



Pharmacovigilance System in India

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ABSTRACT

As per WHO, Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Pharmacovigilance (PV) may be a specialized scientific activity that keeps constant watch on the drug and specific or uncommon Adverse Drug Reactions (ADRs) which were undetected during clinical trials. In India, The Central Drug Standard control organization (CDSCO) whose headquarter is located at New Delhi regulate the PV activity. For smooth and effective working of PV a Pharmacovigilance Program of India (PvPI) was proposed and implemented by government of India in 2010. This assessment provides an outline of the PV system in India, focusing on the current picture, its development, the challenges faced, and the interventions recommended for its improvement. The Pharmacovigilance Program of India (PvPI) is playing a serious role in gathering drug safety related data and adding it to the WHO database. PvPI fulfill the minimum requirements specified by the WHO for any functional national Pharmacovigilance system. The Indian Pharmacopoeia Commission (IPC) is that the national coordinating center under PvPI. PV in India relies primarily upon the spontaneous reporting of adverse drug events. The key confront for PV in India is under-reporting. PvPI established various regional, zonal and peripheral ADR reporting centres for accurate reporting of ADR. It was cleared that any person who detected ADR can report to the nearest centre by filling Suspect ADR Reporting Form or via telephone and email etc. The reported ADRs are collected and processed at the respective centres in Vigi-flow software. The associate at these centres detect signal, reported to CDSCO and World Health Organization (WHO) for the further regulatory action. CDSCO-WHO individually or in collaboration communicates their decision via newsletter, media, journal or official website in favour of public health. However, there is a development in the number of submitted reports after regular training and awareness programmes, which have been conducted by the IPC. The amplification of PV activities in India demands particular consideration in health science curricula. Indeed, a change in state of mind is necessary for prescribers, patients, regulatory agencies, and pharmaceutical companies.

Keywords: Pharmacovigilance, Adverse Drug reactions, Pharmacovigilance program of India, Central Drug Standard Organization, Under –reporting, Uppsala monitoring center, India.

INTRODUCTION

Pharmacovigilance is a system to monitor the safety and effectiveness of medicines and other pharmaceutical products. As per WHO Pharmacovigilance is “science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems”¹. Pharmacovigilance is an essential and integral part of clinical research. Both clinical trials safety and post marketing Pharmacovigilance are critical throughout the lifecycle of the product. The main goal of Pharmacovigilance is thus to promote the safe and effective use of health products, in particular by providing timely to patient, health-care professionals, and the public². There is an immense need to understand the importance of Pharmacovigilance and how it impacts the life cycle of the product. This will enable integration of good Pharmacovigilance practice in the processes and procedures to help ensure regulatory compliance and increase clinical trial safety and post-marketing surveillance. The rapid identification of any adverse effects to medicines is essential and the data produced from the investigation should be assessed in order to

reduce risks in the future use of the product. . Pharmacovigilance (PV) was officially introduced in December 1961 in the Lancet by W. McBride, the Australian doctor who first suspected a causal link between serious fetal deformities (phocomelia) and thalidomide; a drug used during pregnancy, thalidomide was used as an antiemetic and sedative agent in pregnant women. In 1968, the World Health Organization (WHO) promoted the “Programme for International Drug Monitoring”, a pilot project aimed to centralize world data on adverse drug reactions (ADRs). In particular, the main aim of the “World health organization (WHO) Programme” was to identify the earliest possible Pharmacovigilance (PV) signals.

Terminology

Adverse Event

An adverse event is defined as any untoward medical occurrence that may present during treatment with a drug but which does not necessarily have a relationship with its use.



Adverse drug reaction

An adverse drug reaction (ADR) is any noxious, unintended and undesired effect of a drug, which occurs at a dose used in human for prophylaxis, diagnosis, therapy or modification of physiological function.

Post marketing surveillance

Post-marketing surveillance (PMS) is the practice of monitoring the safety of a pharmaceutical drug or device after it has been released in the market.

Clinical trials

Clinical trials are sets of tests in medical research and drug development that generate safety and efficacy data (or more specifically, information about adverse drug reactions and adverse effects of other treatments) for health interventions (e.g., drugs, diagnostics, devices, therapy protocols).

Safety signals

Safety signal refer to a concern about an excess of adverse events compared to what would be expected to be associated with products use, which can arise from post marketing data and other sources, such as pre-clinical data and events associated with other products in the same pharmacological class³.

Major Aims of Pharmacovigilance Are

- To improve patient care and safety in relation to the use of medicines and all premedical interventions,
- To improve public health and safety in relation to the use of medicines,
- To improve public health and safety in relation to the use of medicines,
- To contribute to the assessment of benefit, harm ,effectiveness ,and risk of medicines, encouraging their safe, rational and more effective use,
- To promote understanding, education, and clinical training in Pharmacovigilance and its effective communication to health professionals and the public.

History of Pharmacovigilance in India

In 1962, international center for monitoring of Adverse Drug Reaction by WHO was recognized in Geneva, which was later shifted to Uppsala in Sweden and this is the beginning of Pharmacovigilance. From then, the WHO supported Uppsala monitoring centre has spread headed many activities of Pharmacovigilance all over the world. Pharmacovigilance is still in its infancy in India and there exists very inadequate knowledge about the regulation. India does not have any formal PVG system. In the past to detect Adverse Reactions to drugs as only few drugs were discovered in India. India's regulatory agencies based

their safety assessment of drugs on data derived from long term use in US, EUROPE & JAPANESE MARKETS. Formal PVG activities were initiated in India around 1986. In 1997 India joined the Adverse Drug Reaction monitoring program of WHO below are some good Pharmacovigilance practices which set a measures to facilitates safety monitoring of medicines^{4,5}.

Good Pharmacovigilance Practices (GVP)

Good Pharmacovigilance practices are a set of measures drawn up to facilitates the performance of the safety monitoring of medicines .Abbreviated as GVP.GVP are a set of measures drawn up to facilitates the performance of Pharmacovigilance in the countries. GVP apply to marketing authorization holders, the European Medicines Agency and medicines regulatory authorities in the EU member states. They cover medicines authorized centrally via the agency as well as molecules authorized at the national level.

Guidelines on GVP

The guideline on GVP is divided into chapters that fall into two categories:

- ✚ Modules covering major Pharmacovigilance processes,
- ✚ Product-or population-specific consideration.

The guide on GVP is a key deliverable of the 2010 Pharmacovigilance legislation.

GVP modules I to XVI cover major pharmacovigilance processes,

Module-I: Pharmacovigilance system and their quality systems

Module-II: Pharmacovigilance system master file

Module-III: Pharmacovigilance inspection

Module-IV: Pharmacovigilance audits

Module-V: risk management system

Module-VI: management and reporting of adverse reaction to medicinal products

Module-VII: periodic safety updates report

Module-VIII: post –authorization safety studies

Module-IX: signal management

✚ Module-IX(A)

✚ Module-IX(B)

Module-X: additional monitoring

Module-XI: public participation in Pharmacovigilance

Module-XII: continuous Pharmacovigilance, ongoing benefit-risk, evaluation, regulatory action and planning of public communication

Module-XIII: incident management



Module-XIV: referral procedures for safety reasons

Module-XV: safety communication

Module-XVI: risk minimization measures; selection of tools and effectiveness indicators

Facilities for increasing activity

Number of efforts has been taken by NCC-PvPI for the enhancement of the reporting of ADR. India is now a well connected nation in terms of telecommunication and internet. Considering this connectivity PvPI on 11 October, 2013, started toll free helpline number (1800 180 3024) and on 15 May, 2015 launched Android Application for faster reporting of ADR. To increase

ADR Reporting Criteria

What to report	When to report?	Who to report	How to report	Where to report
-Life-threatening or death -Hospitalization -Congenital anomaly - Medically-significant - Lack of efficacy -All serious /non serious reactions	<ul style="list-style-type: none"> • Non serious cases within 30days. • All serious or death event as soon as possible and within 7 days 	Medical specialists Pharmacists Dentists Midwives	ADR reporting form - Toll free number: 1801803024 E-mail: pvpi@ipcindia.net	-Nearest AMC -Various Zonal offices: East Kolkata, West Mumbai, North Ghaziabad, South Chennai; Or directly to CDSCO/WHO

National Pharmacovigilance Program

The NATIONAL PHARMACOVIGILANCE PROGRAMME (NPP) was launched by CDSCO on 23 November 2004 to improve the current state of functioning of Pharmacovigilance agency. Which became operational from 1 JAN 2005? The NPP was based on the recommendation made in the WHO document titled "SAFETY MONITORING OF MEDICINAL PRODUCTS-GUIDELINES FOR DCGI & approved by ministry of health & family welfare vide orders dated 12th March 2004. However due to some technical difficulties the NPP had to be closed in 2008. It was again resurrected as the PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI) in 14/07/2010 due to the keen efforts of personnel working in this field. Under the PvPI-AIIM, New Delhi was the National Co-coordinating centre; with two zonal centres; five regional centres & an increasing number of peripheral centres. In order to ensure implementation of the programme in a more effective way at NCC at AIIMS New Delhi was shifted to INDIAN PHARMACOPOEIA COMMISSION, GHAZIABAD on 15/04/2011.

Peripheral Pharmacovigilance centers

Primary pharmacovigilance's centers. Relatively smaller medical institutions including individual medical practitioners' clinics, private hospitals, nursing homes, pharmacies etc. First contact ADR data collection unit at a health care facility. They would be identified and coordinated by RPCs / ZPCs in consultation with CDSCO.

Regional Pharmacovigilance Centers (RPCs)

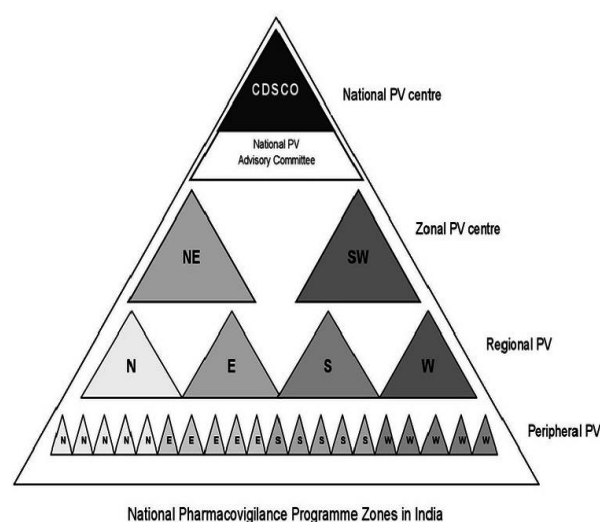
Secondary Pharmacovigilance centers. Relatively larger healthcare facilities attached with medical colleges. They

interest of consumer and Health Care Professionals (HCPs) a feedback letter or form facility was started. All the universities incorporated PV as curricular subject and some private institution have started providing professional courses and training on PV. India is a multi-linguistic nation, for the better understanding of consumer, reporting forms are prepared in vernacular languages which are available 24 × 7 on official website (pvpi.compat@gmail.com). In India it is mandatory for the Marketing Authorization Holders (MAH) to submit PSUR (Periodic safety update reports) to CDSCO twice a year for 2 consecutive years; this attempt helps to collect safety data of on-going marketed product regularly⁶.

would act as second level centers in the administrative structure of the npvi. They will function as first contact adr data collection units also. They would be identified and coordinated by zpcs in consultation with the CDSCO.

Zonal Pharmacovigilance: The Centre (ZPCs)

Tertiary Pharmacovigilance centers. Large healthcare facilities attached with medical colleges in metro cities identified by the CDSCO for the purpose. They would act as third level centers in the administrative structure of the NPPI. They will function as First contact ADE data collection units.



Mission

To safeguard the health of the Indian population by ensuring that the benefits of use of medicines outweigh the risks associated with its use.

Vision

To improve patient safety & welfare in the Indian population by monitoring the drug safety & thereby reducing the risk associated with use of medicines.

Objectives

- To create a nation-wide system designed for patient safety reporting.
- To identify & analyze the latest signal (ADR) from the reported cases.
- To analyze the benefit risk ratio of marketed medications.
- To generate evidence based information on safety of medicines.
- To support the regulatory agencies in the decision making process on use of medicines.
- To communicate the safety information on use of medicines to various stakeholders to minimize the risk.
- To emerge as a national centre of excellence for Pharmacovigilance activities.
- To collaborate with other national centres for the exchange of information & data management.
- To provide training & consultancy support to other national Pharmacovigilance centres located across globe.

Short Term Goals

- To develop & implement Pharmacovigilance system in India.
- To enroll initially all MCI approved medical colleges in the programme covering north, south, east, & west of India.
- To encourage healthcare professionals in reporting of adverse reaction to drugs, vaccines, medical devices & biological products.
- Collection of case reports & data.

Long Term Goals

- To expand the pvg programme to all hospitals (govt & private) & centres of public health programmes located across India.
- To develop & implement electronic reporting system (e-reporting).
- To develop reporting culture amongst healthcare professionals.

- To make ADR reporting mandatory for health care professionals.

Year Roadmap of Pharmacovigilance Programme of India (YEAR 2010-2015)

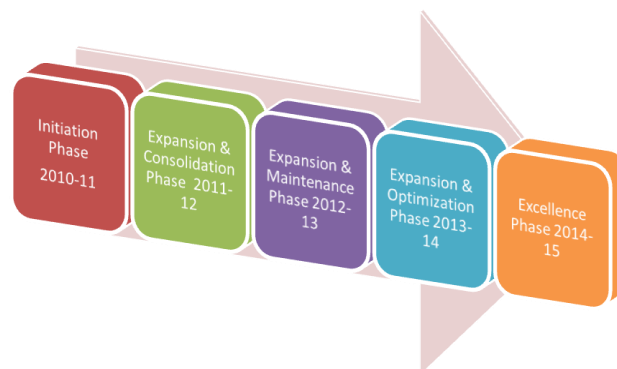


Figure 2: Roadmap

Current Scenario of Pharma Pharmacovigilance

India is an immense country and there are a drug brands more than 6,000 licensed drug manufacturers and over 60,000 branded formulations. India is the fourth leading producer of pharmaceuticals in the world and is also emerging as a hub for clinical trials. Many latest drugs are being introduced in the country, so there is a vast need to advance the Pharmacovigilance system to protect the Indian population from potential harm that may be caused by various new drugs⁵. In the earlier period, India's regulatory agencies and drug companies based on their safety assessments on experiences derived from long-term drug use in the Western markets and there was no valid urgency for the government to set up a strong Pharmacovigilance system of its own. In recent years, however, the interval between when a drug is to be founded in the market and its later accessibility in India has decreased considerably so that the much required longer-term safety data is no longer available. In addition, India-based drug companies have increased their ability to develop and start new drugs through their own research efforts and this has heightened the importance of developing sufficient internal Pharmacovigilance standards to notice adverse drug events. Inspections in all pharmaceutical companies working in India. All pharmaceutical companies should be instructed to maintain and submit to the DCGI the review of Pharmacovigilance System document operating within the company, which would serve as the base for upcoming Pharmacovigilance inspections. A high-level discussion with a combination of stakeholders, i.e., Ministry of Health and Family Welfare (MHW), Indian Council of Medical Research (ICMR), Medical Council of India (MCI), Pharmacy Council, Nursing Council, Dental Council, Pharmaceutical Companies, Consumer Associations, Nongovernmental Organizations (NGOs) and Patient Groups should be initiated in order to make them attentive of how the drug control general of India (DCGI) is planning to improve and develop a full-bodied system in Pharmacovigilance strengthen the DCGI office with

trained scientific and medical assessors for Pharmacovigilance Intensive training should be given in all aspects of Pharmacovigilance to officials working within the Pharmacovigilance department of the DCGI and in the peripheral, regional and zonal centers. This should be a continuing activity with training scheduled twice a year. Creating a single countrywide definite adverse event reporting form to be used by all.

A single countrywide specific adverse event reporting form needs to be considered should not only be used by the National Pharmacovigilance Centers, but also by all registered hospitals (both private and government), teaching hospitals, Drug Information Centers and pharmacies all over the country. It should also be made available to all primary healthcare centers (PHCs) in rural areas and all practicing general practitioners and physicians. Creating a clinical trial and post-marketing database. ADRs for signal detection and access to all relevant data from various stakeholders' full complete data should be made accessible to the DCGI and to the various stakeholders from the date of first registration of the clinical trial in the India. This data should comply with consolidated standards of reporting trials guidelines including overall benefit-risk profile of the product. Current standards of safety reporting as outlined in Schedule and information about all adverse events (AEs) and adverse drug effects (ADRs) per study arm should be thoroughly included as well as detailed description of cases with previously unknown 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 also added to the summary of product characteristics (SPCs). List all new drug indications by maintaining a standard database for all pharmaceutical company a list should be maintained by the regulatory authorities and pharmaceutical companies for every new drugs indication in the database. All new issues have to be set under heightened surveillance. Pharmaceutical companies in these circumstances should have meetings set up with the DCGI to outline their risk management plan (RMP) for the safety issues in question and explain how they would put effective strategies in place to mitigate the Education and training of medical students, pharmacists and nurses in the area of Pharmacovigilance. There are numerous courses conducted by various organizations focusing in clinical research, but to date there is no course relevant to Pharmacovigilance in the country. The various stakeholders including the MCI should include a Pharmacovigilance syllabus within the pharmacology and medicine curricula so that proper theoretical and practical training can be imparted to physicians, similarly, nurses and pharmacists should also be trained in Pharmacovigilance so that they are able to identify adverse drug reaction (ADRs) and extend a culture of reporting ADRs in the future. An awareness program and

a training schedule (both by distance education and face-to-face learning) covering all aspects of Pharmacovigilance. These are intended for the research and development (R and D) based pharmaceutical companies, mostly those involved in new drug research, the medical profession, the pharmacists and chemist-druggist trades and the patients, to be ready to act in detecting ADRs and reporting them to the Indian regulatory agencies, which in turn will investigate and take appropriate corrective action. Collaborating with Pharmacovigilance organizations in enhancing drug safety through advancements in information technology (IT), there has been the emergence of new opportunities for national and international collaborations that can enhance post-marketing surveillance programs and enhance drug safety. The Uppsala Monitoring Center (UMC) is an example of an international collaboration to establish a harmonized post-marketing surveillance database. The system is based on the exchange of adverse reaction information among national drug monitoring centers in 80 countries. The information is transferred, stored and retrieved in a well-timed and secure way through the internet. The UMC database collectively contains over four million records with a huge number of data fields. A similar database can be built for the DCGI with the help of experienced private firms from the safety data acknowledged from clinical trials and post-marketing surveillance. Building a network of Pharmacovigilance and pharmacoepidemiologists in India core group of experts will need to be created which will have representatives from multinational corporations (MNCs), Indian pharmaceutical companies and personnel from the regulatory authority (DCGI). relations with the IT sector in building a robust Pharmacovigilance system for India Software programs developed can be used for collection and analyses of data sets, determining trends of drug usage in various disease areas, compliance, medication errors and drug interactions leading to ADRs⁷.

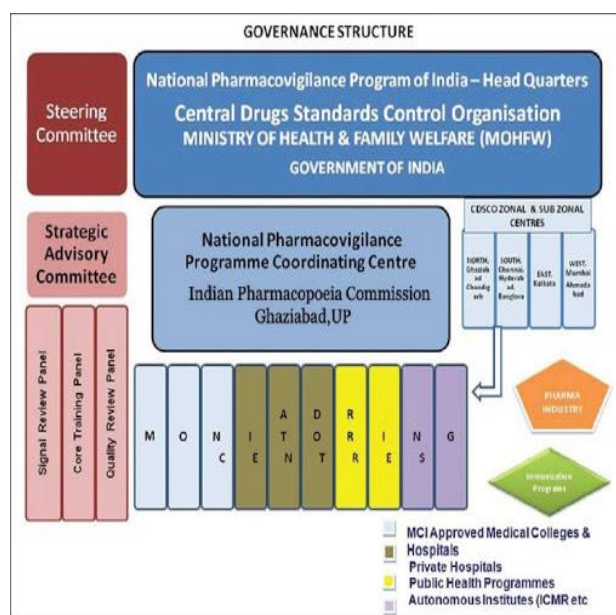


Figure 3: governance structure

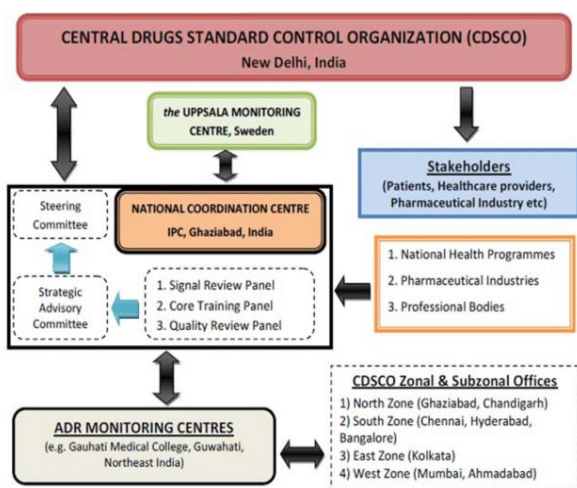


Figure 4: programme communication & flow of ADR reports

Pharmacovigilance Programme in India

In 1986, a formal adverse drug reaction monitoring system having 12 centres was proposed and there was no development and special consideration on the Pharmacovigilance activity. In the year 1997, India Participated in WHO's adverse drug reaction Monitoring Program organized at Uppsala-Sweden. This participation was not sufficient to encourage Pharmacovigilance activity. Hence, on 14th July 2010 the Government of India started the Pharmacovigilance Program for India (PvPI). As part of PvPI, All India Institutes of Medical Sciences (AIIMS), New Delhi selected as National Coordinating Centre (NCC) to safe-guard public health by validating the safety of products. About adverse drug reaction monitoring centres were established in the year 2010 (Fujimoto, 2014) . The NCC was transferred from AIIMS, New Delhi to IPC and Ghaziabad on 15th April 2011 for smooth and efficient functioning of program. Elected eligible medical colleges, hospitals and centres were approved as adverse drug reaction Monitoring Centres (AMCs).

These AMCs collect the Individual Case Safety Reports (ICSRs), analyses and report it to regulatory authority. Till January 2017, 250 AMCs (government and non-government) have been established in PvPI. About 20 Anti-Retroviral Therapy (ART) and 17 Revised National Tuberculosis Program (RNTCP) centres were also established for impulsive adverse drug reaction reporting. The technical associate from Medical Sciences, Banaras Hindu University is an authorized person for collecting ICSR along with its follow up and online database entry in Vigi-Flow software. All the primary health care centres (PHCs) and community health centres (CHCs) submit their adverse drug reaction reports to the regional centre. It was considered that the remedies from natural resource are safe and devoid of adverse drug reaction. But "Charka Samhita", which is the heart of ayurveda illustrates that ADR can occur with herbal drugs also if they are compounded and dispensed improperly. Hence, to put PV

for Ayurveda, Siddha, Unani (ASU) was highly essential to provide ADR data of AYUSH drugs as per WHO guidelines⁸.

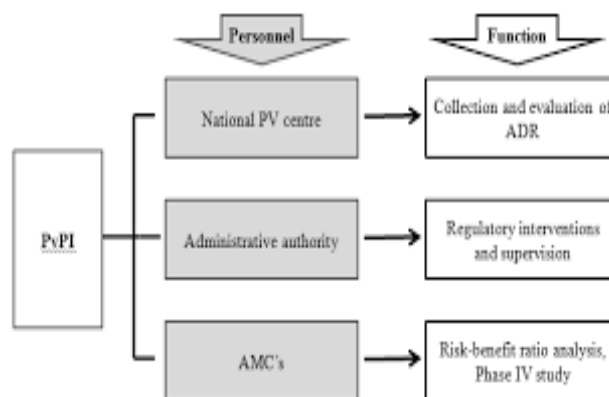


Figure 5: Pharmacovigilance programme in India

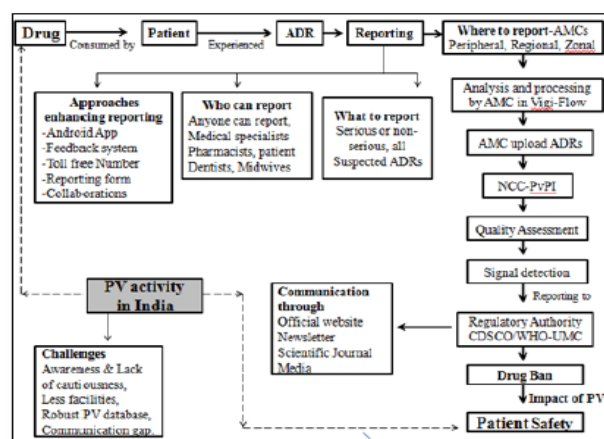


Figure 6: Pharmacovigilance activity

Future prospects

As future prospects increase, PV systems capable to identify new ADRs and taking regulatory actions are desired to protect public health. Little emphasis has been set into generating information that can assist a healthcare professional or a patient in the decision-making process. The gathering and communication of this information is an essential goal of PV Information about the safety of drug active surveillance is necessary. When develop new methods for active post marketing surveillance, one has to consider that the important to collect complete and accurate data on every Serious reported event. Spontaneous reporting is a useful tool in generating signals, but the moderately low number of reports received for a specific association makes it less useful in identifying patient characteristics and risk factors PV methods must also be able to describe which patients are at risk of developing an adverse drug reaction (ADRs). As a source of information, the PV approach would be consistent with the growing patient involvement in drug safety. The PV could play a role in identifying individual risk factors for the occurrence of certain ADRs. In the future, PV has to focus on the patients as a source of information in addition to the

more traditional groups, such as the health professionals. At present, the DCGI should act rapidly to improve PV so as to integrate Good Pharmacovigilance Practice (GPP) into the processes and procedures to help ensure regulatory compliance and enhance clinical trial safety and post marketing surveillance. An appropriately working PV system is fundamental if medicines are to be used carefully. It will assistance healthcare professionals, regulatory authorities, pharmaceutical companies and the consumers. It helps pharmaceutical companies to monitor their medicines for risk. Post-marketing PV is presently a challenging and laborious process, not only industry-wide, but also for regulatory agencies. The aim of the PV is to receive the information, documentation of the work and knowledge online while giving priority to the new and important safety issues. Non serious events have less priority than serious events but important in comparing the changes in health, although they are also screened routinely in present time, GlaxoSmithKline has created a powerful new approach to Pharmacovigilance (PV), integrating traditional, case-based PV methods with disproportionality and data visualization tools. These tools exist within a system framework that facilitates in-stream review, tracking of safety issues and knowledge management. This very modern tool and the processes will help to advance PV by improving efficiency and providing new analytical capabilities. Similar approach may be adopted by pharmaceutical companies for quick detection and analysis of ADRs. Transparency and communication would strengthen consumer reporting, which are positive steps towards involving consumers more in PV^{9,10}.

Other Future considerations are

- Involving professional organizations of healthcare professionals to educate their members about the program important to a sustainable participation.
- Using new communication methods such as email and social media to tap into the patient collection for more effective data aggregation.
- Clearing the legal barriers such as the problem of data privacy while reporting a case, which will in turn enhance the volume of reported cases.
- Address the issue of data possession and data theft issues so as to make case reporting hassle free.
- Increasing the scale of PvPI to that of traditional medicine and treatment modalities such as Ayurveda, Homeopathy and Unani etc.
- Increased focus on drug safety issue on vulnerable population such as children, elderly and pregnant women.

- Create a framework for ADR reporting for alternating medications such as homeopathy, ayurveda etc.
- Incorporate data collection on immunization via public health authorities.
- Develop infrastructure (computers, internet connectivity etc) so that there is maximum reporting and usher in an era of complete reporting.

CONCLUSION

Even though the concept of Pharmacovigilance was present in India form 1980s, unfortunately it was not reachable to everyone and was limited to certain institutions. Because of this it can be said truly that Pharmacovigilance industry in India is still at its infancy. However, there has been a continuous expansion in this field from 2009 and an exponential growth especially from 2012. This trend is due to the hasty growth in the economy, public-private partnerships, policies of regulatory authorities and above all the general awareness of the healthcare practitioners as well as general public. Even though the development is positive, there are many hurdles to be passed. In India Pharmacovigilance (PV) system has increased awareness in people regarding ADR reporting. The issues of underreporting are resolving due to accessible reporting facilities like toll free dial number, message, mail and ADR form in vernacular languages. Different multinational companies have started the outsourcing of PV activity in India which is creating the good Pharmacovigilance (PV) culture. . Pharmacovigilance is comes under drug safety reporting and post marketing surveillance. In this Pharmacovigilance we can report the adverse drug events for efficacy of the drug product.

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