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CONCEPTS OF PHARMACOVIGILANCE

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ABSTRACT

Pharmacovigilance play an important role in the healthcare system through monitoring and interaction of drugs and there effects in the human body. In this article includes good manufacturing practices (GCP) and (ICH) guidelines for pharmaceuticals for human use are examined as an important aspects in the transformation of clinical trial to the objective of pharmacovigilance In pharmaceutical production India becomes third largest country in the world. Nowadays in India pharmacovigilance gives awareness about adverse drug reactions (ADR) and this review gives information about implementation for solving current problems. This article summarized objective and methodology used in pharmacovigilance with their overview of existing in India and their challenges and future expectance.(4) In India, a proper adverse drug reaction monitoring system was started in 1986 with 12 regional centres. In 1997, India Became the member of World health organization Programme for International Drug watching managed by the Upsala Monitoring Centre, Sweden. At origination, 6 regional centres were created in Mumbai, New Delhi, Kolkata, Lucknow, Pondicherry, and Chandigarh for ADR watching within the country. Promoting safe use of drugs may be a priority of Indian Pharmacopoeia Commission that functions as the National Coordination Centre for Pharmacovigilance Programme of India. Today, 179 adverse drug reactions monitoring centrespresently report adverse events to National coordinative centre in India.(5)

1. INTRODUCTION

Pharmacovigilance is the science and exercises identifying with location, appraisal, comprehension and counteraction of antagonistic impacts or some other medication related issues. These unfriendly medications responses (ADRs) add to enduring of patients as well as increment dreariness and mortality alongside a monetary weight on society.(1)To limit the experiencing of the patients ADRs, however troublesome, it is fundamental to build up relaxed connection between the medication and the occasion which is the causality assessment relationship between a medication treatment and the event of an antagonistic even.(2)It is a significant part of pharmacovigilance, adding to better assessment of the danger advantage profiles and is a fundamental piece of assessing ADR reports in early notice frameworks of medications also, for administrative purposes. Response and antagonistic occasions is a significant instrument for social event the wellbeing information for early discovery, it is broadly acknowledged that a medication needs to go through different periods of preliminary to build up its security and viability before it is showcased financially. Be that as it may, the clinical preliminaries offer different restrictions, as; severe measures of incorporation and rejection make it to be utilized in an exceptionally specific gathering of patients: unique populace bunches like children, pregnant woman, and development populace are not considered during the preliminaries; and other element causing drug responses. like hereditary variables, ecological factors, and medication drug connections might not have been contemplated during the clinical preliminaries.(3)These adverse drug reactions (ADRs) not only make patients' lives more difficult, but they also increase morbidity and mortality, putting a financial strain on society. In hospitalised patients, the overall incidence of ADRs is predicted to be 6.7 percent (0.1-0.85 percent) Data shows that in patients who have ADRs, death rates are 19.18 percent higher and hospital stays are 8.25 percent longer. The average increase in total medical costs for patients with ADRs was 19.86 percent. These adverse drug reactions (ADRs) not only make patients' lives more difficult, but they also increase morbidity and mortality, putting a financial strain on society. In hospitalised patients, the overall incidence of ADRs is predicted to be 6.7 percent (0.1-0.85 percent) Data shows that in patients who have ADRs, death rates are 19.18 percent higher and hospital stays are 8.25 percent longer. The average increase in total medical costs for patients with ADRs was 19.86 percent. girl who had undergone chloroform anaesthesia for the removal of an ingrown toenail. In 1950, reports of cases of aplastic anaemia associated with the use of chloramphenicol were recorded in the United States of America [USA]. As a result, the Council on Drugs of the American Medical Association set up a Blood Dyscrasia Registry and, by 1961, the Food and Drug

Administration (FDA) began the systematic collection of reports of all types of ADRs, chiefly through the Hospital Reporting Program. However, it was a letter from Dr WG McBride which was published in the Lancet suggesting a connection between congenital malformations in new-born infants and the drug thalidomide that provided o ne of the most significant carta lists for drug safety monitoring. Thalidomide was first synthesized in 1954, introduced to the public in 1956 and was widely prescribed as a harmless treatment for morning sick ness and nausea. By November 25, 1961, thalidomide was withdrawn from the market by its manufacturer. It has been estimated that between 6000 and 12 000 children had been born with serious congenital malformations as a result of maternal use of thalidomide. By 1968, ten countries (Australia, Canada, Czechoslovakia, Germany, The Nether lands, Ireland, New Zealand, Sweden, United Kingdom, and USA), with national drug monitoring centres, collaborated and joined the World Health Organization (WHO) Pilot Research Project for International Drug Monitoring . In 1972, a report was published that formed the basis of the current international system of national centres collaborating in the WHO programme.The establishment of a pharmacovigilance system is essential to support public health policy. The study of Olsson et al

, in which data regarding pharmacovigilance activities were collected from 55 low- and middle-income countries, revealed that information gathered through these activities was used in variable ways by the countries to assist regulatory functions, advise consumer groups and develop essential medicine lists and drug therapy guidelines.(6) ADR is the sixth leading cause of death in India, which has a population of 1.35 billion people and is the world's fourth largest manufacturer of doctor-prescribed medications, with over 6000 authorised manufacturers and over 60000 marked formulations on the market. ADRs account for 3-7 percent of emergency clinic confirmations in the United States. Between 1999 and 2008, ADRs were projected to account for 1% of all clinic affirmations in England. ADRS are also common in the Australian human services environment, accounting for about 1% of medical clinic admissions. The Indian Pharmacopoeia Commission (IPC) facilitates and the Central Drugs Standard Control Organization directs PV activity in India (CDSCO). The IPC's primary responsibility is to maintain and expand the PV. With a disproportionately high number of high-profile drug withdrawals in recent years, both the pharmaceutical industry and various regulatory authorities around the world have raised existing standards. Early recognition of indicators from post-marketing reconnaissance studies and early-stage clinical trials has now been changed by major pharmaceutical companies in order to notice the risks associated with their therapeutic items as soon as possible under the conditions. If such a hazard exists, robust risk managementprocedures must be implemented throughout the product's life cycle to effectively deal with the threats. These dangers are also called as Risk Minimization Programs/Strategies in the executive's plans. Thalidomide, which was reintroduced through the S.T.E.P.S. program (System for Thalidomide Education and Prescribing Safety) for multiple reasons including Myeloma and Lepra reactions, is a famous example. The ability to recognize signals and manage/minimize risk has been developed. (4)The pharmaceutical industry, as well as numerous regulatory authorities throughout the world, have increased the bar in response to a relatively high number of recent high-profile drug withdrawals. Major pharmaceutical corporations have incorporated early detection signals from post-marketing surveillance studies and clinical trials in early phases to discover dangers connected with their medicinal products as early as possible. If such a risk exists, it must be successfully managed throughout the product's life cycle using powerful risk management plans. Risk minimization is another name for these risk management strategies. PV is particularly worried about adverse drug reactions (ADRs), which are harmful and unanticipated medication reactions that occur at levels typically used for disease prevention, diagnosis, treatment, or alteration of physiological function. Drug effects, side effects, contraindications, and blatant contraindications are all continuously monitored. To maximise benefits while minimising hazards, both longevity and mortality are required. When a drug is marketed and prescribed to vast populations across the country and abroad, no amount of caution and care during the preclinical and clinical testing stages can guarantee absolute safety. Because clinical studies typically involve tens of thousands of individuals, less common side effects and adverse drug reactions (ADRs) are frequently unknown when a medicine is introduced to the market. To discover the links between medications and ADRs, post-marketing PV use approaches such as data analysis of case reports. During the drug development process and later during the life of a marketed medicine, drug regulatory agencies are responsible for having a well-established PV system to monitor ADRs.

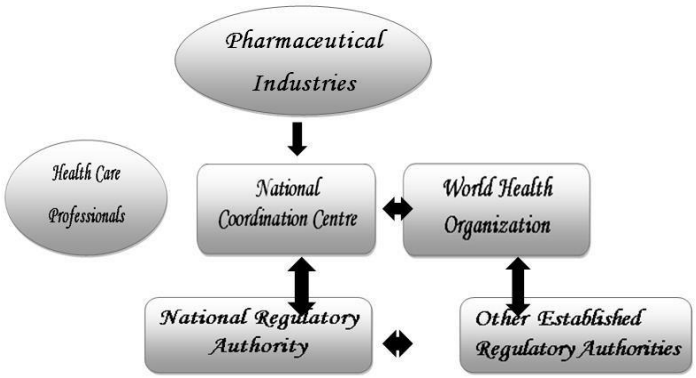

Fig 1 : Diagrammatic representation of the pharmacovigilance.

2. HISTORY

1747	James Lind was the first to describe clinical trials demonstrating the efficacy of lemon juice in treating a variety of ailments.

1937	107 children have died as a result of sulfanilamide poisoning.
1950	Chloramphenicol-induced aplastic anaemia has been reported.
PHARMACOVI1961	GILANCE – A REVIEW Toxicity of thalidomide has resulted in a global calamity.
1963	The 16th World Health Assembly recognises the importance of swift action on adverse drug reactions (ADR).
1968	WHO pilot research project for international drug monitoring
1996	In India, clinical trials to international standards have begun. India has become a member of the World Health Organization's Adverse Drug Reactions
1998	India was the first country to use pharmacovigilance.
2002	India was the first country to use pharmacovigilance.
2004	India was the first country to use pharmacovigilance.
2005	In India, systematic clinical trials are conducted
2009 – 2010	PvPI Initiated

3. BRIEF HISTORY OF PHA RMACOVIGILANCE IN INDIA

PV is not a new notion; it has been warned since the time of Charka Samhita in 700 BC that a fully understood but wrongly administered medicine is a poison, and Vagbhatta, a physician, described adverse events, rationale, and delayed ADRs to Ayurvedic Drugs' approximately 500 AD. Many reports of ADRs from India have since been discovered in the history of modern medicine, but there has been no systematic effort to monitor ADRs since the primary trial was established in 1989.Despite the fact that pharmacovigilance is still in its infancy in India, it is not a new concept. A formal adverse drug reaction (ADR) monitoring system for India, consisting of 12 regional centres covering a population of 50 million people, was proposed in 1986. But nothing happened for another decade, until India joined the World Health Organization's (WHO) Adverse Drug Reaction Monitoring Program in Uppsala, Sweden, in 1997. A National Pharmacovigilance Centre at the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi, and two WHO specialfacilities in Mumbai (KEM Hospital) and Aligarh were identified as

three centres for ADR monitoring, all of which are headquartered in teaching hospitals (JLN Hospital, Aligarh Muslim University). These centres were supposed to report ADRs to India's drug regulatory authority. The main function of these facilities was to keep track of ADRS for drugs sold in India. This was a failed attempt.(7) The commencement of pharmacovigilance in India goes back to 1986, when a lineal adverse drug reaction (ADR) observance system consisting of 12 regional centres, each covering a population of 50 million, was planned for India.India connected with the World Health Organization's (WHO) Adverse Drug Reaction (ADR) Monitoring Programmed based in Uppsala, Sweden in the year 1997. In India, for the observation of Adverse Drug Reaction (ADR's), there were three primary centers known (5)

1. A National Pharmacovigilance Centre in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi
2. WHO special centers in Mumbai (KEM Hospital).
3. Jawaharlal Nehru Hospital, Aligarh Muslim University, Aligarh.

ADRs are reported to India's drug regulatory authorities, the CDSCO (Central drugs standard control organization). These centres' main task was to track adverse drug reactions (ADRs) to prescription medications sold in India. However, they scarcely functioned since information about the requirement to report ADRs and the components of these monitoring centres had yet to reach prescribers, and there was a lack of government funding. This endeavour was unsuccessful, and the WHO-supported and World Bank-funded National Pharmacovigilance Program for India began operations on January 1, 2005. The National Pharmacovigilance Advisory Committee, based at the Central Drugs Standard Control Organization (CDSCO) in New Delhi, intended to oversee the National Pharmacovigilance Program, which was established in January 2005. The South-West zonal centre (located at the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital) and the North-East zonal centre (located at the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital) are the two zonal centres.(6)

4. OBJECTIVES OF PHARMACOVIGILANCE

- To establish a national patient safety reporting system.
- To find and analyse the new signal ADR that has been reported in the cases.
- To examine the benefit-to-risk ratio of commercially available drugs.
- To compile evidence-based information on drug safety.
- To assist regulatory agencies in making decisions about the use of medications.
- To disseminate information about how to take drugs safely to a variety of stakeholders in order to reduce the risk.
- Establishment of a national pharmacovigilance centre of excellence.
- To collaborate with other national exchange centres of data and information management.
- Provide training and consulting to other national pharmacovigilance centres around the world. (5)

5. SCOPE OF PHARMACOVIGILANCE

Prior to the registration and sale of pharmaceuticals in the country, their safety and efficacy are evaluated based on their use in clinical studies. In the general, these trials notice similar ADR. Some critical reactions, such as those that take a long time to develop or occur infrequently, may go undetected in clinical trials. Furthermore, the controlled3 conditions under which drugs are tested in clinical trials do not necessarily reflect how they would be used in practise. To be considered safe, a drug's projected benefits must outweigh any related risks of negative side effects. A continuous post- marketing monitoring system, i.e. PV, is essential for achieving a comprehensive safety profile of drugs. PV uses information from a variety of

sources to monitor the security of pharmaceuticals. These include ADRs that occur on their own. These embrace spontaneous ADRs coverage mechanism; medical literature published worldwide; action taken by regulative authorities in alternative countries. Since there exist substantial social and economic consequences of ADRS and there fore the positive benefit/cost magnitude relation of implementing applicable risk management -there may be a have to be compelled to interact health care professionals and therefore the public at massive, during a well-structured programme to make synergies for watching ADRS within the country. The aim of the PvPI is to col late data, method and analyse it and use the inferences to advocate regulative interventions, besides human action risks to health care professionals and therefore the public.(5)

Aims of Pharmacovigilance –

- Contribute to the evaluation of medical benefit efficiency and risk.
- To improve public safety in the face of new medications.

- Encourage community members to communicate in a healthy manner.
- A To encourage the use of medications in a reasonable and safe manner.
- Drug efficacy and monitoring of drug side effects.
- Pharmacovigilance guards against adverse drug reactions.
- Improve public health and safety by increasing public wareness, ducation, and clinical training in the field of pharmacovigilance.
- The identification of subgroups of patients who are at higher risk of ADRs (dosage, gender, age, and underlying condition).
- The continuous monitoring of a product's safety during its use to ensure that the risks and benefits remain acceptable. This includes the monitoring of safety following the approval of important new indications.
- The adverse drug reaction profile of products in the same therapeutic category class.
- Detecting and preventing the misuse of prescriptions.
- The pharmacological/toxicological qualities of a product, as well as the process by which it causes adverse drug reactions, are being studied further.
- The discovery of substantial drug-drug interactions between new medications and co-therapy with existing market agents, which may only be discovered after widespread use.

6. IMPORTANCE OF PHARMACOVIGILANCE

When a pharmaceutical drug is introduced in the market there are still a lot of things that are unknown about the safety of the new drug. These medicines are used by various patients for different diseases who might be using several other drugs and must be following different traditions and diets which may adversely affect the impact of medicine in them. Also the same medicine might differ in the manner of their production and ingredients. Additionally adverse drug reactions might also occur when drugs are taken along with traditional and herbal medicines which should be monitored through pharmacovigilance. In some cases, adverse drug reactions of certain medicine might occur only in one country or region. To prevent all undue physical, mental and financial suffering of patients, pharmacovigilance proves to be an important monitoring system for the safety of medicines in a country with the support of doctors, pharmacists, nurses and other health professionals of the country.

The importance of pharmacovigilance is as follows.

- Safety monitoring of medicinal products.
- Pharmacoepidemiological studies.
- Clinical trials.
- Case studies.
- Creating a case study series.
- Case-by-case analysis.
- Data mining is used to find product-event combinations.
- Reporting on the spur of the moment.

ADVERSE DRUG REACTION –

Adverse drug reactions (ADRS) are unanticipated and harmful reactions to a health product that occur at levels commonly used or tested for the diagnosis, prevention, or treatment of disease or the altering of an organic function. Because the medicine contains multiple chemicals, it is difficult to identify the causative agent for adverse drug reactions (ADRs). Adverse drug reactions (ADRs) can occur with any drug, and there is a risk whenever a drug is given. When deciding whether or not to employ a certain treatment in a given patient, the importance of risk must be weighed against the importance of potential therapeutic benefit. Adverse drug responses (ADRs) can occur rapidly, after a long period of medication, or even after the drug has been discontinued. Adverse drug reactions (ADRs) are not uncommon; a 10-to-25 percent incidence has been reported. Different clinical settings and are more common with the multiple drug therapy . Adverse drug reactions (ADRs) have been classified into two ways:

- Foreseeable (Type – A) Reaction

- Unpredictable (Type – B) Reaction

A) Predictable (Type-A) Reactions

These are based on pharmacological properties of drugs but quantitatively normal response to the drug which include side effects, toxic effects and consequences of drug withdrawal.

Example- Beta-blocker cause Bradycardia.

B) Unpredictable (Type-B) Reactions

These are based on individuality of patient and not on drug's known actions; include allergy and idiosyncrasy. They are less common, non dose dependent, which is often more problematic and necessitates drug withdrawal Penicillin.

Example- can cause anaphylaxis while anticonvulsants cancausehypersensitivity.

A list of some suspected and known drugs associated with adverse effect:

Drug	Adverse Drug Reactions(ADRs)
Thalidomide	Phocomelia, Multiple defects
Methotrexate	Multiple defects, Foetal death
Androgen	Virilization,limb,esophageal, Cardiac defects
Progestins	Virilization of female foetus
Stilboestrol	Vaginal carcinoma in teenage female offspring
Tetracyclines	Discoloured or deformed teeth, retarded bone growth
Warfarin	Nose,eye and hand defects, growth retardation
Phenytoin	Various malformations
Lithium	Foetal goiter, cardiac and otherabnormalities
Aspirin/Indomethacin	Premature closer of ductus arteriosus

Quinidine	Ringing in ear
Alcohol	Low IQ baby, growth retardation
Carbamazepine	Neural tube defects
Rifampicin	Orange color urine
Chloramphenicol	Grey baby syndrome.
Anticancer drugs	Cleft palate, multiple defects
Valproate sodium	Spina bifida,limb abnormalities
Isotretenoin	Heart and CNS defects

Table 2 – known Drug and its adverse effect.

7. ADVERSE DRUG REACTIONS (ADRS) REPORTING –

The most typically connected wi Reactions (ADRs)/ Adverse Event amount of resources from governme safety departments in pharmaceut data maintenance, review, distrib data are all covered under AE support programmes, reports fr spontaneous reports from health intermediaries, reports from lit including social media and web sit authorities themselves. For pharm that is crucial in determining

th Pharmacovigilance (PV) is Adverse Drug (AE) Reporting, which consumes a substantial nt agencies, drug regulatory bodies, or drug ical corporations . The reception, triage, ution, and reporting of adverse event (AE) reporting. Requested reports from patient om clinical or post-marketing studies, care professionals or patients or other erature sources, reports from the media, es, and reports reported to drug regulatory aceutical companies, AE reporting gives data the risk-benefit ratio the profile of a specific medication Several parts of Adverse Event (AE) Reporting are as follows:

1. A patient who can be identified.
2. A recognisable source.
3. A possible drug.
4. A negative occurrence.

Pharmacovigilance in India –

India has around 500,000 qualified doctors and 15,000 hospitals with a total bed capacity of 6,24,000 people. It is the world's fourth largest producer of pharmaceuticals. It is quickly establishing itself as a major trial centre in the world. In our country, several new pharmaceuticals are being introduced. As a result, the government requires a robust pharmacovigilance system to protect the people from the potential harm that some of these new pharmaceuticals may bring. The Central Drugs Standard Control Organization (CDSCO), well aware of the gravity of the undertaking, has launched a well-structured and highly interactive national pharmacovigilance programme. It is largely based on WHO recommendations in the publication "Safety Monitoring of Medicinal Products-Guidelines for Establishing and Operating a Pharmacovigilance Center."

The specific aims of pharmacovigilance programmers are to:

- Contribute to the regulatory assessment of benefit, harm, effectiveness encouraging their safe, rational and effective use (including cost effective use).
- Improve patient care and in relation to use medicine and all medical and Para medical interventions.
- Improve public health and safety in relation to use of medicines.
- Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

PV Programme in India —

PV Programme –

- Steering committee, technical support committee, and strategic advisory committee are the administrative bodies.
- Zonal PV centres, regional PV centres, and peripheral PV centres are all examples of national PV centres.
- ADRS monitoring centre: MCI-approved medical college, private hospital health centre, and independent PV Programme In India (PV Programme institution.

Goals of pvpi – Short term goals –

- In India, create and execute a pharmacovigilance system.
- To encourage health professionals to report adverse product reactions.
- Data and case reports are gathered.
- The programmes were held at all MCI-approved medical colleges.

Long-term objectives:

- Expanding the pharmacovigilance programme to include all Indian hospitals and public health programmes.
- Make ADR reporting a requirement for healthcare providers.
- Create a system for electronic reporting.

Drugs banned by cdsco –

Drugs	Reason for ban
Terfenadine	Cause cardiac arrhythmias
Rofecoxib and its formulations	Myocardial infarction was reported
Valdecoxib and its formulations	Heart attack and stroke
Cisaprid	Caused cardiac arrhythmias
Gatifloxacin formulations	Causes hyperglycemia and liver damage
Sibutramine	Cardiovascular risk increase by its use
Dextropropoxyphene + formulation ns	Cardiac toxicity

Adverse Drug Reaction Monitoring Centre (AMC) under pvpi —

ADR's are one of the most common causes of illness and mortality around the world. The costs of therapy and hospitalisation are raised as a result of ADRs, putting a strain on the healthcare system. India is a huge, multi- ethnic, and biodiverse nation. A variety of healthcare institutions Disease patterns are diverse due to the country's diverse geographical breadth. The Indian populace is exposed to Adverse Drug Reactions (ADRs) due to a variety of medical systems. Reactions that may be vastly different from those in other countries. As a result, it is critical. To use a highly specialised approach to assess the safety of drugs in a scientific manner Pharmacovigilance is a term that refers to the monitoring of pharmaceuticals. AS a result, in order to obtain a complete safety profile of medicine in a real-world scenario, ongoing research is required. It is necessary to implement a post-marketing surveillance system, which can be performed by System of Pharmacovigilance Any unfavourable occurrences, both known and undiscovered, can be tracked. The means of this system Recognizing the critical need for a reliable ADR reporting system in Ministry of Health and Family Welfare of India Government of India recasted this programme and shifted the National Coordination Centre at Indian Pharmacopoeia Commission (IPC), Ghaziabad vide an Order dated 15th April, 2011.

The Government of India's flagship drug safety monitoring initiative, the Pharmacovigilance Programme of India (PvPI), regularly monitors adverse drug responses from the use of medicinal products across the country. Recognizing the significance of In recent years, pharmacovigilance has become more important, as has the demand for evidence-based indigenous data for policymaking. The PvPI has established a nationwide network of 395 ADRs as a result of its judgements.

AMCs (Assessment and Monitoring Centres) are located throughout the country. PvPI has been working on an extensive and long-term project. A systematic attempt to collect scientific data on adverse drug reaction monitoring from a variety of sources hospitals to assess the benefits and hazards of pharmaceuticals The accumulated Adverse Event/Adverse Situation At NCC-PvPI, experience data is gathered, compiled, and analysed for ADRs, and IPC serves as a clearinghouse. The National Institutes of Health (NIH) receives a significant amount of evidence-based scientific support. The Central Drug Standards Control Organization (CDSCO) is the regulatory authority for Interventions in the regulatory process It's worth noting that the NCC-PvPI has identified and identified 124 issuances drug safety alerts, 57 Prescribing Information Leaflet (PIL) changes including 7 signals for sensitization of stakeholders. NCC is continuously communicating the findings of PvPI to Central Drugs Standards Control Organisation for regulatory actions. India-specific Individual Case Safety Reports (ICSRs) reported under the umbrella of PvPI is to a tune of about 5 lacs and currently India stands tall in becoming 9th largest contributor of ADR data to WHO database. Moreover, the quality of ICSRs from India is much higher as compared to rest of the world.

Recognising the strength and progressive journey of PvPI in the area of Pharmacovigilance, it is a matter of great honour and pride for the nation that NCC-PvPI has been recognized as the “WHO Collaboration Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services”. PvPI has also been working in close collaboration with other National Health Programmes being run in the country such as National Tuberculosis Elimination Programme (NTEP), National AIDS Control Organization (NACO) and National Vector Borne Disease Control Programme (NVBDCP), Universal Immunisation Programme (UIP) etc.

8. CONCLUSION

The only approach to ensure the safety of a medicine throughout its life cycle is to conduct pharmacovigilance. It is critical because clinical studies are limited in their ability to detect rare and extremely rare ADRs. The knowledge and information available on the safety of any drug is critical for drug regulators to make the best decisions possible to protect public health. ADRs are primarily reported by health-care workers. Globally, however, there is a substantial percentage of under-reporting. It is today's greatest challenge. Despite these drawbacks, the spontaneous reporting system is the most extensively used method for reporting ADRS, and it can generate signals for rare and extremely rare types of ADRs. We can make our world safer than it is now if all health care providers regard ADR reporting as an ethical commitment and a substantial responsibility. Every reporting by health care professionals is important, even though focus on the serious unlabelled types of ADRs is more important. There are significant effects on the pharmacovigilance to make it more functional after the concept has emerged and day by day we are getting closer to the destiny. It is our responsibility to ensure well functioning of pharmacovigilance system. ADR reporting should be taken as a very important duty not as an extra clinical burden by health care professionals to ensure the safer drugs use throughout the world.

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