



Indian Pharmacopoeia Commission's Partners for Promoting Public Health

Kalaiselvan V¹, Kumar R^{2*} and Singh GN³

¹Principal Scientific Officer, Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad, UP, India

²Technical Associate, Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad, UP, India

³Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad, UP, India

Abstract

In order to promote the awareness and to monitor the adverse drugs reactions, one of the most noteworthy nation-wide programme initiated by IPC on 15th April 2011 under the aegis of Central Drugs Standard Control Organization (CDSCO), is Pharmacovigilance Programme of India (PvPI). IPC is a National Coordination Centre (NCC) for PvPI, meant for protecting the health of the public by assuring medicines safety. PvPI monitors the benefit-risk profile of medicines & generate independent, evidence based recommendations on safety of medicines & support CDSCO for formulating safety related regulatory decisions for medicines.

With a view to establish a centre of excellence for pharmacovigilance in India, NCC-PvPI collaborated with the WHO-Uppsala Monitoring Centre (UMC), Sweden & participating in International Drug Monitoring Programme & now become a significant contributor for the global drug safety database. The WHO country office for India coordinates with NCC-PvPI in terms of providing technical support for organizing training programmes, awareness programmes, meetings and updating PV toolkit etc.

PvPI has been continuously taken several steps for ensuring patient safety and well being of society, in this regards PvPI expanded its patient safety programme to 150 AMCs across the country & also collaborated with different National Health Programme (AEFI, NACO, RNTCP) as it has been always preeminent to established safety and efficacy of medicines used in these NHP(s). As consumers / patients are the important allies for any country's pharmacovigilance programme, PvPI has taken step towards encouraging consumers reporting by the release of medicines side effect reporting form for consumers in different regional languages.

For the last two decades, pharmacovigilance has been gaining an increasing attention. It is now, high time for national authorities, multilateral agencies, nongovernmental organizations, healthcare institutions, pharmaceutical industries & lay public to work together for the effective implementation of PvPI across the country.

Keywords: Indian pharmacopoeia commission; Pharmacovigilance; Uppsala monitoring centre; Vigi base; Public health programs; PV toolkit

Introduction

Indian Pharmacopoeia Commission (IPC) is an Autonomous Institution of the Ministry of Health and Family Welfare (MoHFW), Government of India (GoI). IPC is playing a vital role in enhancing quality and safety of medicines. IPC is committed for improving Quality of Medicines by way of adding new and updating existing monographs in the form of Indian Pharmacopoeia (IP) on a regular interval. IP contains a collection of authoritative procedures of analysis and specifications for Drugs. The IP, or any part of it, has got legal status under the Second Schedule of the Drugs & Cosmetics Act, 1940 and Rules 1945 there under. It further promotes rational use of generic medicines by publishing National Formulary of India. IPC also provides IP Reference Substances (IPRS) which act as a finger print for identification of an article under test and its purity as prescribed in IP [1-3].

IPC functions as national coordination centre (NCC) for Pharmacovigilance Programme of India (PvPI) to monitor the safety of medicines since 15th April 2011. The purpose of the PvPI is to collate data, analyze it and uses the inferences to recommend informed regulatory interventions, besides communicating risks to healthcare professionals and the public. Since there are considerable social and economic consequences of adverse drug reactions and the positive benefit/cost ratio of medicines, implementing appropriate risk management, it is essential to build a network among healthcare

professionals, public and similarly placed organizations, moreover, NCC-PvPI alone cannot address this issue. Therefore, NCC-PvPI is building sustainable patient's safety partnership with national and international organizations to achieve its sanctified objectives [4,5]. This article describes and discusses the various stakeholders involved in Pharmacovigilance Programme of India and their important role. Figure 1 give brief outline of partners of IPC to improve the patient safety and welfare in Indian population.

Central drugs standard control organization

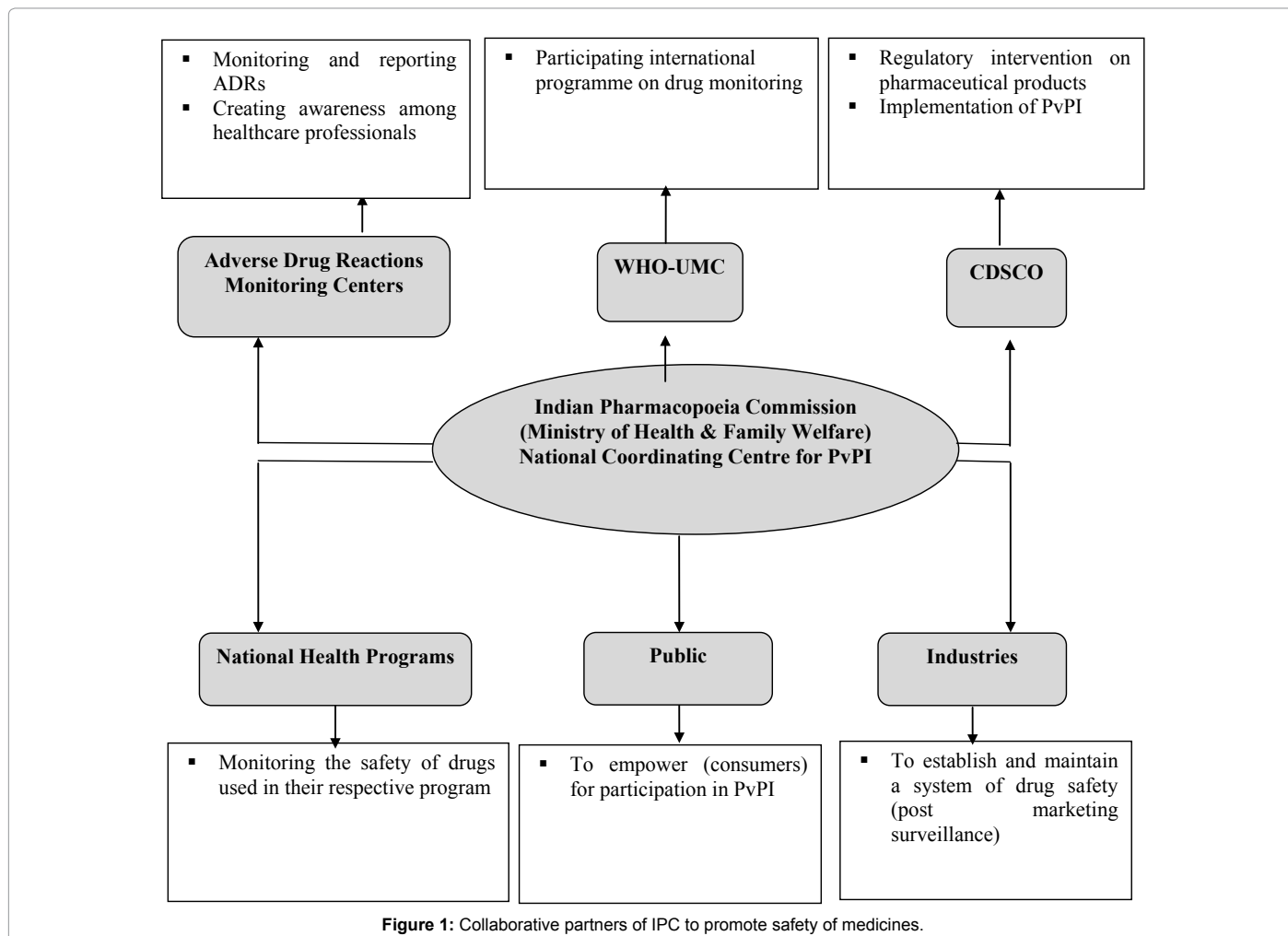
The Central Drugs Standard Control Organization (CDSCO) is the national regulatory body for Indian pharmaceuticals and medical devices. The CDSCO is collaborated with IPC, NCC-PvPI to monitor the safety of medicines and to take a regulatory intervention if required and it propagates the medicine safety related decisions to various stakeholders of PvPI. CDSCO zonal and sub zonal offices provide technical and logistic support and to monitor the functioning of ADRs

***Corresponding author:** Kumar R, Technical Associate, Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad, UP, India, Tel: 91-9015296576; E-mail: ranvirkumar14@gmail.com

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monitoring centres in their respective zone. NCC-PvPI and CDSCO periodically organize training for Pharmacovigilance staff to make them acquainted with the basic and essentials of pharmacovigilance terminologies & its concept, standards & processes for ADR reporting and causality assessment. CDSCO and NCC-PvPI works together in various technical and high level committees such as Steering Committee, Working Group, Signal Review Panel etc constituted by MoHFW. Based on the scientific and clinical expertise, the NCC recommends CDSCO for the regulatory decision on medicines that might materially influence the benefit-risk assessment of a product [6].

Adverse drug reactions monitoring centres (AMCS)

AMCs are the Medical Council of India approved medical colleges & hospitals, medical/central/autonomous institutes, public health programmes or corporate hospitals. They are responsible for collecting the adverse event information from the healthcare professionals/patients, and performing follow up to get supplementary detailed information for scientific evaluation. At present, 150 AMCs are coordinated by NCC-PvPI. Complete list of 150 AMCs are mentioned in the Table1.

In collaboration with NCC, the AMCs deal with

- a. Monitoring and reporting of ADRs.
- b. Coordinating with anti-tuberculosis centre and anti-retroviral

centres to monitor the safety of drugs used in their respective programs.

- c. Organizing training/awareness programme on Pharmacovigilance.
- d. Coordinating with peripheral hospitals/community pharmacies, primary health centres etc.

The programme was initiated with few AMC i.e 22 AMCs in 2010 and then numbers of AMCs have been continuously recognized & added in after years i.e. 60 in 2011, 90 in 2013 and 150 in 2014. These AMCs may vary considerably in size, resources, structure, and scope of activities however collecting spontaneous reports of suspected ADRs remains their core activity. The technical team of AMC consists of coordinator (faculty of the organization) and Technical Associate (appointed by NCC) responsible for monitoring and reporting of ADRs and expanding PvPI activities in their respective region. Scientific policy and guideline issues on PvPI are often discussed with AMCs. Working Group and Coordinators meeting and other similar conferences facilitates such discussions. AMCs have played a significant role in increasing public awareness of drug safety by organizing Continuing Medical Education on Pharmacovigilance; NCC provides financial and technical support to organize such events [3,7]. Once the medical institute is enrolled as an AMCs, then they starts sending the ADR report to the NCC via VigiFlow. On an average 3000 to 3500 ADR

S No	State	ADR Monitoring Centres
	Andhra Pradesh	Andhra Medical College King George Hospital
		Guntur Medical College
		Peoples Education Society Institute of Medical Sciences and Research
		S V Medical College
		Kurnool Medical College
	Assam	Rajiv Gandhi Institute of Medical Sciences
		Government Medical College, Guwahati
		Silchar Medical College & Hospital
	Bihar	Jorhat Medical College & Hospital
		Indira Gandhi Institute of Medical Sciences
		All India Institute of Medical Sciences
	Chhattisgarh	Lord Buddha Koshi Medical College & Hospital
		Pt JNM Medical College
	Goa	Goa Medical College & Hospital
	Gujarat	SMT NHL Municipal Medical College
		BJ Medical College New Civil Hospital
		Government Medical College, Bhavnagar
		Surat Municipal Institute of Medical Education & Research
		MP Shah Medical College
		PDU Medical College
		Gujarat Medical Education & Research Society Medical College
		Pramukhswami Medical College & Shree Krishna Hospital
	Haryana	Government Medical College, Vadodara
		Medanta-The Medicity
		Artemis Hospital
		Pandit Bhagwat Dayal Sharma Post Graduate Institute of Medical Sciences
		BPS Government Medical College for women
	Himachal Pradesh	Maharishi Markandeshwar Institute of Medical Sciences and Research
		Dr Rajendra Prasad Government Medical College
	J&K	Indira Gandhi Medical College
		Government Medical College, Jammu
		Sher-i-Kashmir Institute of Medical Sciences
		Acharya Shri Chander College of Medical Sciences & Hospital
	Jharkhand	Government Medical College, Srinagar
	Karnataka	Rajendra Institute of Medical Sciences
		Bangalore Medical College and Research Institute
		Belgaum Institute of Medical Sciences
		Bidar Institute of Medical Sciences
		JSS Medical College Hospital
		Karnataka Institute of Medical Sciences
		Kasturba Medical College
		Mandya Institute of Medical Sciences
		SDS Tuberculosis Research Centre & Rajiv Gandhi Institute of Chest Disease
		St John's Medical College
		Vydehi Institute of Medical Sciences and Research Centre
		Indira Gandhi Institute of Child Health
	MS Ramaiah Medical College	
	SDM College of Medical Sciences & Hospital	
	Kerala	Government Medical College, Kozhikode
		Government Medical College, Kottayam
		Pushpagiri Institute of Medical Sciences and Research centre
		Amala Institute of Medical Sciences
		Government TD medical college
		Government Medical College, Alappuzha
	Amrita Institute of Medical Sciences	

	Madhya Pradesh	Gandhi Medical College
		RD Gardi Medical College
		SAIMS Medical College
		NSCB Medical College
		All India Institute of Medical Sciences
	Maharashtra	BJ Medical College & Sassoon General Hospital
		Government Medical College & Hospital, Nagpur
		Grant medical college & Sir JJ Group of Hospital
		Indira Gandhi Government Medical College
		Lokmanya Tilak municipal Medical College & General Hospital
		Mahatma Gandhi Institute of Medical Sciences
		Pd Dr DY Patil Medical College
		Aditya Birla Memorial hospital
		Seth GS Medical College & KEM Hospital
		Swami Ramanand Teerth Rural Government Medical College
		TN Medical College & Byl Nair Hospital
		Armed Forces Medical College
		Government Medical College, Miraj
		Government Medical College, Latur
	Manipur	Regional Institute of Medical Sciences
	Meghalaya	North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences
	Odisha	VSS Medical College
		M K C G Medical College
		SCB Medical College and Hospital
		Hi-tech Medical College & Hospital
	Punjab	Christian Medical College and Hospital
		Dayanand Medical College and Hospital
		Sri Guru Ram Das Institute of Medical Sciences & Research
		Guru Gobind Singh Medical College & Hospital
	Rajasthan	Government Medical College, Amritsar
		Sardar Patel Medical College
		SMS Medical College
		Geetanjali Medical College and Hospital
		RNT Medical College
		NIMS Medical College
	Sikkim	All India Institute of Medical Sciences
		Sikkim Manipal Institute of Medical Sciences
	Tamil Nadu	Christian Medical College
		Government Medical College, Kilpauk
		Madras Medical College
		PSG Institute of Medical Sciences & Research
		SRM Medical College Hospital & Research Centre
		Sri Ramachandra Medical College and Research Institute
		Madurai Medical College
		Tirunelveli Medical College
		Coimbatore Medical College & Hospital
	Kovai Medical Center and Hospital	
	Telangana	Kakatiya Medical College
		Nizam Institute of Medical Sciences
		Bhaskar Medical College & Bhaskar General Hospital
		Kamineni Institute of Medical Sciences
		Gandhi Medical College
	Tripura	Osmania medical College
		Agartala Government Medical College
		Tripura Medical College & Dr BRAM Teaching Hospitals

Uttar Pradesh	BRD Medical College & Nehru Hospital
	GSVM Medical College Swaroop Nagar
	Institute of Medical Sciences Banaras Hindu University
	JN Medical College Aligarh Muslim University
	MLB Medical College
	MLN Medical College
	Santosh Medical University
	UP Rural Institute of Medical Sciences and Research
	Muzaffarnagar Medical College & Hospital
	School of Medical Sciences & Research
	Subharati Medical College
	Era's Lucknow Medical College & Hospital
	Central Drug research Institute
	Dr Ram Manohar Lohia Institute of Medical Sciences
Uttarakhand	Government Medical College, Haldwani
	Himalayan Institute of Medical Sciences
	Veer Chandra Singh Garhwali Medical Science and Research Institute
	Shri Guru Ram Rai institute of Medical & Health Sciences
	All India Institute of Medical sciences
West Bengal	School of Tropical Medicine
	RG Kar Medical College
	Calcutta National Medical College
	Institute of Postgraduate Medical Education & Research
	Burdwan Medical college
	Bankura Sammilani Medical College
	Nilratan Sircar Medical College
	College of Medicine & JNM Hospital
	North Bengal Medical College
Murshidabad Medical College & Hospital	
Chandigarh	1. Post Graduate Institute of Medical Education and Research
Delhi	All India Institute of Medical Sciences
	Indraprastha Apollo Hospital
	Lady Hardinge Medical College
	University College of Medical Sciences, and GTB Hospital
	Vallabhbai Patel Chest Institute
	Vardhman Mahavir Medical College & Safdarjung Hospital
	Hamdard Institute of Medical Sciences and Research
	Maulana Azad Medical College
Puducherry	Indira Gandhi Medical College & Research Institute
	Jawaharlal Institute of Postgraduate Medical Education & Research

Table 1: List of 150 ADR Monitoring Centres under Pharmacovigilance Programme of India (PvPI)

reports were received per month at NCC which finally shared to the global safety database after review the quality of these reports.

The Uppsala monitoring centre

The WHO set up its international drug monitoring programme after the thalidomide disaster. Since 1978 the Programme has been carried out by Uppsala Monitoring Centre (UMC) in Sweden. The UMC is an independent foundation and a centre for international service and scientific research. Its priorities are the safety of patients and the safe and effective use of medicines in every part of the world. UMC provides technical support to more than 100 countries worldwide including India on matters pertaining to drug safety [8].

The NCC-PvPI is collaborated with UMC by contributing drug safety data of Indian population to the global safety database, Vigi Base. The principal function of the UMC is to manage the international

database of ADR reports received from National Centres. UMC identifies and analysis new adverse reaction signals from the case report information submitted by all participating countries including India. NCC is having the access of most of the web based tools developed by UMC & now both IPC and UMC are keen to work together in the development of signal analysis methodologies to identify medicine safety issues of regional importance in future [9,10].

National health programs

National Health Programs (NHPs) of MoHFW, GoI aimed to improve the health of target population. It's important to establish that medicines used in NHPs, not only to treat/prevent disease but also equally important to build the public confidence about their safety. PvPI an essential tool in monitoring the safety of medicine used in NHPs. India is facing major challenges in tackling communicable diseases that are responsible for high morbidity and mortality [11]. Huge quantity of

medicines is being used in these National Health Programs (NHPs) for the treatment and it become essential to ensure the safety of medicines used in these programmes. PvPI has also extended its reach to the various NHP(s) running in country, encouraging them to participate and contribute in the nationwide medicine safety programme, leading to patient safety. In this regards, NCC-PvPI collaborated with Revised National Tuberculosis Control Program (RNTCP) on 11th October 2013 and with National AIDS control organization on September 2014 to monitor the safety of antitubercular drugs & antiretroviral drugs used in NHPs. NCC also assists Universal Immunization Programme, MoHFW to monitor the Adverse Event Following Immunization (AEFI) by coordinating with CDSCO and Immunization Technical Support Unit under MoHFW [6].

World Health Organization (WHO) & NCC-PvPI Collaboration

World Health Organization (WHO) Geneva

The World Health Organization (WHO) was founded in 1948 with an ambitious objective – ‘the attainment by all peoples of the highest possible level of health’. Its constitution defined 22 wide-ranging functions, of which the first was ‘to act as the directing and co-ordinating authority on international health work’. WHO’s priority in the area of health systems is moving towards universal health coverage. WHO works together with policy-makers, global health partners, civil society, academia and the private sector to support countries to develop, implement and monitor solid national health plans. In addition, WHO supports countries to assure the availability of equitable integrated people-centred health services at an affordable price; facilitate access to affordable, safe and effective health technologies; and to strengthen health information systems and evidence-based policy-making [12].

WHO collaborating centre for international drug monitoring is the Uppsala Monitoring Centre (UMC) which is an independent foundation and a centre for international service and scientific research. As a WHO Collaborating Centre, UMC adhere to the WHO policies and work in close liaison with its WHO, headquarters, Geneva. In accordance with an agreement between WHO and the Government of Sweden, the WHO Headquarters is responsible for policy issues, while the operational responsibility rests with the UMC.

Functions of the WHO Programme for International Drug Monitoring include:

- Identification and analysis of new adverse reaction signals from the case report information submitted to the National Centres, and sent from them to the WHO ICSR database. A data-mining approach (IC analysis) is used at the UMC to support the clinical analysis made by a panel of signal reviewers.
- Provision of the WHO database as a reference source for signal strengthening and ad hoc investigations. Web-based search facilities and customized services are available.
- Information exchange between WHO, UMC and National Centres, mainly through ‘Vigimed’, an internet based information exchange system.
- Publication of periodicals, newsletters (WHO Pharmaceuticals Newsletter and Uppsala Reports), guidelines and books in the pharmacovigilance and risk management area.
- Supply of tools for management of clinical information

including individual case safety reports. The main products are the WHO Drug Dictionary and the WHO Adverse Reaction Terminology.

- Provision of training and consultancy support to National Centres and countries establishing pharmacovigilance systems.
- Computer software for case report management designed to suit the needs of National Centres (VigiFlow)
- Annual meetings for representatives of National Centres at which current pharmacovigilance issues and the development of the Programme are discussed (China in 2014 and for the 2015 meeting, India)
- Methodological research for the development of pharmacovigilance as a science [13].

WHO-Country Office (India)

WHO-India country office is headquartered in New Delhi with country wide presence. Its key aim is to contribute to improving health and equity in India. It also provide the blueprint for unleashing India’s role on the global health arena alongside the continued pursuit of health improvement in the country. The WHO country office for India coordinates with PvPI by providing technical support in organizing training programmes, meetings, preparation and updation of PV toolkit and other regulatory documents for PvPI. Also IPC in technical collaboration with WHO India office organized meetings for the stakeholders to promote National Formulary of India (a book for rational use of medicines) and implementing Good Laboratory Practices [6].

Consumers/Patient Participation

Community participation and involvement remains the backbone of any good healthcare system as the consumers / patients are important allies in ensuring the safety and efficacy of medicines. Consumer reports may bring to the surface issues and concerns involving drug safety not previously covered in reports by health professionals. They reveal genuine concerns for obtaining better information about the quality and efficacy of health products. The other major initiative of NCC to empower patient’s participation is to introduce a separate consumer reporting form i.e. “Medicines Side Effect Reporting Form (For Consumer)” in English. In PvPI, consumers are being encouraged to report ADRs to spontaneous reporting system. Consumers often have the most details about what they are experiencing and are in a unique position to identify new safety signals earlier. Since consumer reporting of adverse reactions would be useful in monitoring the adverse events due to over the counter medicines and herbal medicines. Henceforth, NCC-PvPI takes initiatives to empower consumers (patients) participation in PvPI. The major initiative in this regard is the launch of helpline number 1800-180-3024 (Toll Free) for providing assistance in ADRs reporting [14,15]. This initiative provides information to the patients and healthcare professionals how, what and where to report ADRs at nearby AMCs. The helpline also upgraded with the facility of sending SMS acknowledgement for the ADRs reporter to build their confidence on the system [14,16].

In India there are many barriers in direct patients reporting; language is one among them. Therefore, NCC-PvPI released first version of “Medicines Side Effect Reporting Form (For Consumer)” in different regional languages (Hindi, Bengali, Tamil, Gujarati, Kannada, Oriya and Malayalam). The objective is to encourage the consumer reporting as consumers/patients are the important key partner in this

medicine safety programme.

Academic Institutions and Research Institutions

NCC is also closely working with academic institutions and research institutions to introduce the concept of Pharmacovigilance and Pharmacopoeia standards in educational curriculum. Since professional's bodies plays a vital role in distributing reporting forms and creating awareness about adverse reactions to medicines, NCC-PvPI in technical collaboration with these organizes workshop on Pharmacovigilance and patients safety. To build the public relation, NCC maintains good rapport with media and journals also.

Conclusion

The effective implementation of PvPI is based on fruitful collaboration with other Clusters/Departments of similarly placed organizations both at national and international levels, healthcare professionals, pharmaceutical manufacturers and patients.

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