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Review Article

History of Pharmacovigilance in India (1983-2022)

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ABSTRACT

The present paper covers the history of Pharmacovigilance in India. Earlier also, attempts were made to compile the history of Pharmacovigilance, but in bits and pieces. While writing the history of any episode, chapter, or section, one should not be biased and prejudiced. The discipline of Pharmacovigilance in India evolved with the contribution of many scientists, physicians, and administrators. Pharmacovigilance activities in India were started much before the initiation of National Pharmacovigilance Program of India (PvPI). This paper includes not only the settings of initiation of pharmacovigilance activities in India, but also how it evolved through training and teaching in medical and allied health science colleges. Precise details on the initiative of Pharmacovigilance for AYUSH drugs is also placed herewith. It has been tried to compile the entire history chronologically including the description of other sub-specializations of the discipline like human pharmacovigilance, veterinary pharmacovigilance, herbovigilance, cosmetovigilance, materiovigilance, haemovigilance for blood and blood products, and environmental pharmacovigilance.

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INTRODUCTION

Before we start the history of pharmacovigilance in India, it would better if we see the origin of this field of specialization. Pharmacovigilance, a science relating to safety of drugs, helps in promoting the safe use of medications and provides balanced information for the effective assessment of the risk-benefit profile of medicines.

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There must have been several mild, moderate, and serious adverse drug reactions including deaths before the first recorded adverse drug reaction of a patient 15 years old Hanna Greener, who died due to routine chloroform anesthesia on January 28, 1848.[1] Likewise, many episodes occurred in 1937, when Sulfanilamide (Prontosil), already in use since 1932 for treatment of streptococcal infections, was launched as a syrup, containing Diethyleneglycol as a solvent. Although it was tested regarding pharmacokinetic aspect, taste, and odor, but its safety was not evaluated before launching. The drug was responsible for the death of

105 individuals (34 children and 71 adults) and Diethyleneglycol was incriminated.[2] This tragedy caused the American Congress to approve the Food Drug and Cosmetic Act, in 1938 under which pharmaceutical product manufacturers would have to show scientific evidence of the safety of the drugs before releasing them for sale.

For practical purposes, the story of modern pharmacovigilance begins after the incidence of the thalidomide disaster.[3] Thalidomide was a sedative drug, which after years of extensive animal tests, was first marketed as an over-the-counter (OTC) drug. It came to be used by pregnant women in many countries during the late 1950s and early 1960s as a treatment for morning sickness. By the time the drug was banned, more than 10,000 children had been born with the major problem of limb deformities, termed phocomelia from the Greek word for 'seal limbs', including shortening or missing arms with hands extending from the shoulders, absence of the thumb and the adjoining bone in the lower arm and similar problems with the lower extremities. The drug also caused abnormalities in the eyes, ears, heart, genitals, kidneys, digestive tract (including the lips and mouth), and nervous system. This tragedy triggered many minds to actually initiate a system that could measure the adverse effects of drugs. It led to studying the risk management such as fetal malformation by simply avoidance of the drug during pregnancy and another concept that is central to the practice of pharmacovigilance – the balance of risk and benefit. In 1962, after reports of numerous cases of phocomelia, it was discontinued. In the same year, the Kefauver-Harris amendment was approved, requiring scientific evidence of efficacy and safety before drug tests in humans.

WHO Program for International Drug Monitoring (PIDM)

The Sixteenth World Health Assembly (1963) of WHO adopted a resolution (WHA 16.36) to reaffirm the need for early action in regard to rapid dissemination of information on adverse drug reactions (ADRs). In 1968, WHO Program for International Drug Monitoring (PIDM) was launched as a Pilot Research Project to develop a system, applicable internationally, for detecting previously unknown or poorly understood AEs of medicines, which started collecting international ADR reports in a central database (VigiBase™). As per its definition, Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. The WHO PIDM aims are (1) To enhance patient care and patient safety in relation to the use of medicines, and (2) to support public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines. VigiBase is managed and maintained by the WHO Collaborating Centre for International Drug Monitoring, known as Uppsala Monitoring Centre. In October 2021, there were over 28 million reports of adverse reactions in VigiBase. Data in VigiBase are recorded in a structured and comprehensive way to allow the detection of potential medicinal safety hazards. In April 2015, WHO launched VigiAccess. VigiAccess is a new web application that will allow anyone to access information and encourage the reporting of adverse effects from medicinal products.

WHO Collaborating Centre for International Drug Monitoring (WHO-UMC)

In 1978, Uppsala Monitoring Centre (UMC) was established as a WHO Collaborating Centre for International Drug Monitoring to manage the technical and scientific aspects of the program. The WHO Program for International Drug Monitoring (WHO PIDM) is now an international collaboration with the goal to ensure timely identification of medicines-related safety problems using VigiBase™. With more than 170 full members and associate members in the program in 2022, it covers about 99% of the world's population.

Beginning of Pharmacovigilance Activities in India

Scientific Session of IPS on Pharmacovigilance, 1983

As in other parts of the world, when many medical scientists started rational use of medicine and monitoring ADRs in the late 1960s, many eminent pharmacologists of India also started studying ADRs and trying to understand the concept of Pharmacovigilance. It was a clear understanding that all available and approved drugs were not safe and might pose adverse reactions at the therapeutic doses. To create and generate awareness about the problem of adverse reactions at normal doses, a national seminar on pharmacovigilance was organized under the auspices of Indian Pharmacological Society (IPS) during the Silver Jubilee Celebrations program at Maulana Azad Medical College, New Delhi from 21-22 October 1983. Prof. K. K. Agarwal was the organizing secretary. Five sessions on adverse drug reaction were constituted. The group leaders for these five sessions were Dr. K. C. Singhal (Aligarh), Dr. J. D. Sharma (Srinagar), Dr. (Mrs.) G. Satyawati (ICMR, Delhi), Dr. F.S.K. Barar (Jaipur) and Dr. B.N. Dhawan (Lucknow). They had good academic deliberations and realized the importance of the subject.[2]

Afterwards, many scientists like Dr. B. N. Dhawan, Dr. S. A. Dhanukar, Dr. K. C. Singhal, Dr. C. A. Adithan, Dr. N.A. Kshirsagar, Dr. N. J. Gogtay and Dr. S. Z. Rahman published many research papers on this subject from different perspectives in 1990s and 2000s AD.

First Scientific Project of ICMR on Pharmacovigilance in India (1989-1992)

ICMR sponsored the first project on multi-centric monitoring of epidemiological profiles and factors for adverse drug reactions in India for three years from 1989 to 1992 at the Department of Pharmacology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh. The principal investigator was Prof. K. C. Singhal. He, as a coordinator constituted a team comprising of Prof. Sant

Kumar (Aligarh), Prof. K. C. Garg (MAMC, New Delhi), Prof. V. K. Kulshrestha (MLBMC, Jhansi), Prof. Alice Kuruvilla (CMC, Vellore), Prof. V. K. Srivastav (LLRM, Meerut), Prof. J. K. Grover (AIIMS, New Delhi) and Dr. A. K. Kothari (LLRM, Meerut). During these 4 years, information of ADRs captured in a specially designed ADR form (Fig. 1) of more than 58000 patients (approx. 58194) had been collected and submitted to ICMR. Groups of drugs causing ADRs in >50% of patients have belonged to Antipsychotic (76.47%) and Antidepressants (51.14%). Groups of drugs causing ADRs in >15% of patients belonged to Antiamoebic (24.2%), Drugs used in CCU (21.2%), Antiepileptics (21.34%), and Narcotic analgesics (15.6%). Groups of drugs causing ADRs in <15% patients belonged to NSAIDs (14.64%), Antituberculosis (12.9%), Chloroquine (13.5%), Bronchodilators (8.01%), Corticosteroids (9.57%), Drugs for GIT disorders (4.65%), Uterine stimulants (4.1%) and Drugs acting on CVS (3.14%).[2,4]

ICMR Task-force on ADR Monitoring (1993-1999)

ICMR upgraded the first project to "Task-force on ADR Monitoring" from 1.4.1993 to 1999. The study was then carried out at 12 different centres selected on the basis of different geographical regions of the county (ethnic, climate and other variations).[4]

The task-force project was coordinated through the Department of Pharmacology, J. N. Medical College, AMU, Aligarh by Prof. K. C. Singhal. Identified centers have submitted data on ADRs from more than One Lakh patients to ICMR. Following were the centers and their chief investigators during this period:

SNo	Identified Medical College	City	Chief Investigator
1	Baroda Medical College	Vadodara	Prof. K. G. Hemavati/ Prof. K. K. Shah
2	Gandhi Medical College	Bhopal	Dr. V. S. Rao,
3	L. T. M. Medical College	Mumbai	Prof. C. K. Chauhan
4	Govt. Medical College	Guwahati	Prof. H. C. Prasad/ Prof. A. Deka
5	Osmania Medical College	Hyderabad	Prof. C. Indira Devi
6	Govt Medical College	Jammu	Prof. R. K. Raina
7	Govt Medical College	Chennai	Prof. V. Vijaysekaran/ Dr. Annabela Rajsekaran
8	Maulana Azad Medical College	New Delhi	Prof. J. S. Bapna/ Dr. Usha Gupta
9	Govt. Medical College	Thiruvananthpuram	Prof. P. Prem Kumari Devi/ Dr. Zillie Tresa
10	Christian Medical College	Vellore	Prof. Alice Kuruvilla
11	St John Medical College	Bangalore	Prof. Shobha Guido

Multicentric Monitoring of New Drugs (circa 1989-

Parallel to ICMR Multicentric Study, the Ministry of Health and Family Welfare, New Delhi, had another program on "Multicentric Monitoring of New Drugs", which was coordinated by Prof. P. L. Sharma (Chandigarh), Prof. R. C. Saxena (Lucknow), Prof. A. H. Siddiqui (N. Delhi), Prof. Molly Thomas (Vellore) and Prof. Nilima Kshirsagar (Mumbai).

First Scientific Conference on Pharmacovigilance

The first conference on adverse reaction monitoring, spontaneous ADR reports, prevention and treatment of ADRs, was held in January 1997 under the aegis of the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai. Prof. Neelima Kshirshagar and Prof. Urmila Thatte were the organizers.

WHO Special Centres for ADR Monitoring in India

In 1997, an agreement was signed between the WHO Headquarters, Geneva, and the Indian Drugs Controller General (DCGI), wherein it was decided to establish working relationships with the WHO Collaborating Centre for International Drug Monitoring, Uppsala-Sweden (UMC) and Pharmacovigilance Centres in India. These national centres mainly based in the teaching hospitals namely "WHO Special Centres for ADR Monitoring" collaborated with WHO PIDM. Prof. K. C. Singhal and Prof. Neelima Kshirsagar were appointed as "Honorary Consultants to WHO-UMC.[4] The identified special centres were

1. Department of Pharmacology, All India Institute of Medical Sciences, New Delhi
2. Department of Pharmacology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh and
3. Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai

These three centers were to report ADRs to the drug regulatory authority of India. The major role of these centers was to monitor ADRs to medicines marketed in India. However, they were non-functional as information about the need to report ADRs and about the functions of these monitoring centers never reached the prescribers and there was a lack of funding from the government.

International Workshop on ADR Monitoring

India became the collaborator of the International Drug Monitoring Program in 1997. To train the young pharmacologists and allied health scientists, the first international workshop on Adverse Drug Reaction Monitoring was held at JNU Auditorium, New Delhi during November 9-12, 1998. It was hosted by Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh. Prof. K. C. Singhal was the organizing secretary for this event.[5]

The experts from abroad were Prof. John Autian (Memphis, USA), Prof. R.H.B.Meyboom (LAREB, Netherlands), Prof. Rakesh Bhandari (Ontario, Canada), Dr. Sten Olsson (Uppsala, Sweden) and Prof. Peter A Chyka (University of Tennessee, Memphis, USA). The resource persons from India were: Prof. B.N. Dhawan (Lucknow), Prof. Alice

Kuruvilla (CMC, Vellore), Prof. O. D. Gulati (Baroda), Prof. (Mrs.) C. K. Chauhan (Mumbai), Prof. K. C. Singhal (Aligarh), Prof. O. P. Asthana (Lucknow), Prof. S. K. Gupta (AIIMS, New Delhi), Prof. Rakesh Bhargava (JNMC, Aligarh), Prof. B. S. Goel (Aligarh), Dr. Atul Singhal (Aligarh) and Dr. Rajeev Sharma (Aligarh). This workshop was attended by 150 participants. The inaugural program at JNU Auditorium was conducted by Dr. Syed Ziaur Rahman (JNMC, Aligarh).

Society of Pharmacovigilance India

During the international workshop mentioned above, it was deliberated to have an exclusive platform where scientists can share their own experiences related to ADR related issues, hence a separate society namely 'Society of Pharmacovigilance, India' (SoPI) was constituted and registered in 1999 with multiple aims and objectives[6]. The main aim was to promote the study of the use and effects of drugs in population in a rational way; to determine the risk/benefit ratio of drugs in an individual and in general population and to establish a dialogue on Pharmacovigilance as a distinct and influential clinical specialization.

SoPI was the first national professional society in the world after European Society of Pharmacovigilance (ESoP). Prof. K. C. Singhal (Aligarh) was elected as the first president of the SoPI. Coincidentally, International Society of Pharmacovigilance (ISoP) was also formed in 1999. ISoP is originated from ESoP. For decades, ISoP and SoPI remained the only specialized societies in the world where like-minded consultants met and deliberated.

SoPI got registered under the Societies Registration Act of 1950 at Ahmedabad (No. F7199/Ahmedabad, dated 27.9.1999). Dr. R. K. Goyal, the then Professor at L. M. College of Pharmacy, Ahmedabad, assisted in getting it registered. It is renewed every 5 years. Lastly in 2016, the society was renewed in Agra on 31.8.2021 vide reference number 01830/2021-2022. The society organizes annual conferences and CMEs in different parts of India. In 2016, SoPI organised the joint annual meeting with International Association of Pharmacovigilance (ISoP) in Agra.[7]

In 2001, SoPI started publishing a quarterly periodical namely "Journal of Pharmacovigilance and Drug Safety" (JPDS). The journal plays an important role in disseminating pharmacovigilance issues, case reports, adverse drug reactions, and matters related to drug safety.[8] When JPDS was started, there was only one existing journal of ISoP dedicated to the same subject of pharmacovigilance, 'The International Journal of Risk and Safety in Medicine'. In addition, SoPI initiated publishing "Newsletter" from the Dept. of Pharmacology, JNMC, AMU, Aligarh (Editor, Dr. Syed Ziaur Rahman). Only two issues came into existence one in 2003 and another in 2004.

National Pharmacovigilance Program (NPVP) in India (2005-2010)

The government of India under the command of the Central Drug Standard Control Organisation (CDSCO), Ministry of Health & Family Welfare, Government of India, New Delhi, officially launched the WHO-sponsored and World Bank-funded National Pharmacovigilance Program (NPVP) for India on January 1, 2005, which was largely based on the recommendations made by WHO in its document titled "Safety Monitoring of Medicinal Products – Guidelines for Setting Up and Running a Pharmacovigilance Centre".[9] The program was to be overseen by the National Pharmacovigilance Advisory Committee based at the Central Drugs Standard Control Organization (CDSCO). Before the launch of NPVP, the DCGI Dr. Ashwani Kumar (Chairman, National Pharmacovigilance Advisory Committee, NPVP), Dr. Brijesh Regal (Advisor, NPVP), and Dr. R. K. Rishi (Senior Scientific Assistance, CDSCO), played a significant role in its establishment.

Under this NPVP, the Department of Pharmacology, All India Institute of Medical Sciences, New Delhi (under the head of Prof. S. K. Gupta) was designated as the National Coordinating Centre (NCC) for monitoring Adverse Drug Reactions (ADR) in the country to safeguard Public Health. NPVP structure is shown in Figure 1. Two zonal centers, the South-West (SW) zonal center (located in the Department of Clinical Pharmacology, Seth GS Medical College and KEM Hospital, Mumbai) and the North-East (NE) zonal center (located in the Department of Pharmacology, AIIMS, New Delhi) were to collect the information from all over the country and send it to the committee as well as to the Uppsala Monitoring Centre (UMC) in Sweden. Each regional center, in turn, would have several peripheral centers (24 in total) reporting to it (Figure 1). The program had three broad objectives. The short-term objective was to foster a reporting culture, the intermediate objective was to involve a large number of healthcare professionals in the system in information dissemination, and the long-term objective was for the program to be a benchmark for global drug monitoring.

This program which continued for 5 years (2005 to 2010) played a momentous role in gathering ADR data like past WHO Special Centres. Unfortunately, many good institutes were not taken in the loop of NPVP especially those which were already sensitized like all past WHO Special Centres.

Many drugs under NPVP are brought to the notice of the Technical Drug Advisory Board (TDAB) and Drugs Consultative Committee (DCC) under the CDSCO, Ministry of Health and Family Welfare by the National Pharmacovigilance Advisory Committee, for necessary action either withdrawal or warning. Many drugs like the use of Nimesulide below the age of 12, Antibiotic Gatifloxacin, COX 2 Inhibitors like Rofecoxib and Valdecoxib (indicated for arthritis and acute pain), and Diclofenac in veterinary practices were announced banned during 2005 and 2007 under the Drugs and Cosmetic Act.

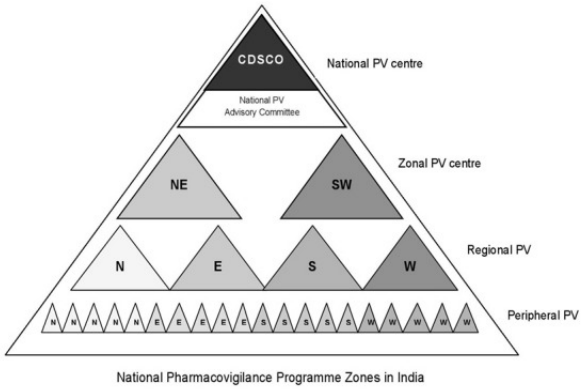

Figure 1

NCC-PvPI at Indian Pharmacopoeia Commission, Ghaziabad (2010 and Contd.)

To ensure the implementation of NPP in a more effective way, a decision was taken to christen NPVP as "Pharmacovigilance Program of India (PvPI)" after the brainstorming workshop jointly organized by the Department of Pharmacology, AIIMS, and CDSCO in late 2009. A framework of the new and current program was formulated. PvPI was initiated by the Government of India on 14th July 2010 with the AIIMS, New Delhi as the National Coordination Centre (NCC) for monitoring ADRs in the country for safeguarding public health. In the year 2010, 22 ADR monitoring centers including AIIMS, New Delhi were set up under this program. To ensure the implementation of this program in a more effective way, the NCC was shifted from the AIIMS, New Delhi to the Indian Pharmacopoeia Commission (IPC), Ghaziabad, Uttar Pradesh on 15th April 2011. The main aim of the NCC-PvPI at IPC is to generate independent data on the safety of medicines, which will be at par with global drug safety monitoring standards.

NCC-PvPI was thus started functioning under the guidance of Dr. G. N. Singh (the then DCGI and Scientific Secretary cum Director, IPC) with a broad objective to safeguard the health of the Indian population. Under PvPI, adverse drug reactions (ADRs) are reported from all over the country to NCC-PvPI, which works in collaboration with the global ADR monitoring center (WHO-UMC), Sweden to contribute to the global ADRs database. Dr. Shanthi Pal, Pharmacovigilance Program Manager, Quality Assurance and Safety: Medicines, Department of Essential Medicines and Health Products, World Health Organization, Geneva, Switzerland was the force behind its launching.

NCC-PvPI monitors the ADRs among the Indian population and helps the regulatory authority of India (CDSCO) in taking decisions for safe use of medicines. It is being envisaged that all the medical institutions, hospitals, colleges, and public health programs in the country, both government as well as private, will take part in the PvPI and report ADRs to IPC, so that all the data generated will be collated and analyzed at one place.

Since 2010, PvPI has been enriching the quality of performance and expanding its field activity. The quality parameters in respect of signal detection, quality review, training programs, and other activities have been maintained at higher than the expected levels. Within a span of ten years, PvPI has become a formidable force at the international level for the best pharmacovigilance practices including Adverse Drug Reactions (ADRs) reporting and providing skill development.

The Individual Case Safety Reports (ICSRs) are collected/collated at the AMC by PV staff including Pv Associate who checked for the validity of the report and conducted provisional causality assessment in a scientific way. The same has been analyzed to facilitate appropriate decisions at CDSCO. A significant scope for the extension of PvPI activities exists for moving ahead, connecting a network of ADR reporters over the country, and earning the trustworthiness of the masses. NCC-PvPI is fast extending its activities within the country and abroad for ensuring the safety of drugs. There are hundreds of functioning Adverse Drug Monitoring Centres in the country (in medical colleges and corporate hospitals) as part of the Pharmacovigilance Program of India.

Organizational structure of PvPI and the respective responsibilities of each AMCs are shown in Figure 2. The ADR forms are dispatched to the coordinating center. The AMC staff maintains a log of all the activities of the center and the selected AMCs also carry out focused ADR monitoring of drugs as per the watch list. The coordinating centers are conducting causality assessment and upload the reports into the PV database. The coordinating center also prepare a consolidated report of ADRs collected at defined time intervals and then implement and integrate PV activities into public health programs involving mass usage of drugs. Finally, the integrated ADR data is then transmitted through VigiFlow interface into the UMC adverse reaction database where signal processing can be carried out. There is a quality review panel which ensures the quality of ADR data that has been constituted for maintaining quality assurance in the program. All the centers will be assessed based on performance metrics criteria, completeness of reports, training imparted, and other parameters mentioned in the PV program protocol.

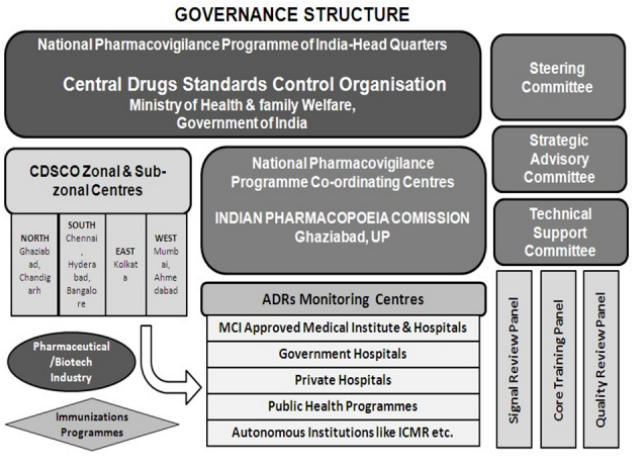

Figure 2

PvPI publishes a quarterly newsletter (ISSN 2320-7760) and assisted many academic activities at the national level. To make the program more robust, IPC had a memorandum of understanding with the National AIDS Control Organization (NACO), the National Accreditation Board of Hospitals and Healthcare Providers (NABH), and NVBDCP with WHO Country Office, India.

Presently, Dr Rajeev Singh Raghuvanshi is the Secretary-cum-Scientific Director of IPC, while Dr. Jai Prakash, the Officer-in-Charge of the running PvPI.[10]

WHO Collaborating Centre for Pharmacovigilance in Public Health Programs and Regulatory Services, IPC, NCC-PvPI (October 30, 2017)

The National Regulatory Authority of India (NRA) competencies were reiterated with the WHO Global Benchmarking Tool during a comprehensive review by WHO-led team of international experts from 13-17 February 2017. The Indian NRA was declared functional with Pharmacovigilance as one of the core functions with a maturity level of 4 in the WHO global NRA benchmarking undertaken in February 2017.

Afterwards, WHO Collaborating Centre for Pharmacovigilance was launched at IPC, NCC-PvPI on October 30, 2017. This would be the first WHO Collaborating Centre on this theme globally and the first in the entire WHO South East Asia Region". The event also witnessed the launch of "National Strategic Plan for upscale-up of Pharmacovigilance in India" and "Pharmacovigilance Guidelines for Stakeholders". As part of the event, a technical session on "WHO Global Patient Safety Challenge - Medication without Harm" was also organized.[11] Like in the IPC-PvPI, Dr Shanthi Pal from World Health Organization, Geneva, Switzerland was the force behind its launching along with Dr. Madhur Gupta, Technical Officer-Pharmaceuticals, WHO Country Office for India, who is also Focal person for Smart Safety Surveillance Activities in India.

Access to Medicines is a critical factor for achieving our public health goals and for success in the 2030 Sustainable Development Agenda. The issue of safeguarding public health in India fully aligns with one of the three pillars of Universal Health Coverage; ensuring access to safe and quality medicines and vaccines in the country. The Pharmacovigilance Program of India (PvPI) has progressed considerably in the last few years.

Focused Pharmacovigilance

Under the 'Focused ADR Monitoring Program', NCC-IPC has signed a memorandum of understanding (MoU) for ensuring patient safety against drugs used in the National Health Programme such as with NACO for special vigilance of HIV-AIDS drugs, RNTCP for TB and MDR medicines and Union Ministry of Health and Family Welfare for Albendazole ADRs, which is administered as a deworming medicine provided in tablet and syrup every year during the National Deworming Day observed from February 10 to February 16.

Pharmacovigilance – AS CURRICULUM IN TEACHING COLLEGES

Pharmacovigilance Committee in each Medical College

In a notification vide reference number MCI.34(41)/2008-Med./34787 issued on December 1, 2008, Medical Council of India amended and added under clause A.1.19 that every medical college should have a "Pharmacovigilance Committee". As per MCI guidelines, following are the objectives: to identify and report cases of ADRs in all patients attending the attached hospital, to create awareness amongst health care professionals about the importance of ADR reporting and to ensure the quality of filled ADR forms, to monitor risk-benefit profile of drugs, biologicals, vaccines, blood, and blood products, generate independent, evidence-based safety information about medicines, to support the CDSCO for formulating safety-related regulatory decisions for medicines.

Later, MCI incorporated the teaching of pharmacovigilance and ADR reporting into the medical curriculum. Both undergraduate and postgraduate students should be well versed in ADR reporting and know about the software Vigiflow.

Pharmacy Council of India and Indian Nursing Council

Pharmacopoeia Commission has also suggested to the Pharmacy Council of India and Nursing Council of India to include pharmacovigilance and adverse drug reaction (ADR) reporting as part of the educational curriculum in pharmacy and nursing institutions like in medical colleges.

Pharmacovigilance Training Courses

Many institutions, and organisations like SoPI and ADR Monitoring Centres (AMCs) attempted to provide training courses, CMEs and webinars in the discipline of Pharmacovigilance. IPC also stresses that all AMCs and MDMCs should organize training programs on a regular basis. Here are the significant institutions and organizations that organized pharmacovigilance training courses.

Indian Medical Association (IMA)

In September 2008, a two-day workshop was organized in collaboration by both the Indian Medical Association (IMA) and Johnson & Johnson on drug safety at Hyderabad after a remarkable realization on the part of IMA. During the workshop, it was stressed that IMA should train its members about the importance and general awareness of adverse drug reactions (ADRs). IMA issued notices to each state and districts branches and laid stressed that India needs its own ADR database. This is called as 'IMA-PvPI Pharmacovigilance Initiative'.

IMA-PvPI Pharmacovigilance is working towards promoting patient safety in the country. They have agreed to

cooperate and work together including a separate PvPI–IMA patient safety monitoring cell at the IMA Head Quarters in New Delhi.

JSS University, Mysore

JSS University, Mysore (Karnataka) organized pharmacovigilance training courses in association with Uppsala Monitoring Centre (UMC) and the International Society of Pharmacovigilance (ISoP).

The '2nd ISoP UMC' training course was held during January 12 to 14, 2015 with the theme, 'Risk Management through fostering good Pharmacovigilance practice in emerging markets'. This three-day course, the second joint training in Asia, was conducted with expertise from ISoP and Uppsala Monitoring Centre, and designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used. The program was focused on providing expert perspective and guidance on key elements of pharmacovigilance for the provision of risk management, and conduct of signal detection, with a focus on activities in emerging markets. It covered topics such as pharmacovigilance beyond ADRs, pharmacovigilance of generics and biosimilars, the role of regulatory agencies and industries in pharmacovigilance, risk-benefit assessment, and risk communication. Dr. G Parthasarathi, Dean, Faculty of Pharmacy, Professor, Pharmacy Practice, JSS University, was the organizing secretary.

The second joint training namely 'First Asia Pacific pharmacovigilance training course' was held from February 16 to 28, 2015. This joint training course was to further develop effective and sustainable pharmacovigilance for member countries of the WHO international drug monitoring program by creating a unique opportunity for learning and collaboration. The course included sessions to strengthen the overall WHO program and a management component that is designed to help participants improve their capacity to influence sustainable change in their countries. Issues related to health economics, communications, fundraising and risk management was also covered. International pharmacovigilance experts from the WHO, US FDA, WHO Collaborating Centers, UMC, JSS University and pharmacovigilance experts from reputed universities, academic institutions and pharmaceutical industries across India led the sessions. The course was tailored for representatives of national pharmacovigilance centres, ministries of health and public health programs and for healthcare professionals such as physicians, pharmacists and nurses. Consequently, the 3rd Asia Pacific Pharmacovigilance Training Course was organized for two-weeks in collaboration with World Health Organization (WHO) Collaborating Centre for International Drug Monitoring Centre, Uppsala Sweden, and was inaugurated by Dr. B Suresh, Vice-Chancellor, JSS University and Sten Olsson, WHO program expert from UMC, Sweden.

Symogen Ltd (2007-2008)

Symogen Ltd. is a leading pharmacovigilance, pharmacoepidemiology, medical writing and regulatory affairs service provider to the pharmaceutical industry with offices in the UK, USA and India. It was initiated by Dr. Pipasha Biswas in late 2000.[12]

In 2007, Symogen India Ltd started 'Certificate Course in Pharmacovigilance and Pharmacoepidemiology' that continued for 2 academic sessions till 2008. The classes were held at India Habitat Centre, New Delhi on all aspects of Pharmacovigilance, Pharmacoepidemiology, Medical Writing and Regulatory services, QPPV Services Medical Device Vigilance; Cosmetovigilance, Signal detection, analysis and evaluation Product Risk Management, Pharmacovigilance systems Validation Data Migration from one platform to another and ARGUS Pharmacovigilance Audit (FDA, EMA, MHRA and other EU Regulatory Agencies). Many eminent resource persons were invited including Dr. Ashwani Kumar, Prof. K. C. Singhal, Dr. Brijesh Regal, Dr. S. Z. Rahman and Dr. R. K. Rishi.

PVCON

PVCON is an established consulting and auditing service based in Mumbai. It provides all pharmacovigilance needs of the client. It is founded by Mr. Mon Don, who is also the executive director of PVCON. The organization helps in developing training matrix, plans, and training material, in conducting 'Boot Camp' and training stakeholders in a MAH set up, in customized training on good Pv practices, and safety regulation updates, and in providing customized training material and corporate training.[13]

Global Pharmacovigilance Society

Global Pharmacovigilance Society is a new professional body instituted in 2019 at Berhampur, Orissa. It is led by a team of pharmacovigilance professionals and leaders across the world. The founder president of the Society is Mr. Chinmaya Mahapatra, Pharmacovigilance Associate at the Indian Pharmacopoeia Commission. The aim of the society is to protect patients from any serious adverse event following the administration of any drug. The society organizes webinars and conferences and publishes a journal 'Journal of Pharmacovigilance and Drug Research' since 2020.[14]

Oviya MedSafe

This organization was started in 2012 and has been working to promote the cause of medicine safety and pharmacovigilance. The unique quality of Oviya MedSafe is that it regularly publishes newsletter and till now 116 editions have been published. Dr. J. Vijay Venkatraman from Coimbatore is the Managing Director and CEO of Oviya MedSafe Pvt Ltd. In collaboration with ICSR, this organization also organizes CMEs on Pharmacovigilance.[15]

Special areas of Pharmacovigilance

Pharmacovigilance for Traditional Medicine

Comparative to modern drugs, there are many specific challenges to do pharmacovigilance for traditional medicine products.[16] The complexity of the herbal product, chemical complexity, and non-uniformity are other primary reasons the for seriousness in studying the safety of traditional medicine.[17] WHO emphasizes that modern pharmacovigilance should include the traditional medicines in the Pharmacovigilance system and published 'Guidelines on Safety Monitoring of Herbal Medicines in Pharmacovigilance Systems.[18]

Centre for Safety & Rational Use of Indian Systems of Medicine

In the context of traditional medicine especially Ayurveda, Siddha, and Unani (ASU), it was felt that a separate mechanism is required to be put in place to address the related issues. The number of adverse reactions to ASU drugs reported in the National Pharmacovigilance Program in India is negligible. The strong belief that ASU medicines are safe contributes to a large extent to this situation. Moreover, the lack of knowledge about the concept and importance of Pharmacovigilance in ASU among ASU practitioners aggravated the problem. To promote the guidelines of WHO for the safety monitoring of herbal medicines published in 2004, Ibn Sina Academy of Medieval Medicine & Sciences (Aligarh), first time took a novel task of improving the use of Indian-originated drugs and their adverse reaction monitoring by establishing a special cell, CSRUISM (Centre for Safety & Rational Use of Indian Systems of Medicine) in early 2005.[19]

The CSRUISM receives many ADRs of herbal drugs, which were never reported earlier. These reactions for their causal relationships are assessed according to WHO Causality Categories and Naranjo ADR Probability Scale Evaluation. The CSRUISM has a significantly large collection of Pharmacovigilance literature. This literature was exhibited especially at various scientific platforms like Awareness Week of IPC, SOPICON-2014, etc.

National Symposium on Relevance of Herbal Pharmacovigilance

The First National Symposium on Relevance of Herbal Pharmacovigilance sponsored by the Department of AYUSH, Ministry of Health and Family Welfare, Govt. of India, was held on November 4, 2006 at the Department of Pharmacology, Jawaharlal Nehru Medical College (JNMC), AMU, Aligarh, under the aegis of Society of Pharmacovigilance, India (SoPI) and CSRUISM of Ibn Sina Academy, Aligarh. Many researchers from JNMC and Ajmal Khan Tibbiya College along with scientists from CCRUM attended the first-of-its-kind symposium on herbal Pharmacovigilance. Prof. K. C. Singhal, Prof. Anis Ahmad Ansari, Prof. Syed Zillur Rahman, Dr. Abdul Latif, and Dr. Syed Ziaur Rahman, played a significant role in making the symposium successful. The report of the Symposium with a recommendation to start an exclusive National Pharmacovigilance Program for ASU drugs was submitted to the Dept. of AYUSH.[20]

Training Program in Pharmacovigilance of Ayurveda Medicine – "Update Ayurveda"

The Department of Clinical Pharmacology, TNMC and BYL Nair Hospital, Mumbai, organized a 'Training program in Pharmacovigilance of Ayurveda Medicine' as a part of "Update Ayurveda" during 2006 with an objective to generate awareness regarding Pharmacovigilance among Ayurveda physicians and to formulate guidelines for reporting ADR Ayurveda medicines.[21]

National Workshop on Herbal Pharmacovigilance

A two-day workshop on 'Pharmacovigilance for Ayurvedic Drugs: Scope, Limitations, and Method of Implementation' was organized by the Institute of Post Graduate Teaching & Research in Ayurveda (IPGT & RA), Jamnagar, during 3rd and 4th December 2007 under the support of WHO Country Office-India. Prof. M. S. Baghel, Dr. Rabinarayan Acharya and Dr. Galib R contributed immensely in making the workshop successful.

On the basis of the recommendations of the workshop, a Pharmacovigilance Cell (PV Cell), the first of its kind in India for Ayurveda, was established at IPGT & RA, Jamnagar, and Dr. Rabinarayan Acharya was nominated as the coordinator. Further, a Consultative Committee was constituted to provide technical support and streamline the activities. Reporting Form for suspected adverse reactions of Ayurvedic formulations was developed and distributed amongst the faculty members, research scholars, and physicians under intimation to the Department of AYUSH, Ministry of Health and FW, Govt. of India.

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National Consultative Meeting for adoption and implementation of National Pharmacovigilance Program for ASU Drugs

The first National Consultative Committee Meeting for adoption and implementation of the National Pharmacovigilance Program for ASU Drugs was organized by the Department of AYUSH at its headquarters, on 29th and 30th August 2008. The meeting was attended by Mr. Samuel Verghese, Joint Secretary, Department of AYUSH, Dr. SK Sharma, Advisor (Ayurveda), and was chaired by

Prof. K. C. Singhal. The meeting also witnessed the presence of representatives from the AYUSH research councils (CCRAS, CCRUM) and other consultative committee members. It was suggested to launch a national program for the monitoring drugs of ISM. The national draft protocol was technically reviewed and finalized.[22] The finalized draft was then circulated among the experts who attended the meeting for the comments and inputs if any. Based on the feedback received, the final document was released as a part of the launching of the National Pharmacovigilance Program for ASU drugs with sanction of an amount of Rs. 57.66 lacs.

National Pharmacovigilance Program for ASU Drugs

Following the recommendations of the above meeting, the program was launched as a National Pharmacovigilance Program for ASU Drugs on 29th September 2008. This program was coordinated by the National Pharmacovigilance Consultative Committee for ASU drugs constituted by the Department of AYUSH, Ministry of Health and FW, Govt. of India. Under this Program, Gujarat Ayurvedic University, Jamnagar was designated as National Pharmacovigilance Resource Centre (NPRC) with Prof. M. S. Baghel as Director and Dr. Rabinarayan Acharya as the coordinator. This was highly essential to monitor the program centrally.

The program aimed to provide adverse drug reaction data related to various drugs of herbal, mineral, metallic, animal, and of other origins available in the country. National Pharmacovigilance Resource Centre for ASU drugs (NPRC-ASU), IPGT & RA, Jamnagar, was also the National Coordination Centre (NCC) and attached to it initially, there were eight Regional Pharmacovigilance Centres (RPC) and 30 Peripheral Pharmacovigilance Centres (PPC) identified from the Ayurveda, Siddha and Unani colleges. NPRC arranged many workshops/CMEs for ASU consultants, teachers, physicians, and paramedical staff under the guidance of Technical Advisory Committee. Because of the efforts of NPRC-ASU, pharmacovigilance has been included in the UG and PG curriculum of CCIM (now NCISM).

To make the ADR terminology easier and more understandable, the translation of ADR Terminology of WHO-UMC ADR Monitoring was done in Hindi by Prof. K. C. Singhal. This Hindi dictionary was published by the Society of Pharmacovigilance India (SoPI).[23]

One-week ROTP for teachers of Ayurveda by IPGT&RA, Jamnagar.

NPRC has organized the first one-week reorientation training program (RoTP) in Pharmacovigilance for the teachers of Ayurveda from 17th to 22nd November 2008 at IPGT & RA, Jamnagar. During 11th and 12th December 2008; another training program was organized exclusively for the coordinators of newly identified regional and peripheral centers under the sponsorship of WHO Country Office for India.

NCC-PvPI and Ministry of AYUSH, Government of India

NCC-PvPI from IPC (Ghaziabad) invited AYUSH industry partners, academicians, regulators as participants in a symposium on Pharmacovigilance for Herbal Medicine on 20.11.2017. Ministry of AYUSH signed MoU with NCC-IPC and passed by IFD (Finance) to start the program from March 2018. This program has been restructured by the Ministry of Ayush under the Central Sector Scheme including Homoeopathy component (i.e. ASU&H drugs) in support and guidance of the Indian Pharmacopoeia Commission (IPC) and concerned program officers of the WHO Country Office, India. The All India Institute of Ayurveda, New Delhi, has been recognized as National Pharmacovigilance Coordination Centre (NPvCC) for this program. The purpose of this initiative is to collect, collate and analyze data related to suspected adverse drug reactions (ADRs) and undertake surveillance of advertisements related to ASU&H drugs thus establishing evidence clinical safety of these drugs in a scientific manner.[24]

Currently, the scenario for monitoring ASU&H Drugs is as below (Figure 3):

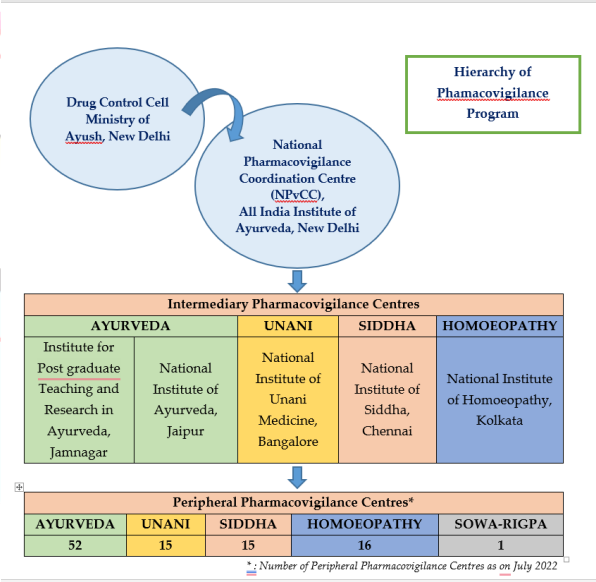

Figure 3

This program aims at

i. inculcating reporting culture among ASU&H stakeholders to facilitate documentation of suspected ADRs ASU & H drugs;
ii. inculcating reporting culture among ASU&H stakeholders to facilitate documentation of misleading advertisements for ASU & H drugs;
iii. evolving evidence-based recommendations regarding the clinical safety and objectionable advertisements of ASU&H drugs for regulatory actions.

Since its inception, the involved centers are functioning in line with the defined objectives and frequently organising sensitization programs for various stakeholders across the nation. Dr. Galib is presently looking the program as national coordinator.

Cosmetovigilance and PPCPs

Cosmetovigilance is a discipline of pharmaceutical science and aesthetic art related to detection, assessment, monitoring and prevention of adverse effects of Cosmetoceutics and Personal Care Products (CPCPs).[25]

Adverse Events Following Immunization (AEFI)

Like drugs and other pharmaceutical products, vaccines are not entirely without risk. Adverse reactions with vaccines may occur. Being a large consumer, leading manufacturer and exporter of vaccines, India is expected to have a well-developed AEFI Surveillance system. AEFI surveillance program demonstrates the country's intent of delivering quality immunization services with safe vaccines and ensure vaccine confidence. The AEFI surveillance system has been in place since 1988. The national AEFI guidelines were revised in 2005, 2010 and 2015. The guidelines provide information to health care providers and program managers at national, state, district, block, and primary health care levels for establishing a sensitive AEFI surveillance system. The national AEFI guidelines provide complete guidance and other details for reporting, investigating, and conducting the causality assessment of cases reported as AEFIs.

The new guidelines define Adverse Events Following Immunization (AEFI) as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of vaccines. These events may include one or more unfavorable or unintended sign, symptoms or laboratory findings which raises concern among immunization program managers, policy makers, family of beneficiary and the community. AEFIs can be common and minor (like fever, local pain and swelling), severe (like pain and swelling which spreads beyond the nearest joint or high-grade fever) and serious AEFIs (conditions requiring hospitalization or leading to death or disability). The AEFI Surveillance guidelines are an update to the AEFI Operational Guidelines, 2010 and are in line with the revised WHO/Council for International Organisations of Medical Sciences (CIOMS) guidelines.

The Immunization Division of the MoHFW has taken several steps to improve the National AEFI surveillance system, including the quality of investigation of cases at the state level and their causality assessment at the national level. Considering the importance and critical nature of the task, SOPs for Causality Assessment (CA) have been laid down as quality assurance. Likewise, the Immunization Division, MoHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, and obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct a causality assessment of AEFIs following COVID-19 vaccination.

Materiovigilance Program of India (MvPI)

Indian Pharmacopoeia Commission as National Coordination Centre (NCC) for Materiovigilance Program of India (MvPI) has developed MvPI tools to promote safety of Medical Devices which was launched on February 8, 2019.[26] Medical devices are used not only in modern system of medicine but also in traditional system of medicine.[27,28] NCC for Materiovigilance Program of India (MvPI) has been organising 'Brain Storming Sessions' to encourage the MDMCs Coordinators for active participation in MDAE reporting and various Training Program such as "Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events" to strengthen the materiovigilance program pan India via digital/virtual platform, in association with Andhra Pradesh MedTech Zone (AMTZ), Vishakhapatnam, Andhra Pradesh and Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum Thiruvananthapuram.

MDMC are selected after the approval of the Technical Support Group for Enrolment and Excel in Functioning of Medical Device Adverse Event Monitoring Centers (TSG-EEFM). Dr. Vivekanandan Kalaiselvan is the Senior Principal Scientific Officer looking the newly launched MvPI and Dr. Shatrunajay Shukla and Dr. Nikita Mishra are very active MvPI Associates.

Haemovigilance Program (HvPI)

The Haemovigilance Program of India (HvPI) was launched on 10th December, 2012 in the country under the aegis of National Institute of Biologicals, Ministry of Health and Family Welfare, Government of India, New Delhi. National Institute of Biologicals publishes a quarterly newsletter on HvPI and assisted many academic activities at national level.

Haemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence and recurrence. It is an important tool for improving safe blood transfusion practices in a country.

Veterinary Pharmacovigilance

Veterinary pharmacovigilance is a monitoring system for ensuring the safety of medicinal products for veterinary purposes**,** including vaccines with marketing authorization, used for preventing, diagnosing or treating animal illnesses. The task of veterinary pharmacovigilance is to ensure: the safe use of medicinal products in animals

Veterinary medicines have their own set of stringent regulations similar to pharmacovigilance in humans. These regulations must be followed to ensure animals are provided with the best medicines, providing maximum benefit and minimum risk. The complex nature of the Veterinary medicines arena is compounded by the fact that the wide

variety of different species may react very differently to the same medicine. Even within a species, the complex nature of understanding different dosages and different weights for animals, together with changing pharmacokinetics due to age and gender differences, produces its own unique set of challenges apart from human Pharmacovigilance.

Environmental Pharmacovigilance

Indian scientist proposed the discipline of Environmental Pharmacovigilance for monitoring adverse events of drugs on other flora and fauna after administration of medicine either in human or animal.[29] This is different than human and veterinary pharmacovigilance. These therapeutic drugs are eliminated into the environment via living organisms. Environmental Risk Assessment (ERA) if done properly, before the clinical trial may minimize the risk and impact of drugs on environment.[30] This discipline initially was termed as "Pharmacoenvironmentology", but later known by other names such as EcoPharmacovigilance, PharmEcovigilance, and PharmaEcostewarship.

Challenges of PV in India

The biggest challenge facing the PVPI is the gross underreporting of adverse effects. There are many reasons for this, including lack of medical expertise in drug administration and adequate skilled resources in PV, and inadequate nationwide awareness of PV. The other challenges are infrastructure which are still conservative, wide time interval between guidelines and laws, orthodox attitude to new drug research, and PV and regulatory inspections that are almost non-existent. However, sometimes ADRs are not recognized by the physicians on admission and ADRs may be responsible for the death of many patients. Patients sometime do not divulge about the administration of drugs of other system of medicine.[31] Furthermore, the financial cost of ADRs to the healthcare system is also vast. In the market, when new medicines are launched without long term safety studies by the regulatory authorities, patients self-medicate and switch from prescription-only medicines (POM) to over-the-counter (OTC) more widely, and this is the main reason of exposing itself to ADRs. In the earlier period, India's regulatory agencies and drug companies based their safety assessments on experiences derived from long-term use.

Reporting and understanding of Pharmacovigilance for traditional system of medicine is rather more challenging. Every complementary and traditional medicine has its own way of treatment based on their theories and principles such as the concept of substitution of drugs (Abdal al-Advia)[32] and misidentification due to lack of pharmacognosy.[33]

Future prospects of Pv in India

The system needs to be refined with the help of PV experts in collaboration with information technology (IT) because India boasts of a highly developed IT sector. Since PV deals with large numbers of ADRs, it would be wise for PV experts to collaborate with software professionals to develop and build a robust system. 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 ADRs. Moreover, with more clinical research and PV outsourcing work now being conducted in India, it has been worthwhile for the DCGI to invest in a robust PV system to enable assessors and decision makers to analyze safety data and take regulatory decisions without the need to depend on other countries.

In recent years, many Indian companies are increasing their investment in research and development and are enhancing their capacity to develop and market new drugs with their own research efforts. Once a product is marketed, new information will be generated, which may have an impact on the benefit-risk profile of the product. The detailed evaluation of the new information generated through PV activities is important for all products to ensure their safe use. Hence, DCGI should take some tough decisions and make commitments to make PV mandatory and start the culture of PV inspections.

ADR form could be developed more mobile friendly as it is easy to carry it as mobile application. Each system of medicine could develop their own mobile application. Following is an example of few mobile applications:

1. ADR PvPI Mobile application (https://play.google.com/store/apps/details?id=com.vinfotech.suspectedadversedrugreaction&hl=en_IN&gl=US)
2. SiddAR Mobile Application (https://play.google.com/store/apps/details?id=siddha.drug.documentation&hl=en_IN&gl=US) developed for Siddha System of Medicine

CONCLUSION

The PV in India has become an important public health issue as regulators, drug manufacturers, consumers, and healthcare professionals are faced with a number of challenges. The PV in India continues to grow, evolve, and improve. India is the largest producer of pharmaceuticals and now emerging as an important clinical trial hub in the world. Apparently, the requirements for professional specialization, a combined view on Pharmacogenetic, Pharmacogenomic and clinical requirements are needed.[34] That helps to identify factors that increase the risk of unwanted outcomes from drug therapy and prior to commencing drug treatment and in tailoring drug treatment for individual patients. The PV has also involved in Data Mining Technology in spontaneous reports submit to the national surveillance systems. The PVPI is coordinated at IPC through NCC under the control of Indian Government to generate an independent data on safety of medicines, which will be at par with global drug safety monitoring standards. National and regional PV systems are well-adapted bodies, attuned to the intricate collection and analysis of ADR data

that leads to timely alerts and interventions to protect population health. Furthermore, it is responsible in India of entire campaign to improve PV knowledge and increase the number of ADRs reports up to the gold standard level established by the WHO.

The adverse events reported by PV system will potentially benefit to the community due to their proximity to both the population and public health practitioners, in terms of language and knowledge of the lifestyle and habits of patients, enables easy contact with reporters, for example by telephone, Email, text massages by mobile phones. The development of new and effective medicinal products makes a positive contribution to the health and wellbeing of individuals. However, there is a need to improve PV systems to more effectively monitor and take action on safety issues associated with medicines to enhance their contribution to public health. Hence, PV for medicinal product safety to help the patients get well and to manage optimally or ideally, avoid illness is a collective responsibility of industry, drug regulators and clinicians and other healthcare professionals. The financial support and future projects should help to achieve a more comprehensive PV activity in India.

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