, reducing these risks by creating a risk management plan is also completed through a pharmacovigilance plan.
- Gathering data and managing all the "possible adverse reactions" (PDA), is essential for checking the records of medication [2].
- Signal detection as well as management is another important part of analysing data in order to determine the signals for safety issues. In this regard, a report regarding adverse reactions of a drug can be analysed effectively. Changing safety concerns can be analysed effectively through pharmacovigilance methods.
- Conducting "benefit-risk monitoring" of multiple medicines through "periodic safety update reports (PSURs)".

However, managing all the drug related information through additional monitoring is important for following the initiative of pharmacovigilance method. In India, MoHFW takes the responsibility for monitoring drug safety protocols in an advanced manner. There are multiple PHPs as well as regulatory services proposed by the government of India that helps in ensuring drug safety which helps a lot of patients to have a proper treatment in this country.

METHODS AND PROCEDURE

Multiple research methods and strategies are present for conducting a study regarding any pharmacology studies. Selection of an appropriate method in a research provides a proper guidance to the researcher that helps in achieving success in a research [3]. In this study, qualitative and quantitative types of data are collected from various papers. Data that are already published in various journals, articles, research papers and authorised websites are collected by the researcher for completing this study effectively. Hence, multiple secondary data are collected by the researcher for interpreting the results of the study. However, journals and articles published between 2019 and 2023 are used in this study and the researcher used proper keyword search patterns in order to include data in this study. Keywords such as "Pharmacovigilance, Pharmacovigilance program in India" are used for gathering data full of information regarding the concerned research topic.

RESULTS

In order to maintain drug safety in India, a Pharmacovigilance program is arranged by the government. MoHFW launched a program in the year 2010 in AIIMS, New Delhi as "National Coordinating Centre". However, selection of this program provided a lot of acts and rules that are important to be followed in India by any pharma company. As one of the top leading producers of cost effective and quality controlled generic drugs, India supplies 20% of the international demands in volume.

Table 1: Healthcare market India

Years	Value in billion USD
2008	45
2009	52
2010	60
2011	68
2012	73
2014	81
2015	104
2016	140
2017	160
2020	280
2022	372

Source: [4]

According to the reports, the healthcare market in India has increased from 160 billion USD in 2017 to 372 billion USD in 2022. This is the largest sector of India in terms of employment and revenue. Hence, a rapid growth in the healthcare market is observed in India. Previously, the size of the healthcare market was 45 billion USD in 2008 that reached 140 billion USD in 2016 [4]. In addition, the reports further specify that the pharmaceutical and health sector of India is the fastest growing industry of the world that is expected to reach 754% between 2017 and 2060. A steady growth in the Indian pharmaceutical market can be observed through following different initiatives. In the year 2015, India earned 21 billion USD through bio-similars within the prescribed drug market. According to the reports, the share of the generic drugs market in India has grown by 70%.

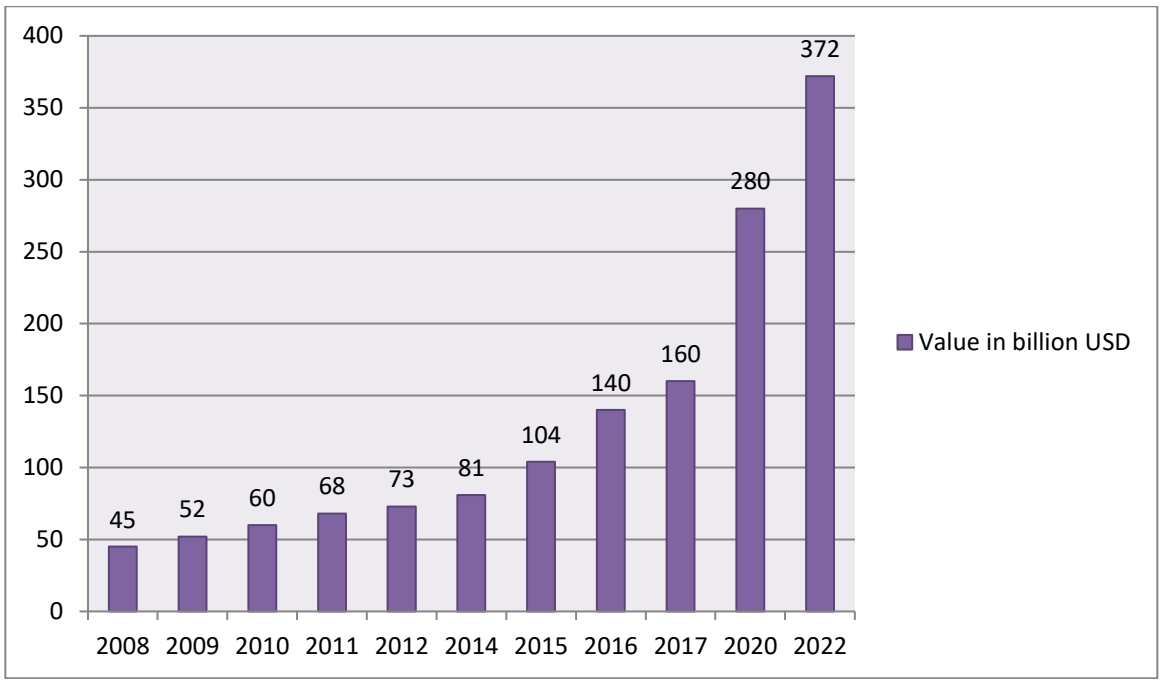

Figure 1: Healthcare market India Source: [4]

In addition to this, the total revenue of the pharmaceutical industry within the emerging market was 290 billion USD in the year 2022. Additionally, the value of Indian pharma exports was 22.2 billion INR. These statistical information represented that the pharmaceutical industry revenue and market size in India is huge. India also exports different kinds of medicines to other countries. In this regard, maintaining a robust monitoring method is important for following proper safety issues [5]. Minimisation of risks is essential through implementing effective approaches. Installing procedures in order to rapid decision making as well as triggering actions for maintaining safety concerns is an essential part of pharmacovigilance.

The drugs are essential for preventing, curing as well as treating any kind of disease. In addition, a mild adverse effect of drug reaction within patients can be observed. Thus, pharmacovigilance (PV) develops the approach to safe medicines as well as healthcare. Public healthcare remains a critical challenge in multiple nations. Hence, the pharmacovigilance process in India that was launched in the year 2010 helped to check the components in each drug in order to monitor the health and safety of all patients consumed that drug [6] MoHFW and Indian Pharmacopoeia Commission (IPC) have taken the responsibility to follow different approaches in order to follow proper initiatives. However, presently India is known as the region of international clinical trials as well as clinical research studies. An efficient as well as prudent operation is followed by people in India in order to monitor the chemical components of the drug.

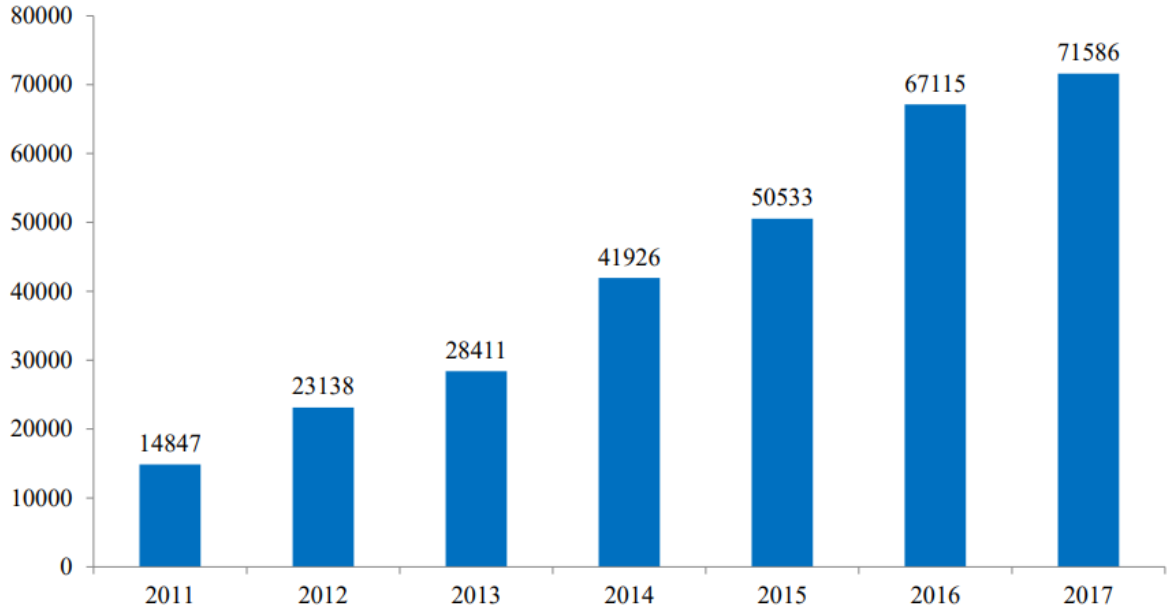

Figure 2: ADRs Reporting Status in India Source: [5]

According to the reports, the ADRs reporting status in India has increased in the last few years. Government hospitals, district hospitals, municipal hospitals, army hospitals, corporate hospitals and 80 are centres have taken the responsibility for monitoring the adverse effects of multiple drugs among the population [7]. Pharmacovigilance system in India is completed by creating a master file about the impact of multiple drugs on human health. A risk management plan is beneficial to avoid critical issues. Drug alerts should be given in the updated packaging of the product. After analysing several key studies about the impact of the drug on human health, it is essential to take immediate action to protect the health of other people in the country.

DISCUSSION

Importance of pharmacovigilance system

The implementation of this system in India can be followed by several steps. The short term goal of this system is to encourage all healthcare professions in reporting the adverse reaction of various vaccines, medicines and medical devices. Along with the 1.2 billion population in India, it is challenging to analyse the prevalence pattern of multiple devices, socioeconomic status and different systems of multiple medicines [7]. Thus, pharmacovigilance systems can help in standardising drug safety in the nation. In addition to this, gathering data and case reports is another important part of the pharmacovigilance system in India. Pharmacovigilance systems in India can help in implementing an electronic reporting system. A reporting culture should be present in order to follow this system in an effective manner.

Reasons for failure in implementation process

Multiple new drugs are now introduced in the nation; hence it is essential to develop the pharmacovigilance system for protecting the population of India. Moreover, numerous issues as well as challenges that are prevented through robust pharmacovigilance systems in this nation. In addition to this, a pharmacovigilance system is not systematised and well funded for a vast nation like India for service to the public and patients [8]. Along with that, the information gathered from various zone centres are often not analysed well and poorly. The inadequate research of multiple drugs is still unknown to patients. Another issue that has been found is the lack of involvement of healthcare employees in pharmacovigilance. Healthcare professionals in urban and rural areas are

not having proper motivation and knowledge regarding pharmacovigilance. Hence, the negligible knowledge of these healthcare professionals is another main issue of implementing pharmacovigilance in India. Additionally, the little encouragement of healthcare employees in different departments is causing several issues for patients. Hence, providing proper training and creating awareness amongst healthcare employees is essential for better reporting. Apart from that, there are many customer groups in India which encourage patients to report adverse reactions of different drugs. Hence, ADRs directly can communicate with the patient authority to gather sufficient information.

Methods of pharmacovigilance

Pharmacovigilance can be followed by two different methods, one is active surveillance another is passive surveillance. Passive surveillance can be followed through encompassing all types of AEFI reporting process. Additionally, immunisation service providing authority can also report regarding the pharmacovigilance. Apart from that, state or territory authority can also look after the pharmacovigilance process. However, active surveillance can be followed through determining the characterisation of AEFI profile, risk factors and rates. In addition to this, resource constraints and logistical constraints can be limited to wide applications [9]. However, AEFI regulations can be followed in community settings such as cohort monitoring. Apart from that, epidemiological studies can be conducted such as case control, cohort study and the study of case series. However, focusing on some selected vaccinations can be helpful for hoc studies in the pharmacovigilance system of the country. Causality hypotheses are important to be tested in an appropriate way for determining the possible threats in relation to pharmacovigilance.

Spontaneous reporting is a well developed process that can be completed through a voluntary interaction between consumers, and healthcare professionals of an organisation. Regulatory authorities can also take an initiative to follow the spontaneous reporting method. Along with that, the adverse reactions of drugs are important to be looked after by the concerned authority in order to avoid any kind of critical issues. Understanding the risks can help to prevent serious complications in human health. Safety signals are essential to be determined by healthcare professionals in order to determine the rare effect of adverse events.

Spontaneous reporting plays a critical role in determining the safety signals of all medicines in the market. In multiple occurrences these reports can also alert an organisation to rare adverse science which was not identified in the initial clinical trials. Hence, the issues that are identified through spontaneous reporting can cause severe risk factors for patients suffering from different kinds of diseases [10]. An innovative and systematic method for determining the safety signals through spontaneous reports are now used by multiple people. Therefore this spontaneous reporting process can be followed through determining the safety signals and following some basic calculations. Signal detection processes and data mining technology are used by people in order to understand the adverse effects of a few medications. Signal case reports can be helpful for analysing the negative impacts of some drugs. Along with that the data mining methods can boost the evaluation of the reporting standards through the use of some statistical methods that are essential for following a passive surveillance process. Apart from spontaneous reporting processes some case series can also be understood for pharmacovigilance processes. A series of multiple case reports could be delivered which is important to analyse the adverse events of different medicines. Hence identifying the case series can provide a lot of valuable information for producing theories to understand the relationship between medicine outcome as well as exposure.

Another method of pharmacovigilance that can be followed by healthcare professionals is stimulated reporting. A number of techniques can be used for reassuring as well as simplifying the reporting standards by healthcare professionals in order to analyse the circumstances for innovative products as well as the partial time periods. However all of the adverse events are important to be reported in an effective manner for identifying the criticalness of any medication. In perfect information and discriminating reporting can cause several issues for the patient [11]. Hence all the spontaneous events should be reported accurately and their food stimulated reporting process can be followed effectively for determining the incidence rates as well as impact of the adverse effects on the patient. However active reporting of ADR is important for recognising the issues of the particular medication to that patient.

Active surveillance is better than the passive surveillance process as it can help to provide detailed information about the adverse events by using pre organised methods. Therefore the pre organised process can be followed in a constant manner by following an active surveillance process. A wide ranging database is available in the reporting process that can be helpful for analysing the adverse events in a detailed way. Medicine events can also be monitored for the following pharmacovigilance process [12]. A lot of studies are followed by multiple researchers that can help to analyse the medication monitoring process easily. Patients can be acknowledged through automated health insurance schemes. A single prescription given to the patient can be monitored effectively for following the pharmacovigilance process. Hence the use of proper questionnaires can be helpful to prescribe accurate medications to the patient in order to avoid any kind of health related complications. In modern days the reporting standards are extremely technology oriented. Hence the data of the patients are directly stored in multiple online platforms that are extremely beneficial to analyse the clinical events, treatment procedures, medicine doses and the duration of multiple therapies of a patient [13]. The past history of a patient can be analysed effectively by accessing all the previous records available in insurance documents. However, medical events and the restrictions of multiple medicines of a particular patient are important to be identified by the patient as well as the physician in order to avoid any kind of adverse impact of wrong medication.

This study specifically highlights that the pharmacovigilance program is extremely crucial for providing the correct medicine to the patient and avoiding any kind of complicated health risk [14]. Therefore, following the correct form of vigilance process is important in India in order to prevent different kinds of critical cases of physical issues. Patient protection regulations can be easily followed by the healthcare employees in order to provide quality care to the patient. Norms and regulations established by the government of India in order to protect the health of all patients by pharmacovigilance in the country. Registry is another process of following the correct form of vigilance process in India. The registry refers to the list of patience with proper identical representatives [15]. The disease registry and medicine registry are properly followed by healthcare professionals in order to control the drug exposure. Apart from that case control studies are also followed by multiple organisations in order to follow proper clinical investigations.

All the clinical investigations and cohort studies are essential for protecting the population from the risk of having any kind of critical disease. Knowledge on the exposure status should be accessible by the healthcare professionals for individual patients [16]. A single patient may be exposed to a medicine for more than one time but this time it may hurt the patient in a negative manner. It is essential to determine the medicine exposure rate to the single patient in order to improve the medical facilities given to the patient. In India there are multiple laws and regulations created by the government for following pharmacovigilance processes in an accurate manner. For example the national health policy describes that pharmacovigilance must consist of the prescription of antibiotic uses of a particular patient. According to the drug and cosmetic act 1945 establishment of pharmacovigilance in the pharmaceutical industry is necessary and mandatory [17]. There are multiple reporting tools used by healthcare professionals and other pharmaceutical stakeholders in order to follow the pharmacovigilance process in an accurate manner in this country.

Case processing, safety alert communication, ADR monitoring at the basic methods to follow the basic norms of pharmacovigilance process [18]. Understanding more about the drug consumption process and its reaction is essential for improving the health condition of an individual. In this regard copper awareness regarding different drugs and its reaction on the human body is essential to be identified by people. Different kinds of health care related campaigns can be organised by the public health committee in India for improving the current condition of the health of the population [19]. It has been reported that the population rate in this country is growing rapidly and their food is extremely essential for people to understand the importance of pharmacovigilance to provide quality care to the patients. All the regulations and norms proposed by the government of the country are extremely important to be followed in an acute manner for improving the medication process followed in the country [20]. The pharmaceutical industry in the country has taken the responsibility to provide quality care and high quality medications to the patients by improving the drug manufacturing process however it is highly important to analyse the adverse effect of multiple drugs for individual patients [21]. In this regard all the regulations and norms proposed by the government of the country should be accurately followed by health care

professionals in order to protect the population from different kinds of health disease.

CONCLUSION

According to the results of this study, it can be concluded that a stable working pharmacovigilance system is necessary for medicinal safety. Healthcare professionals, pharmaceutical companies as well as regulatory authorities need to follow proper methods of following clinical investigation before the industrialisation of any drug. This aids all pharmaceutical organisations for monitoring the medicines to determine risks through proper risk management strategies. However, drugs can be saved from critical circumstances. The findings of this paper also confirmed that creating and managing a proper pharmacovigilance system can help in developing the current industrial revenue. Listing of all drugs that are new in the market within the standard database is essential for each pharmaceutical organisation. In addition to this, introducing new pharmacovigilance inspectors can help to report the mandatory details regarding different drugs. Along with that, a high level of conversation with all the stakeholders of pharmaceutical companies is essential for following a correct approach of pharmacovigilance. It will provide a lot of advantages to regulatory authorities, healthcare professionals as well as pharmaceutical organisations to determine the risks of multiple medications. Pharmacovigilance is essential for determining which patients are at risk of using particular medicine, Hence a proper pharmacovigilance system in India can help to use medicines in a prudent manner. However, safeguarding the public health is possible through following proper approaches of pharmacovigilance systems. Thus, all the regulations and acts proposed by the government is important to be followed accurately for ensuring patient safety in the country.

REFERENCES

World Health Organization, 2018. Safety of medicines: pharmacovigilance programme of India. *WHO Drug Information*, *32*(1), pp.10-17.

Karnwal, S., 2022. Size of the healthcare sector in India 2008-2022, available at: https://www.statista.com/statistics/701556/healthcare-sector-size-india/ [Accessed on 20.05.2023]

Karnwal, S., 2022. Pharma industry in India - statistics & facts, Available at: https://www.statista.com/topics/5456/pharmaceuticals-in-india/#topicOverview [Accessed on 20.05.2023]

Mandal, S.C. and Mandal, M., 2017. Evolution of pharmacovigilance programme: Present status in India. *Pharma times*, *49*(5), pp.31-6.

Kalaiselvan, V. 2023. Pharmacovigilance Programme of India, Available at: https://www.pmda.go.jp/files/000225777.pdf [Accessed on 20.05.2023]

Srinivasan, V., Sheela, D. and Mridula, D., 2017. Knowledge, attitude and practice of pharmacovigilance among the healthcare professionals in a tertiary care hospital–A questionnaire study. *Biomedical & Pharmacology Journal*, *10*(3), pp.1441-1447.

Jain, A., Singh, A., Verma, A.K. and Soni, M., 2018. Assessment of awareness towards pharmacovigilance programme of India and reporting of adverse drug reactions among nurses in a tertiary care hospital. *Int J Basic ClinPharmacol*, *7*, pp.1357-64.

Kumari, P., Sahoo, J. and Satapathy, A., 2022. The safety of nutraceuticals monitoring through pharmacovigilance programme of India.

Jain, S., Jain, D.V. and Sharma, R., 2018. Pharmacovigilance system and the future challengesin India-A Perspective. *International Journal of Pharmacy Research & Technology (IJPRT)*, *8*(2), pp.27-31.

Mahajan, R., 2017. Inclusion of medical colleges as adverse drug reaction monitoring centers under pharmacovigilance programme of India: Missing the targets. *International Journal of Applied and Basic Medical Research*, *7*(4), p.217.

Thota, P., Sidhu, S., Medhi, B., Sarma, P., Prakash, A., Vivekanandan, K. and Thota, A., 2019. Targeted spontaneous reporting on drug safety alerts issued by pharmacovigilance programme of India: A new origin of pharmacovigilance in India. *Journal of Pharmacology and Pharmacotherapeutics*, *10*(1), pp.33-34.

Gupte, N. and Pradhan, S., 2020. Pharmacovigilance: Perspectives in India. *Journal of Medical Academics*, *3*(2), pp.59-62.

Rasheed, R.A., Mokkaiyan, P. and Mani, G., 2019. A study to assess the knowledge and attitude regarding Pharmacovigilance Programme of India among interns in a tertiary care hospital. *National Journal of Physiology, Pharmacy and Pharmacology*, *9*(7), pp.647-647.
Pandey, A. and Jain, S., 2020. PHARMACOVIGILANCE, HAEMOVIGILANCE AND MATERIOVIGILANCE PROGRAMME OF INDIA: AN OVERVIEW. *FOR HEALTHCARE PROFESSIONALS: SCOPE AND OPPORTUNITIES*, p.159.
Varghese, M.A., Jasmy, E.S., Varghese, S.A., Baby, A., Yeldhos, S. and Shindya, B., 2020. Pharmacovigilance: An Overview. *Volume*, *9*, pp.648-659.
Pant, J., Marwah, H., Singh, R.M. and Hazra, S., 2021. An overview of the worldwide master key for pharmacovigilance and its role in India. *Journal of Pharmacovigilance and Drug Research*, *2*(2), pp.19-26.
Agrawal, M., Singh, P. and Joshi, U., 2021. Antimicrobials associated adverse drug reaction profiling: a four years retrospective study (Pharmacovigilance study). *Alexandria Journal of Medicine*, *57*(1), pp.177-187.
Duarairajan, P., Pushpam, M. and Pavithira, S., 2017. Assessment of knowledge, awareness and reporting of pharmacovigilance among the healthcare providers in a tertiary care center. *World Journal of Pharmaceutical Sciences*, pp.72-76.
Masurkar, P., 2017. A need of better pharmacovigilance system in India. *Asian J Pharm Clin Res*, *10*(1), pp.22-24.
Jain, S., Jain, V.K., Jain, V. and Sharma, R., 2020. MODERN APPROACHES IN PHARMACOVIGILANCE SYSTEM IN INDIA TO ASSURING DRUG SAFETY. *FOR HEALTHCARE PROFESSIONALS: SCOPE AND OPPORTUNITIES*, p.151.
Dass, A.P., Desai, S. and Kaniganti, S., 2018. Assessment of knowledge, attitude, and practice of pharmacovigilance among clinicians and postgraduate students in a teaching medical institution-A questionnaire study. *National Journal of Physiology, Pharmacy and Pharmacology*, *8*(5), pp.619-619.