



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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## PROGRESSIVE YEAR 2015

*PvPI Global Outreach*

*Garnering WHO  
Recognition*

*Drug Safety Information*

*Focus on Efficient  
ADR Report*

*Training &  
Education*

*Important  
Events of PvPI*

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## *Secretary-cum- Scientific Director's Message*



Dear Readers,

It's a great time of the year for us at the Indian Pharmacopoeia Commission (IPC) as we reflect upon the marvellous accomplishments and wonderful achievements of the just concluded 2015. Ticking off several successful activities and their consecutive results, give us great feeling.

I am very proud and honoured to say that in India, IPC is set to become the first WHO Collaborating Centre for safety of medicines and vaccines in the South-East Asia Region as announced in the 38<sup>th</sup> Annual meeting of the representatives of the National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring, jointly organised by IPC and WHO.

I have no words to express my gratitude to the WHO for choosing India (IPC) to host the meeting. When we review the last year, the launch of Mobile App for ADR reporting, visit of various international delegates at the IPC shows various avenues in strengthening of the established pharmacovigilance system.

Launch of Materiovigilance Programme of India; a system has been put in place to ensure the safety in usage of medical devices. In order to enhance the ADR reporting and to outbreak the barrier of the languages in the ADR reporting, NCC-PvPI has released the ADR reporting form in total 10 vernacular languages of India for direct involvement of patients.

Various training and education programmes organised at IPC and AMCs of PvPI has created more awareness across the country towards patient safety. Highlighting the signal detection workshop with the UMC team will surely help us in identifying new signals from reported ICSRs and we seek their support in future also. The meeting organised with the stake holders of PvPI, especially with the industries, was fruitful as a result the industries contribution to PvPI in terms of ADR reporting turned out to be 18.80% in the year 2015.

I also acknowledge all the efforts of the PvPI team for their significant contribution which lead and recognised the system globally. Looking forward, I wish this Year may bring you immense happiness in all you do. May the spirit bring you 'The sound of Victory' for the challenges of the coming year.

**Dr. G. N. SINGH**

Secretary cum Scientific Director,  
Indian Pharmacopoeia Commission,  
Ministry of Health & Family Welfare  
Government of India.



# The Ministry ends year on a high note

THE UNION HEALTH MINISTER ENDS THE YEAR WITH DYNAMIC INITIATIVES FOR FACILITATING AND IMPROVING GENERIC DRUGS, ADR MONITORING OF MEDICINES COMBINED WITH WHO COLLABORATION FOR DRUG MONITORING.

The Union Minister of Health & Family Welfare, Government of India, Shri. J. P. Nadda, inaugurated the 38<sup>th</sup> Annual Meeting of the National Pharmacovigilance Centres participating in the World Health Organization Programme for the International Drug Monitoring (PIDM), jointly organised by Indian Pharmacopoeia Commission and WHO at Hotel Grand, New Delhi in which several international delegates representing different countries of the world had participated. He underlined the importance of Pharmacovigilance, monitoring of adverse effects of drugs in the country and

mentioned that India has made considerable progress in this field in the last five years, including setting up of Pharmacovigilance system in Tuberculosis and HIV-AIDS related public health programmes.

The Hon'ble Minister said that drug safety related issues pose a major challenge for healthcare professionals, regulators and pharmaceutical industries and this is where Pharmacovigilance, the monitoring of adverse effects of drugs, plays a significant role in ensuring quality and efficacy of medical products. Given the critical role that it plays, it is imperative that Pharmacovigilance is developed

as an effective instrument for understanding and prevention of adverse effects or any other drug related problems. The Minister applauded the WHO Collaborating Centres across the globe, which serve as a platform for knowledge transfer and act as catalysts for developing the next level of Good Pharmacovigilance Practices and awareness of adverse reactions and their reporting.

IPC is set to become the first WHO Collaborating Centre for Safety of Medicines and Vaccines in the South-East Asia Region, as stated by Shri J. P. Nadda, while addressing the delegates.



Shri J. P. Nadda, MoHFW, GOI addressing the delegates



Shri J. P. Nadda, Hon'ble Health Minister along with Shri B. P. Sharma, Secretary Health, Dr. Jagdish Prasad, DG, DGHS, Shri K. B. Aggarwal, Additional Secretary, MoHFW, Govt. of India and Dr. Lambit Rago, WHO Geneva releasing the Position Paper of Pharmacovigilance Programme of India on 4<sup>th</sup> Nov 2015 on 38<sup>th</sup> Annual Meeting of Representatives of the National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring at New Delhi

The Hon'ble Health Minister said that our efforts have gained momentum after the IPC was notified as the National Coordination Centre for Pharmacovigilance to monitor adverse drug reactions. The minister said that we need to continue promoting generic drugs. However, what we need to doubly ensure is that these are of high quality and efficacy.

Hon'ble Health Minister along with Shri B. P. Sharma, Secretary Health, Dr. Jagdish Prasad, DG, DGHS, Shri K. B. Aggarwal, Additional Secretary, MoHFW, Govt. of India and Dr. Lambit Rago, WHO Geneva, released the Position Paper of Pharmacovigilance Programme of India (PvPI) 38<sup>th</sup> Annual Meeting of the WHO-PIDM at New Delhi.

The Position Paper of PvPI released during the event consisted of concise current scenario, landmark achievements, pipeline activities and future aspects.

## Emphasis on Pharmacovigilance

The Hon'ble Health Minister emphasized that success of pharmacovigilance depends on state of art reporting, cutting edge use of information and communications technology to process and analyse information for immediate corrective measures. This needs to be supported by a highly calibrated audit process, he added. He also said that building a strong pharmacovigilance frame-work in all countries is essential for ensuring public health outcomes.

This would require close collaboration between a large number of professionals and multi-constituency stakeholders – both nationally and internationally, and internationally recognized standards on pharmacovigilance.

Shri Nadda also added that establishment of a robust Pharmacovigilance system and increasing its reach, quality and credibility is vital for development of safe medical products.

This is the only way to increase accessibility of such drugs. India is also in the process of implementing free drugs initiatives across the country so that those who cannot afford are also able to get the high quality medicines.

He also laid stress on creating a nation-wide system for patient-safety-reporting, to identify and analyse risk benefit ratio of marketed medicines, to generate evidence on the safety of medicines and to support regulatory agencies in decision making.



We pledge to uphold the highest ethical practices in PvPI

# *PvPI Benefaction - 38<sup>th</sup> Annual Meeting of WHO-PIDM*

Pharmacovigilance Programme of India has progressed considerably in the outgoing year. The programme has clearly broadened its horizon of activities, as a result

of IPC-WHO (India) Country office collaboration work and has provided the perfect backdrop for current discussions and partnerships in Pharmacovigilance.

IPC-PvPI has tremendously contributed for the WHO-PIDM. From the pre-meeting upto the main meeting sessions IPC-PvPI, has been working continuously day-in and day-out. PvPI team participated in several working groups to discuss the various issues and challenges regarding the Pharmacovigilance globally.

Initially, the WHO PIDM consisted of only 10 countries as its members. As of February 2015, 149 countries are part of the WHO PIDM, with 129 countries submitting reports of adverse reactions associated with medicinal products to the WHO global database, Vigibase. The WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre manages and maintains the



A glimpse of cultural programme by PvPI team during the PIDM



VigiBase on behalf of the WHO and Member States. There are over 10 million reports of adverse reactions in VigiBase.

Two pre-meetings were scheduled to precede the main meeting on the 2<sup>nd</sup> and 3<sup>rd</sup> November 2015, a workshop on the WHO ATC/DDD methodology and drug utilization research. On the 3<sup>rd</sup> November 2015, 'let's talk' PV by UMC' and the main high

level meet was held from 4<sup>th</sup> to 6<sup>th</sup> November 2015, to discuss safety of medicines manufactured and sold in the country.

Valuable recommendations aroused as an outcome of the working groups, which was organized to discuss the various challenges/issues & initiatives regarding Pharmacovigilance of respective countries in the meeting. All this was followed by the brain

storming sessions of the main meeting. A refreshing and sparkling cultural event was organised on the eve of 4<sup>th</sup> November 2015 by IPC.

In the end, the PvPI team presented their full-fledged participation and left no stone unturned to portray the rich cultural heritage of India. The year 2015 has been a promising year in achieving new milestones in the era of Pharmacovigilance.

## Scope to Promote Patient Safety

### THE NATIONAL FORMULARY OF INDIA - 2016

Also, the 5th edition of the National Formulary of India, 2016 (NFI 2016) was released by Shri. J.P. Nadda on 14<sup>th</sup> November 2015 in the presence of the Guest of Honour, Gen. (Dr.) V. K. Singh (Retd.), Hon'ble Minister of State for External Affairs, Indian Overseas Affairs, Statistics & Programme Implementation (I/c), Government of India, along with officials of the Ministry of Health & Family Welfare and IPC at IPC office, Ghaziabad, Uttar Pradesh.

The principal objective of NFI is to promote rational use of medicines. It is a guidance document for healthcare professionals such as clinicians, pharmacists, nurses, dentists etc. This edition is designed, keeping in view the changing healthcare and pharmaceutical scenario along with content validation by expert panel.



Shri J. P. Nadda (Fifth from left) and Gen. (Dr.) V. K. Singh (Retd.) (Sixth from left) along with other eminent personalities releasing NFI 2016 at IPC, Ghaziabad

## Salient features

- Contains Thirty three chapters, therapeutic categories wise, including 521 drug monographs containing 33 fixed dose combinations, 20 immunologicals and 12 vitamins monographs.
- Entire coverage of drugs listed in the National List of Essential Medicines, 2011, India.
- Drugs used in the National Health Programmes of India.
- Chapter on Medication/Prescription errors.
- Management of Diabetes Mellitus
- Drugs used in psychiatric disorders substance use & Antiepileptic/ Anticonvulsants.
- 22 appendices containing unique supplementary information including information on PvPI and various ADR reporting forms.
- In view of expansion of Pharmacovigilance Programme of India, relevant appendices are incorporated in the revised form.
- Suspected Adverse Drug Reaction Reported Form and, the Medicines Side Effect Reporting Form (For Consumers) have been attached to promote ADR reporting to NCC-PvPI by healthcare professionals and patients.



*The Health Minister emphasized that success of Pharmacovigilance depends on state of art reporting, cutting edge use of information and communications technology to process and analyse information for immediate corrective measures. This should be supported by a highly calibrated audit process, which needs to be strengthened*

Shri J. P. Nadda Hon'ble Health Minister inaugurating the Benefit-Risk Assessment cell of PvPI on 14th November 2015

# Benefit-Risk Assessment Cell Inaugurated

The PvPI Benefit-Risk Assessment Cell was inaugurated by Shri J. P. Nadda on the 14<sup>th</sup> November 2015 at IPC, NCC, Ghaziabad. The Risk Management Plan (RMP) is a documented plan that describes the risks (adverse drug reactions and potential adverse reactions) associated with the use of drugs and how they are being handled (with warnings on the drug label or on packet inserts about possible side effects). The overall goal of the RMP is to assure a positive risk-benefit profile once the drug has been marketed.

Benefit-Risk Assessment aims

at minimizing the risks while maximizing the beneficial effects of a medicine by ensuring its proper use by the patients. If the overall balance of benefits and risks are judged to be negative, then the medicine may be withdrawn unless risk reduction strategies can be identified which would swing the balance away from risk. In this respect, the following actions may be considered.

- Continue to passively monitor the issue: may be appropriate for non-serious adverse events where causality is not established.
- Actively collect further data:

if causality is not established, mechanism unclear, risk factors are not identified.

- Add warnings to the product label: for less serious adverse effects, particularly which are unavoidable, warning health care professionals and patients may be the only action necessary.
- Changes to the product label to reduce risk: restrict the indication, contraindicate those at greater risk, advice monitoring.
- Monitor effects of action taken: ensure that the action effectively protects public health.



# PvPI Initiatives for skill development and expansion

ZONAL AND REGIONAL WORKSHOPS WERE HELD TO IMPROVE ADR REPORTING ACROSS THE COUNTRY. SKILL DEVELOPMENT OF HEALTHCARE PROFESSIONALS AND EMPOWERING THEIR PARTICIPATION IN PvPI IS THE NEED OF THE HOUR FOR PATIENT SAFETY.

## Second Core Training Panel & First RTC Coordinators Meeting of PvPI

The Core Training Panel of PvPI identifies trainers, training needs, training content and zone-wise training centres for the Pharmacovigilance Training Programme. The Core Training Panel interacts with international agencies for participation and implementation of training programmes related to Pharmacovigilance. It organizes training and projects budgetary requirements. Training modules and training schedules were also developed by this panel.

- Overview of existing & new Regional Training Centre (RTC) State & Union Territories under their purview.
- Discussion on strategies for strengthening of RTC: Capacity building for Infrastructure/ technical support/ financial support etc.
- Preparation of Calendar of Events for Training

Programmes / CME to be organized by RTC in the year 2016.

- Role of IMA in Pharmacovigilance Training and Education for the Medical Fraternity.

The Panel Members reviewed the activities of individual RTC and discussed the strategies to improve the awareness status

in their purview regions. Panel Members reviewed SOP's for the functioning of RTC and proposed some amendments. Panel suggested that each RTC shall finalize activities related to training, CMEs & Awareness programmes be organized during the year 2016 and same shall be communicated to NCC-PvPI, for preparation of calendar of events.

Dr. K. K. Aggarwal Senior Vice President, IMA shared his views to enhance ADR reporting by training and education for medical fraternity. He emphasized that greater participation by the HCPs would be an important tool for increasing the reporting of ADRs and other drug-related problems. He hoped that IMA & IPC will work together in collaborations for the expansion of programme.

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# IPC-UMC joint signal detection workshop



Joint Signal Detection Workshop of international facilitator & PvPI staff at NCC-PvPI

One of the foremost endeavours of Pharmacovigilance is the early detection of signals with regard to possible adverse drug reactions. To identify safety signals of adverse events from spontaneous reports, there should be a robust method of signal detection and clinical assessment of ICSRs. For this purpose, joint signal detection workshop was conducted on 5<sup>th</sup> - 8<sup>th</sup> October 2015, at IPC Ghaziabad. This was graced by Dr. Ruth Lesley Savage,

Senior Medical Advisor, Dr. Ola Caster, Senior Researcher and Ms. Lovisa Sandberg, Analysis Specialist, UMC Sweden. The main objective of this workshop was to mimic the current signal detection process of UMC and to detect the potential signal of its relevance to the Indian context.

The final outcome of the workshop was that a total number of 168 drug-ADR combinations were reviewed for the potential signal, out of which 11 drug-

ADR combination are considered as potential signal. These cases of potential signals were further discussed with Dr Ruth Lesley Savage, to validate these drug-ADR combination as a signal. Based on the decisive evaluation, following drug-ADR combination can be considered as signals:

1. **Citicoline** – Hallucination
2. **Azithromycin** - Acute Generalized Exanthematous Pustulosis (AGEP)
3. **Amikacin** - Drug hypersensitivity Syndrome
4. **Cloxacillin** - Acute Generalized Exanthematous Pustulosis (AGEP)
5. **Artemisinin derivatives** – Steven Johnson Syndrome
6. **Phenytoin** - Vestibular Disorder
7. **Betamethasone** – Photo-sensitivity

Since this has also been reviewed by SRP- PvPI, NCC is committed to take forward the outcomes to CDSCO for appropriate regulatory measures.

## “Induction cum Training Programme on Pharmacovigilance for Coordinators of Newly Recognized AMCs under PvPI”

NCC identified 29 newly recognized AMCs for Induction-cum-training programme to train their coordinators. Out of

which coordinators of 28 AMCs participated the event conducted on 3<sup>rd</sup> - 4<sup>th</sup> September 2015 at IPC, Ghaziabad in order to understand

the concept and adopt Good Pharmacovigilance Practices.

Dr. G.N Singh welcomed all the dignitaries and the



Shri K. B. Agarwal, Additional Secretary, MoHFW, GoI, illuminating lamp along with Dr. G. N. Singh & the distinguished dignitaries

participants and expressed his organization commitments to promote PvPI in the country.

Mr. K. B. Agarwal, Additional Secretary, MoHFW, GoI, chief guest of the event encouraged the participants for their effective participation. While his address he urged the stakeholders for, Proper utilisation of available resources, implementation of valuable recommendations and suggestions made by the experts are keys to attain the goal of PvPI. Lack of proper qualifications of the personnel, unclear communication and delay in prompt implementation can pose a setback and hinder the entire programme.

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***Shri K. B. Agarwal,  
Additional Secretary,  
MoHFW, GoI, congratulated  
the NCC-PvPI for the  
entire progress made in the  
recent years***

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He also emphasized on the need of the incorporation of Information Technology is necessary for the massive data storage system as it facilitates rapid and efficient access to relevant information. This helps in the data mining of signal detection.

Dr. Sudha Prasad, HOD, Obstetrics and Gynaecology -Maulana Azad Medical College, New Delhi, said that, "the involvement of each and every HCP in this patient safety programme is essential for creating awareness about Pharmacovigilance. Greater participation by HCPs would be an important tool for increasing the reporting of ADRs and other drug-related problems."

She suggested that a MCI person should be involved as a part of Pharmacovigilance Committee for PvPI. She also mentioned about the NABH accreditation for the hospitals. She appreciated all the participants





The mentors, coordinators and NCC-PvPI team

for their active participation in this patient's safety programme to make it grand success.

Dr. Nilima Kshirsagar, Chairperson, Core Training Panel (CTP)-PvPI, shared her experiences and knowledge and asserted on the importance of

safety monitoring of the drugs to ensure the patient's safety in the country. She mentioned about the necessity of a proper administrative structure for the Pharmacovigilance Cell in the hospitals all over the country so that Pharmacovigilance

activities could be carried out smoothly.

The participants have been equipped to learn, perform, and enhance their potential by including multi skill to accomplish the objective of PvPI.

## Training-PGIMER Chandigarh and IPGMER Kolkata



Speakers at PGIMER Chandigarh training

RTC provides training to the medical colleges and hospitals of that particular region. The training programme was organised on 8<sup>th</sup> - 9<sup>th</sup> December 2015 which was attended by 250 delegates including Drug regulators, HCPs, Pharmacists, Pharmacy students and other stake holders of PvPI. Also a meeting was held with Registrar, Punjab Medical Council and IPC officials on 8<sup>th</sup> December 2015 for effective implementation and betterment of ADR monitoring in Punjab state.

A meeting was held on 8<sup>th</sup> December 2015 at PGIMER, Chandigarh and it was proposed to implement Pharmacovigilance in state medical educational curriculum. It has been discussed that ADR Reporting form should be attached with the admission files of in-patient as well as out-patient departments in the hospitals of the State of Punjab as it has been done by the AMC - PGIMER, Chandigarh since April 2015. A letter from the Director, Medical Education & Research Punjab has been issued to all the medical colleges to implement the ADR monitoring in their institutes as directed by the Registrar, Punjab Medical council on 10<sup>th</sup> December 2015.

# Eastern Regional Workshop on Pharmacovigilance

The Third Eastern Regional Workshop on Pharmacovigilance was organized by the PvPI East Zone RTC, at Institute of Postgraduate Medical Education & Research (IPGMER), Kolkata on 27<sup>th</sup> November 2015. The Department of Pharmacology, IPGMER, which runs the ADR Monitoring Centre at IPGMER, Kolkata, served as the host department. The workshop was organized with technical and financial support from the Pharmacovigilance

Programme of India PvPI under the aegis of the National Coordination Centre. The day-long programme was structured to overview and presentations followed by discussion on problems and concerns of individual ADR Monitoring Centres, demonstration of online data entry into VigiFlow and discussions on reporting of problematic ADR. The details of the PvPI and summary of the activities of the NCC were highlighted.

**East Zone training programme was held on 27<sup>th</sup> November 2015 at IPGMER-Kolkata headed by Dr. Suparna Chatterjee. This training programme was attended by 13 special invitees and 93 delegates.**



Participants at IPGMER Kolkata training



Releasing of Workshop Brochure during Regional Training Programme at IPGMER-Kolkata

# New Drugs Approved Status in India

The following drugs were approved during the period of August to December 2015 by the Central Drugs Standards Control Organization (CDSCO).

S.No	Drug	Indication
1.	Vilazodone Hydrochloride 20mg/40mg and Bulk	For the treatment of major depressive disorders in adults.
2.	Gemigliptin 50mg tablets	As an adjunct to the diet & exercise to improve glycemic control in adults with type-2 diabetes mellitus, as an monotherapy or in combination with metformin in patients with inadequate glycemic control on metformin alone
3.	Atosiban Acetate Injection 6.75mg/0.9ml and Bulk	Indicated to delay imminent pre-term birth in pregnant adult women with: <ul style="list-style-type: none"> <li>➤ Regular uterine contractions of at least 30 seconds duration at the rate of <math>\geq 4</math> per 30 minutes</li> <li>➤ A cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of <math>\geq 50\%</math></li> <li>➤ A gestational age from 24 until 33 completed weeks a normal fetal heart rate</li> </ul>

- Healthcare professionals are urged to closely monitor the safety of these drugs.
- ADRs if (any) to be reported to PvPI

## Overview Of Herbal Drugs

The inclusion of phytopharmaceuticals in the D&C Rules comes in after taking into consideration the growing use of these drugs in the country. This rule has come into force on the date of its publication in the Official Gazette which was 30<sup>th</sup> November 2015.

Herbal products (HPs) are widely used as pharmaceutical and nutraceutical agents in India. The existing Pharmacovigilance Programme of India

(PvPI) encourages reporting of adverse events related to HPs to monitor their safety. To analyze the reported adverse reactions suspected with the use of HPs all reports submitted to the National Coordination Centre (NCC) for PvPI during the period July 2011–December 2013 were assessed on the probability of a causal link between the use of the medication and the reported adverse reaction.

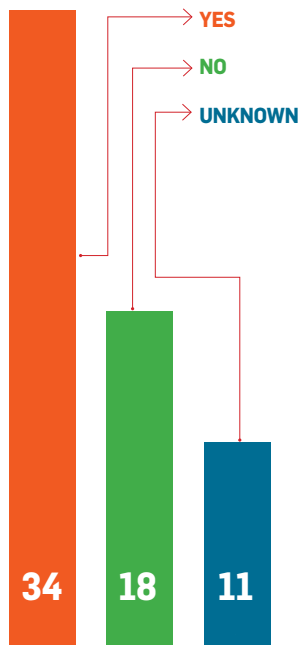
### HERBAL DRUGS OVERVIEW

An overview was compiled of all reports relating to severe adverse due to Herbal Drugs. The NCC-PvPI database contained 63 reports of suspected adverse reactions to HPs in which 34 of them were classified as serious, 18 were non serious and 11 were unassessable.

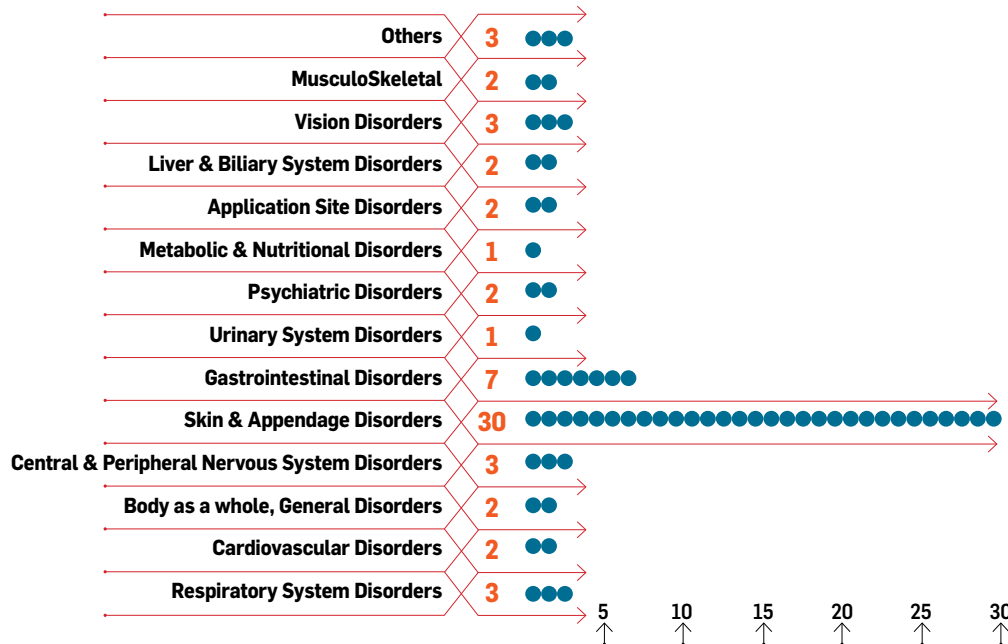
The cases were further categorized by System Organ Classification (SOC) and it was found that 52.5% were related to skin



## SERIOUSNESS OF ICSRs



## SYSTEM ORGAN CLASS



and appendages disorders. The suspected HPs were Gudmar-Ameda, Shankhpushi, Mahavat Vidhwansan, Dashmool Kwath, Shemar Yesaka, Melascream, Senna Extract, Aloe Vera, Mustard oil, Digitalis,

Garlic, Menthol and Turmeric. Causality assessment as per the WHO scale revealed that five cases were probable/likely, 17 were possible, one was unlikely and the rest of them were inaccessible or blank.

Healthcare providers and consumers must be educated to ensure the safe use of herbal products. Also rigorous monitoring to ensure the safe use of HPs through PvPI is essential to safeguard public health.

# Field Activities

## ADR REPORTING INITIATIVES IN THE NORTH EAST

To enhance & promote the network of Pharmacovigilance in the North-Eastern Region, the NCC recognized Arunachal State Hospital, Naharlagun as an ADR Monitoring Centre. This centre has started ADR reporting since the month of October 2015 to NCC-PvPI thereby contributing to patient safety. Reporting in Arunachal Pradesh has gained pace and will become widespread in the near future.

## APPRECIABLE CONTRIBUTION OF SCB MEDICAL COLLEGE, CUTTACK- IN CREATING AWARENESS TOWARDS ADR REPORTING

SCB medical college has been working tremendously towards awareness of Pharmacovigilance. Great efforts have been made towards promoting patient safety by collecting & reporting Serious Adverse Events (SAEs). We would like to express our sincere gratitude towards these efforts in promotion of PvPI, as Patient safety is an essential and vital component of Pharmacovigilance. By continuing and ensuring the quality of reporting, awareness of PvPI will attain its goal in the near future.

# Drug Safety Information On Cards

THE SIXTH SIGNAL REVIEW PANEL MEETING RECOMMENDATIONS SUGGEST ADDING FOLLOWING INFORMATION ABOUT DRUGS AND THEIR SIDE EFFECTS TO THE CDSCO.

In view of strong causal relationship and with supportive Indian ICSRs the SRP recommended for label change of the following medicinal products and insert the following adverse reaction to the corresponding package inserts.

S.NO	DRUG	REACTION	INDIAN STATUS OF ICSRs
1	RANITIDINE	CARDIAC ARREST	1
2	ANTI RABIES VACCINE	ERYTHEMA MULTIFORME	2
3	SURFACTANT	PULMONARY HAEMORRHAGE	4

Further SRP recommended CDSCO, to instruct concerned Marketing Authorization Holders (MAHs) to comply the above adverse drug reactions in their package insert.

## RANITIDINE INDUCED CARDIAC ARREST

The NCC-PvPI presented one ICSR of ranitidine associated with Cardiac arrest with three Indian case reports published in different journals. The case was considered to be having immense public impact hence it was put forward to the chair. All cases were evaluated and it was observed that all the literature case reports were of intravenous ranitidine whereas ICSRs received was of effervescent tablet.

Based on the critical evaluation on this drug-ADR combination it was concluded that the causal relationship between intravenous

ranitidine and cardiac arrest can be established but, no association can be established with effervescent tablet with available data. Product labelling information is as below "Other H2 receptor antagonists bradycardia, AV-block and, injection only" was mentioned in package insert of ranitidine IV marketed in UK.

**Recommendation:** The SRP suggested that same label should be incorporated in the Indian package insert of marketed ranitidine IV medicinal products.

## ANTI-RABIES VACCINES INDUCED ERYTHEMA MULTIFORME

NCC-PvPI, database has two ICSRs for Anti-rabies Vaccines (Rabipur) and Erythema Multiforme and both the cases were reported from the same AMC. Apart from this one case report of erythema multiforme with Rabipur vaccine was published in Pediatric Dermatology Journal, (Verma P. Erythema multiforme possibly triggered by rabies vaccine in a 10-year-old boy. *Pediatr Dermatol.* 2013 November-December; 30 (6):e297-8. doi: 10.1111/j.1525-1470.2012.01842.x.), from UCMS- GTB hospital. After reviewing these cases, SRP panel suggested that there may be a causal relationship between the drug and adverse event.

**Recommendation:** The SRP concluded that there was a strong temporal relationship between the drug and the ADR (Anti

rabies Vaccines & Erythema Multiforme) and hence it should be incorporated in package inserts of suspected drug marketed domestically. This would be communicated to CDSCO.

## SURFACTANT INDUCED PULMONARY HAEMORRHAGE

The SRP reviewed all ICSRs of Surfactant and Pulmonary Haemorrhage received by NCC-PvPI, IPC.

**Recommendation:** SRP suggested that the domestic PIL (Patient Information Leaflet) for this drug - ADR combination should be checked.

## FINAL SIGNALS DETECTED

For the workshop, UMC had prepared a list of drug-ADR pairs which were relevant to the Indian context. The combination list was based on current data in VigiBase, the WHO Global ICSRs database, of suspected adverse drug reactions, and the VigiRank algorithm was used to screen and rank the drug-ADR pairs according to the strength of evidence of being true adverse effects.

The in-depth assessment of drug-ADR combination was done under the guidance of Dr Ruth Lesley Savage, Dr Ola Caster and Ms Lovisa Sandberg of Uppsala Monitoring Centre, Sweden.

Based on the decisive evaluation following drug-ADR combination were considered as potential signal.

S.NO	DRUG	REACTION	INDIAN STATUS OF ICSRs	GLOBAL STATUS OF ICSRs
1	BETAMETHASONE	PHOTOSENSITIVITY REACTION	5	20
2	AZITHROMYCIN	ACUTE GENERALISED EXANTHEMATOUS PUSTULOSIS (AGEP)	3	26
3	DICLOFENAC	LIP ULCERATION	2	23
4	CLOXACILLIN	ACUTE GENERALISED EXANTHEMATOUS PUSTULOSIS (AGEP)	2	25
5	FOLIC ACID	OEDEMA MOUTH	2	13
6	ZIDOVUDINE	SKIN EXFOLIATION	11	5

### DRUG SAFETY ALERT

Tramadol is a specific type of narcotic medicine called an opioid analgesic that is approved to treat moderate to moderately severe pain in adults. The FDA is investigating the use of analgesic in aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with Tramadol analgesic after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in children. In India there was no report of any child having same reaction with the drug. Healthcare professionals should be aware of this and consider being vigilant by prescribing alternative FDA-approved medicines for children.

Reference-www.fda.gov

## Calender Event

S.No	Date	Title	Organised by	Organised at	Participants/ Target Audiences
1	15 <sup>th</sup> - 19 <sup>th</sup> Feb.	Induction cum Training Programme for Newly Recruited Technical Associates	IPC, NCC-PvPI	IPC, Ghaziabad	Newly Recruited Technical Associates
2	2 <sup>nd</sup> or 3 <sup>rd</sup> week March *	CME on Pharmacovigilance for the state of Gujarat & Rajasthan	B. J. Medical College, Ahmedabad		All Healthcare Professionals of states under purview of BJMC Ahmedabad
3	19 <sup>th</sup> March	Advance Level Training on Pharmacovigilance cum Coordinators meeting for the state of Maharashtra & Goa	KEM, Mumbai	Dept. of Clinical Pharmacology KEM, Mumbai	AMC Coordinators & TAs of states under purview of KEM, Mumbai
4	26 <sup>th</sup> March	Advance level Training on Pharmacovigilance cum Coordinators Meeting for the state of Assam, Arunachal Pradesh, Nagaland Manipur, Meghalaya, Mizoram, Tripura & Sikkim	Silchar Medical College & Hospital, Silchar	Silchar Medical College & Hospital, Silchar	AMC Coordinators & TAs of states under purview of Silchar Medical College, Silchar
5	28 <sup>th</sup> March	CME on Pharmacovigilance for the state of Assam, Arunachal Pradesh, Nagaland, Manipur, Meghalaya, Mizoram, Tripura & Sikkim	Silchar Medical College & Hospital, Silchar	Jorhat Medical College & Hospital, Jorhat	All Healthcare Professionals of states under purview of Silchar Medical College & Hospital, Silchar
6	25 <sup>th</sup> March to 5 <sup>th</sup> April*	CME on Pharmacovigilance for the state of Andhra Pradesh & Telangana	Nizam Institute of Medical Sciences (NIMS), Hyderabad	Visakhapatnam	All Healthcare Professionals of states under purview of NIMS Hyderabad

\* Tentative Date



### 67<sup>th</sup> Indian Pharmaceutical Congress (IPC) Highlights

The 67<sup>th</sup> Indian Pharmaceutical Congress (IPC) was held from 19<sup>th</sup> - 21<sup>st</sup> December 2015 at the JSS University campus, Mysuru. The Vision Document was unveiled by the Union Health Minister Shri J. P. Nadda re-instating the objective of Swasth and Swachh Bharat mandating healthy and clean India. India is called the pharmacy of the world; with over 70 per cent of the pocket expenses allocated for drugs, hence there is a serious concern to ensure quality of medicines. Most of the population of the world consumes medicines exported from India. Dr. G. N. Singh, Drugs Controller General of India and President, 67<sup>th</sup> IPC, highlighted to focus on preventive healthcare by educating people. Dr B Suresh, Vice Chancellor, JSS University Mysuru, President Pharmacy Council of India (PCI) and the Chairman of the Local Organising Committee, announced a Vision Document which called for pharmacists to support the primary healthcare in the country, provide access to quality medication, advocate preventive healthcare practices, ensure continuity of care, engage in evidence based practices and promote medication safety. The IPC concluded on a positive note as pharmacists vowed to partner with the Government to enable patient centric focus and disease prevention.

PvPI in Continuous Pharmacy Education (CPE) Programme patient safety is a high priority issue for health care professional including pharmacist, who cares for health and general well being of people. Patient safety is defined as the prevention of harm to patients, including through errors of commission and omission. The prevention of harm to patients due to medicine shall be reduced by the way of reporting ADR to the AMC functioning under PvPI. In order to promote patient safety, pharmacist has to report ADRs. To consider this as responsibility Dr. G. N. Singh, wrote a letter to the registrar of all state pharmacy council as, state pharmacy councils are playing a crucial role in pharmacy education and practice. It is a great opportunity to approach for implementation of ADR reporting by pharmacists during their professional services. This can be implemented as mandatory credit hours to renewal of pharmacist registration in the state pharmacy council. This has been already implemented in Kerala, Haryana and Himachal Pradesh.

## Collaboration of NCC PvPI-IMA

The Vision of PvPI is to improve patient safety and welfare in Indian population by monitoring drug safety and thereby reducing the risk associated with the use of medicines. The main objective of IMA is to promote and advance medical and allied sciences. To promote the improvement of public health and medical education in India and to fulfil the vision of PvPI, both the organizations have decided to sign the Letter of Intent (LOI) to enhance their mutual understanding to promote Adverse Drug Reactions (ADRs) reporting in the country.

### FUTURE WORKING AREAS:

- PvPI-IMA patient safety monitoring cell to be started at IMA headquarter.
- Organising CMEs, disseminating PvPI information/ concept of Pharmacovigilance (Pv) in IMA in news, journals etc.
- Training to the nodal coordinators /medical officers.
- Development/up-gradation of mobile application. for ADR monitoring.
- Other areas to promote patient safety.

## PvPI in International Arena Visit of Dr. Sunita Vohra

Dr. Sunita Vohra, Director of Integrative Health Alberta, Canada, visited the Indian Pharmacopoeia Commission to discuss the possibilities to work jointly with the IPC. The scientific publications of NCC-PvPI in reputed journals impressed Dr. Sunita Vohra and so she visited IPC on 15<sup>th</sup> Dec 2015 to discuss the various parameters for collaboration, towards patient safety. Dr. Sunita Vohra & Dr. G. N. Singh mutually agreed for the Indian Pharmacopoeia Commission and the University of Alberta, Canada to collaborate for the joint activities as mentioned below:-

- To build partnership in ensuring the safety of OTC products.
- Knowledge translation on OTC products to enhance the identification & awareness of adverse event reporting due to traditional medicine.
- Generating the scientific evidence on herbal drug interaction.

## भारतीय भेषज संहिता आयोग – एक मनोयोग

हृदय में रस धारा बही, इच्छा शक्ति भी प्रबल रही।  
 प्रबुद्धता हुई चिन्तनशील, लक्ष्य शिखर पर मननशील।  
 कर्मठी मानव रहता जहाँ, प्रश्न चिन्ह भी आ ठहरता वहाँ।  
 क्यों न आई.पी. आयोग भी साजे, जो विश्व में अग्रणीय विराजे।  
 उमंग के इस भेषज चमन में, उमड़ती सांसारिक स्पर्धा के गगन में,  
 एन.ए.बी.एल. और डब्लू. एच. ओ. से प्रमाणित, भारत सरकार से उत्साहित,  
 सर्व सुखायःचमकाता कर्मयोग है, आई.पी. आयोग एक मनोयोग है।  
 औषधि सतर्कता के प्रसंग में, पी.वी.पी.आई. के संग में,  
 पी.वी.पी.आई. आयोग की शान है, औषधि सतर्कता का कार्य महान है।  
 आई.पी., एन.एफ.आई. प्रकाशन व संशोधन, आई.पी.आर.एस. मानकता व अनुमोदन,  
 नई औषधि जॉच व शोधन, प्रशिक्षण व आइ.पी. मोनोग्राफ संवर्धन,  
 औषधि गुणवत्ता व सुरक्षा सन्दर्भ में, जन पशु स्वास्थ्य रक्षाप्रसंग में,  
 बहुआयामी बोध गम्य संयोग है, आई.पी.सी. प्रगतिशील मनोयोग है।  
 इस मनोयोग की वेला मे, जनकल्याण व सेवा में,  
 हम तत्पर हरदम रहेंगे, खुदा कसम किसी से कम नहीं रहेंगे।  
 कष्ट मिटे, सुख समृद्धि, बड़े देश भक्ति व ज्ञान।  
 सब लोकों में भारत की, बड़े निरन्तर शान।  
 हम कर्म करें महान, रक्षा करें भगवान।

जयहिन्द

### रचयिता

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*let us join hands with PvPI to ensure patient safety*

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