



# Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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# Secretary-cum-Scientific Director's Message



Dear Readers,

The first and foremost task of NCC-PvPI, IPC in conjunction with all healthcare stakeholders, including marketing authorization holders (MAHs), must be to bolster awareness among the common masses for reporting ADRs, as and when, observed by the patient/consumer/attendant or healthcare professionals.

To further this initiative PvPI has been steadily accomplishing the goal of widening its network of Adverse drug-reaction Monitoring Centres (AMCs), with the specific objective of making these centres efficacious and tool-oriented to report ADRs in the prescribed digitised format as well by PvPI Helpline and android Mobile App.

The 10-day skill development programme for HCPs, which is held bi-monthly at NCC-PvPI, IPC, Ghaziabad, needs to be made widespread, ensuring the enrolment of more healthcare stakeholders from varied professional background.

Having earned the coveted distinction as a WHO-Collaborating Centre for pharmacovigilance in Public Health Programmes and regulatory services, NCC-PvPI has been at the forefront, strengthening PV in low-and-middle income countries (LMICs) in Asia.

As a step forward in this direction, Smart Safety Surveillance (3S) project, which aims at identifying, assessing and managing the risks associated with new medicines and vaccines, was unveiled at New Delhi in April 2018. A PV Scoping Mission meeting in furtherance of the 3S Project was held at Indian Pharmacopoeia Commission (IPC) on April 12, 2018.

Again in pursuit of offering technical training and knowhow in pharmacovigilance to LMICs, a delegation from Bhutan's Drug Regulatory Authority (DRA) attended a four-day training programme at IPC in June 2018. The visiting Bhutan delegates were also familiarized with the Materiovigilance Programme of India (MvPI) and Medical Device safety measures.

I earnestly wish PvPI success in its efforts to raise public awareness on reporting adverse drug reactions at the grassroot level.

## **Dr. G. N. SINGH**

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

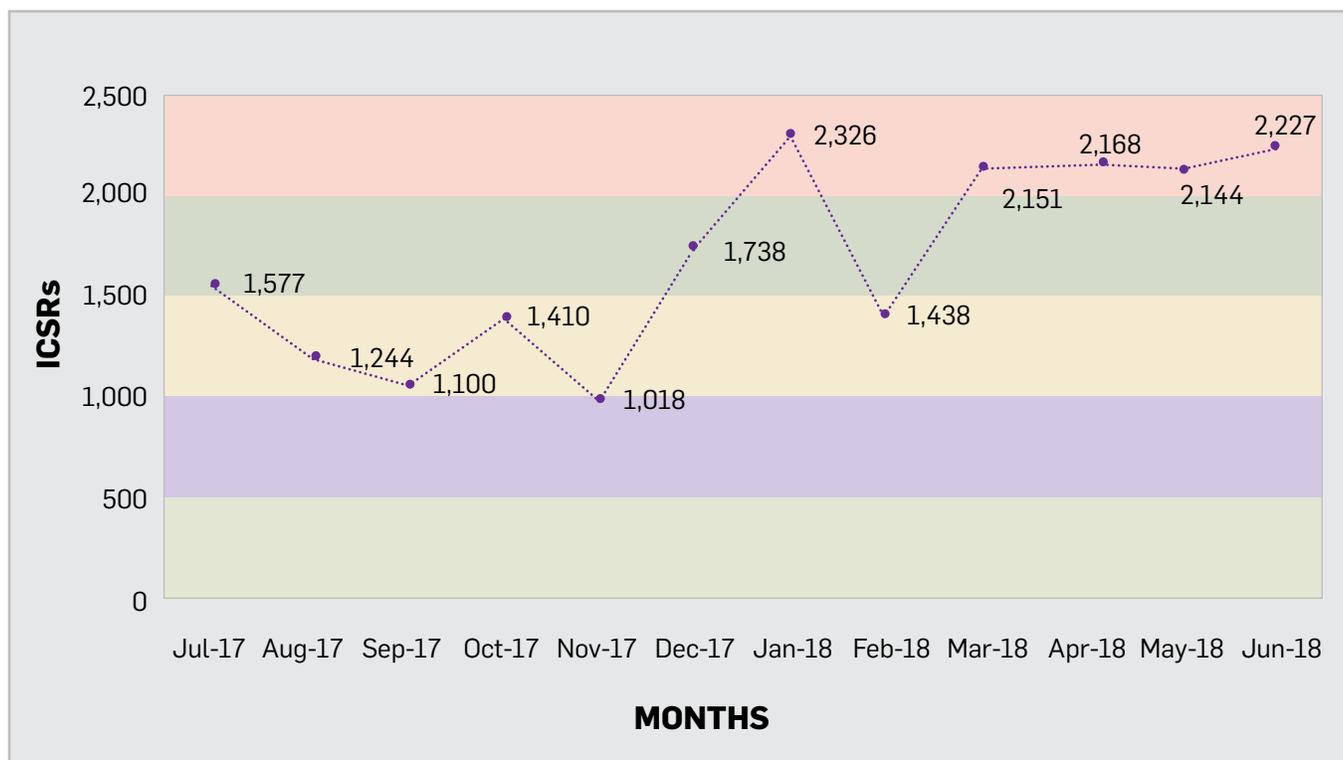
# PV policy for MAHs



India is a leading manufacturing and importing site for pharmaceutical products. With every licensed pharmaceutical product are associated benefits and risks. To monitor the safety profile of these products the Indian Pharmacopoeia Commission (IPC) as the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) collects suspected ADRs from all stakeholders, including marketing authorization holders (MAHs). PvPI reviews the safety information on a regular basis as a counterpart of the regulatory

authority – the Central Drugs Standards Control Organization (CDSCO) – enabling the CDSCO to make appropriate regulatory decisions.

MAHs play a crucial role in monitoring the safety of medicines approved for human use in India. In recent years PvPI has received an overwhelming response from MAHs as the safety database at NCC-PvPI is pronounced every year. More than 75 MAHs are enrolled with PvPI and the graph here-in-below depicts the contribution of MAHs to the PvPI database:



**A copy of comprehensive Post-Marketing Surveillance (PMS)/Periodic Safety Update Report (PSUR) has to be submitted to the regulatory authority/NCC-PvPI in a timely manner as per the norms stipulated in the Schedule Y of the Drugs & Cosmetics Act and Rules. As per the recent amendment to the Drugs & Cosmetics Rules 1945, Schedule Y and the Gazette notification GSR 287 (E) dated March 8, 2016, the setting up of a Pharmacovigilance (PV) system is mandatory for all MAHs.**

To guide MAHs on reporting ADRs and establishing a sustainable PV system at their respective sites, the PvPI in collaboration with CDSCO has released the “Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products”. Released by then Union Health Secretary, Govt of India on September 29, 2017, the Guidance Document for MAHs lays down the role and responsibilities for MAHs of pharmaceutical products to have a pharmacovigilance system in place for collecting, processing and forwarding report/s on ADRs emerging from the use of any medicine manufactured or marketed by the applicant in the country, to the licensing authority. The feedback by MAHs following the establishment of an effective PV system at their

site/sector has been quite encouraging as it helps ensure patient safety by drug safety.

PSURs are intended to be submitted to CDSCO and NCC-PvPI, IPC by the MAHs during the post-marketing phase, in order to monitor the safety and effectiveness of pharmaceutical products marketed in India.

**To train pharma industry professionals in Pharmacovigilance system establishment and capacity building at pharmaceutical companies, PvPI conducts regular technical training programmes at NCC-PvPI, IPC, Ghaziabad.**

**Quantity-based Top 10 MAHs**

COMPANY	NUMBER OF REPORTS (JUNE 2017 TO JUNE 2018)
Novartis India Ltd	8303
Baxter India Ltd	1838
Pfizer Ltd	1232
Roche Products India Pvt Ltd	757
Mylan Laboratories Ltd	719
Bayer India Ltd	692
Torrent Pharmaceuticals Ltd	536
Glenmark Pharmaceuticals	536
IPCA Laboratories Ltd	504
MSD Pharmaceuticals Pvt Ltd	479

**Quality-based Top 10 MAHs**

COMPANY	ICSR QUALITY SCORE* (JUNE 2017 TO JUNE 2018)
Serum Institute of India Ltd	0.70
Novartis India Ltd	0.52
Bayer India Ltd	0.44
Baxter India Ltd	0.42
MSD Pharmaceuticals Pvt Ltd	0.42
Roche India Ltd	0.41
Pfizer Ltd	0.40
Lupin pharmaceuticals Pvt Ltd	0.39
Glenmark Pharma Ltd	0.38
Torrent Pharmaceuticals Ltd	0.32

\* Quality score (out of 1)



**Effective from January 2018**

**Applicable to PvPI, CDSCO and State(s)/ UT(s) Drugs Control Department**

**Ensures compliance of good Pharmacovigilance practices.**

The guidance document for MAHs, which ensures the compliance of Good Pharmacovigilance Practices, comprises the following modules:

- **Module 1**  
Pharmacovigilance System Master File
- **Module 2**  
Collection, Processing & Reporting of Individual Case Safety Reports
- **Module 3**  
Preparation & Submission of Periodic Safety Update Reports
- **Module 4**  
Quality Management System at Marketing Authorization Holder
- **Module 5**  
Audits & Inspections of Pharmacovigilance System at MAHs
- **Module 6**  
Submission of Risk Management Plan

# DRA-Bhutan visits IPC for PV, MvPI training

**D**elegates from Drug Regulatory Authority (DRA) of Bhutan visited Indian Pharmacopoeia Commission (IPC), Ghaziabad for conceptual training on basic, technical and regulatory aspects of Pharmacovigilance (PV) and its procedures in India. The four-day training programme from

June 11 to June 14, 2018 also served as a platform for sharing the healthcare safety and management systems prevalent in both countries. The visiting delegates attended technical sessions and seminars conducted by Pharmacovigilance Programme of India (PvPI) officials and experts and also made field-visits to AIIMS-National Drugs Dependence Treatment Centre (NDDTC), Ghaziabad, UP and Yashoda Hospital, Kaushambi, UP (both AMCs under PvPI).

Delegates from Bhutan included Mr Jigme Dorji, Ms Priya Sharma, Mr Choki Dorji, Mr Yangchen, Dr Meena Devi Samal, Mr Lobzang Dawa.

Dr Jai Prakash, on behalf of IPC, gave a comprehensive overview of PvPI and made a Power Point Presentation (PPP), explaining the current and future prospects of PV and their achievements so far.

The visiting Bhutan delegates were also familiarized with the Materiovigilance Programme of India (MvPI) and Medical Device safety measures. They were presented an overview of MvPI and imparted training on how to fill Medical Device Adverse Event (MDAE) reporting form.



Bhutan delegation during a briefing session on functioning of AMC at AIIMS-NDDTC



Bhutan officials during their visit to various wards at AIIMS-NDDTC, Ghaziabad

### SALIENT FEATURES

- Bhutan delegates were keen to know the procedure to set up a good PV system at their organization and how to collect ADRs and report them to their Regulatory Authority.
- Detailed discussion on case studies and causality assessment.
- Visiting delegates assured to have better management plans for effective PV in Bhutan, seeking cooperation and participation of PvPI officials in future endeavours.

Thanking IPC for convening the PV training programme, Mr Choki Dorji made a PPP on “Pharmacovigilance system in Bhutan” explaining ICSR and aggregate report submission by healthcare professionals (HCPs) to the regulatory agency in Bhutan. He also underlined the status of PV system and the need for improvement in



Dr G N Singh, IPC Secretary-cum-Scientific Director, 2<sup>nd</sup> right (seated) and IPC officials with Bhutan delegation at IPC, Ghaziabad on June 14, 2018



Bhutan delegation during its interaction with doctors, nurses and pharmacists at Yashoda hospital (AMC) in Ghaziabad.

Bhutan's PV management.

Bhutan delegation committed they would share their inputs with PvPI while identifying new signals or risks associated with use of drugs like Tramadol-induced PICA & Disulfiram-induced erythroderma identified at AIIMS-NDDTC.

## WHO-BMGF 3S Project unveiled

A three-day Smart Safety Surveillance (3S) project – a 2016 initiative by WHO-Bill and Melinda Gates Foundation (BMGF) to identify, assess and manage the risks associated with new medicines and vaccines -- was unveiled from April 11-13, 2018 at New Delhi. The 3S project aims at strengthening PV in low-and-middle income countries (LMICs) in Asia. The first phase of the project is scheduled to be completed by June 2019. A PV Scoping Mission meeting in furtherance of the 3S Project was held at Indian Pharmacopoeia Commission on April 12, 2018.

### KEY POINTS

- The National Coordination Centre-Pharmacovigilance Programme of India (PvPI), NRA-Central Drugs Standard Control Organization (CDSCO) and

Universal Immunization Programme (UIP) in India to introduce the 3S initiative.

- Work with PvPI and Immunization programme to form an Institutional Development Plan (IDP), and identify ways in which WHO could support PV development meeting timelines.
- Map PV activities carried out by all stakeholders.
- Review PV preparedness for monitoring new products, including Rotavac, and identify gaps.

A new rotavirus vaccine Rotavac – licensed in India in January 2014 – has been chosen as a 3S Project “candidate” based on the selection criteria developed by WHO Safety and Vigilance (SAV).

# Workshop on 'PSUR evaluation, PV Audits/Inspections'

# A

two-day training session-cum-workshop on "Capacity building, strengthening of PSUR evaluation, PV Audits and Inspections" was held at NCC-PvPI, IPC, Ghaziabad on April 26-27, 2018. The programme was attended by PvPI and CDSCO officials. Welcoming participants to the workshop, IPC Principal Scientific Officer, Dr V Kalaiselvan, highlighted the importance of the workshop for ensuring effective implementation of PSUR review and evaluation process at NCC-PvPI and conducting of PV Audits and Inspections for Pharmacovigilance system at MAHs by NCC-PvPI, IPC.

CDSCO ADC(I) Dr Somnath Basu made a presentation on "Format, structure and requirements of PSUR", delving upon the

suggested the date of marketing be considered for first PSUR submission. The PSURs submitted by MAHs to the regulatory authority comprise only global data and Indian data is generally missing. As per the PV Guidance Document for MAHs they have to report Indian data through their channel of ADR-reporting.

### GROUP EXERCISE

- Participants who attended the workshop were divided into different groups and given PSURs received from various MAHs for Evaluation of PSUR by each group & presentation by group Leader following speakers' inputs for the PSURs reviewed and evaluated.



contents of PSURs in "section details" for PSURs submitted by MAHs. Speakers Dr Moin Don and Dr Naveen Chhabra made a presentation on the following topics :

- Basic concepts and need for PSUR
- Difference between PSUR & PBRER
- Difference between EU GPVP Module & Indian Guidelines
- Developing easy checklist to master PSUR evaluation

### "PSUR REPORTING: CURRENT STATUS AND CHALLENGES"

- Participants expressed concern on PSUR submission: whether it ought to be from the date of approval or date of marketing. Dr Moin Don

### SPEAKERS' RECOMMENDATIONS

- Pharmacovigilance Guidance Document & Activity be made mandatory and incorporated in D&C Act
- MAHs should present "Executive Summary" for submitted PSURs to NCC-PvPI, IPC
- PvPI should share their ICSR data with MAHs to increase the PSUR data
- PSUR submission period be extended from 30 days to 60 days after data lock point
- PSUR submission for all marketed products be made mandatory throughout the life-cycle of the product
- NCC-PvPI, IPC with CDSCO officials should conduct PV Audits and Inspections for Pharmacovigilance system at MAHs

## National AEFI Committee Meet

N

ational Adverse Event Following Immunization (AEFI) Committee meeting was held at NIHFWS in New Delhi on June 14, 2018. Causality assessment for all serious AEFI cases

was discussed and evaluated by committee members. The Committee also recommended to CDSCO that regular meetings be held with MAHs for vaccine PSUR.



## 10<sup>th</sup> GAELF Meet

10<sup>th</sup>

Global Alliance to Eliminate Lymphatic Filariasis (GAELF) meeting was held at hotel Le Meridien in New Delhi from June 13-15, 2018. Its objective was to assess the progress towards elimination of Lymphatic Filariasis (LF) under the banner “Voices from the field on overcoming programme challenges”.

### FOCAL POINTS

- After inauguration of the 10th GAELF meeting by Mr J P Nadda, India’s Union Minister for Health & Family Welfare, the need for eradication of LF was discussed threadbare by representatives of all countries. The global meeting was attended by programme officials and subject experts representing MoHFW, New Delhi, NVBDCP, WHO Country Office for India and NCC-PvPI, IPC, Ghaziabad.
- Discussion by programme officials on Elimination of Lymphatic Filariasis included global reports on LF, treatment regimens, enhancing post-Mass Drug Administration (MDA) surveillance to verify elimination and the need for Morbidity Management and Disability Prevention (MMDP).
- Dr Nupur Roy laid emphasis on the accelerated elimination plan for LF with focussed Pharmacovigilance (PV) for the approved drugs. She stressed that PV data is a mandatory regulatory requirement for MDA.



# 6<sup>th</sup> Regional Workshop on PV, MvPI in Pharma sector

6<sup>th</sup>

Regional Workshop on the “Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries” was held at SDSTRC & RGICD in Bengaluru, Karnataka on May 25, 2018. The workshop was conducted to raise awareness and understand pharmacovigilance as practised at MAHs.

**Materiovigilance Programme of India (MvPI)** made an elaborate presentation, encompassing the safety oversight by MvPI on Medical Devices. The audience was sensitized to the need for **Medical Device Adverse Event (MDAE) reporting**. MvPI's Dr Shatrunajay Shukla during his visit to Narayana Hrudalaya Hospital, Bengaluru, which is a Medical Device Monitoring Centre (MDMC), stressed upon the relevance of, and need for, efficient MDAE reporting.

### TOPICS DEBATED BY PvPI:

- Pharmacovigilance System Master File
- QPPV/PvOI Roles and Responsibilities

- Collection, Processing and Reporting of Individual Case Safety Reports (ICSRs)
- Preparation and Submission of Periodic Safety Update Report (PSURs)
- Periodic Benefit-Risk Evaluation Report (PBRER)
- Quality Management System (QMS)
- PV Audits and Inspections at MAHs
- Submission of Risk Management Plan (RMP)
- Medical Devices Adverse Event (MDAE) reporting

### OUTCOME

- Participants taught to carry out good Pharmacovigilance (PV) practices and how to put in place an effective PV system at pharmaceutical companies
- Threadbare discussion on ICSR, PSUR and RMP submission as per the requirements for MAHs in India and various regulatory authorities' PV guidelines
- PV performance at MAHs in coordination with NCC-PvPI



Delegates at 6th Regional Workshop on “Basics of PV system in Pharmaceutical Industries”, at Bengaluru, Karnataka on May 25,2018.

# MvPI girds on Medical Device safety

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## MEETING WITH BUREAU OF INDIAN STANDARDS (BIS)

A meeting with Bureau of Indian Standards (BIS) was held at BIS head office, New Delhi on May 14, 2018. The meeting focussed on the protocol to access Notified Medical Device standards formulated by BIS, intended to be incorporated into Medical Devices Guidance Document by Materiovigilance Programme of India (MvPI). The meeting was attended by BIS and MvPI officials. The latter were represented by Dr V Kalaiselvan and Ms Ritu Jain. BIS officials briefed their IPC counterpart on the process to purchase BIS standards, and a list of 22 Notified Medical Devices' standards was provided by BIS to IPC.

## DATA COLLATION AND PROCESSING OF MDAE REPORTS AT NCC-MvPI

During the index period April-June 2018, NCC-MvPI received 184 MDAE reports from AMCs/MDMCs/ Medical Device industry. The reported cases are under assessment for completeness and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.

## WORKSHOP ON QUALITY & SAFETY OF MEDICAL DEVICES

A series of meetings between Technical consultant, Ms Sumati Randeo and MvPI officials for planning a model workshop on Quality and Safety of Medical Devices as well as a review of reference document for quality of medical devices was held in May and June 2018.

## MvPI REVIEW MEET WITH NHSRC

The meeting by MvPI with National Health System Resources Centre to review the progress of Medical Devices Guidance Document and Materiovigilance Programme of India (MvPI) was convened at IPC, Ghaziabad on May 22, 2018.

## KEY POINTS DEBATED

- Reference documents for standards of Medical

Devices: Role of NHSRC in procurement policy of medical devices

- First National workshop on quality and safety of Medical Devices
- Approval for revised version of MvPI Guidance Document and MDAE reporting form
- Review of SOPs



## IPC at 'Continuing Education Programme'



**'Continuing Education Programme'** on Pharmacovigilance was organised by Indian Hospital Pharmacists Association and B L Kapur Memorial Hospital at B L Kapur Memorial Hospital, Pusa Road, New Delhi on May 6, 2018. Indian Pharmacopoeia Commission (IPC) Sr PSO, Dr Jai Prakash, and Dr R S Ray, Scientific Assistant, attended the programme. Dr Jai Prakash made a presentation on **"Pharmacovigilance Programme of India"** and delivered a lecture on **"National Formulary of India"**. The programme was attended, among others, by healthcare professionals (HCPs) such as pharmacists and doctors.



## IPC at Bharat Institute of Technology, Meerut



Dr. Jai Prakash, SPSO, IPC, Officer In charge PvPI delivered a lecture about safety of Generic Medicines on 12th May, 2018 at Bharat Institute of Technology, Meerut.

## PvPI Helpline promotion in Chhattisgarh

A

meeting aimed at promoting PV in Chhattisgarh was held at Office of Drugs Controller, FDA, in Raipur, Chhattisgarh, which stressed to popularise PV among stakeholders. Posters embossed with PvPI tollfree Helpline were displayed at pharmacies, hospital OPDs/IPD, etc



Jawaharlal Nehru Memorial (JNM) Medical College AMC coordinator Dr Rajesh Hishikar (left) with Chhattisgarh Drug Controller Mr Narsinga Rao (right) and Deputy Drug Controller Mr Hiren Patel during a 'PvPI Helpline promotion' meeting at Office of Drugs Controller, FDA, in Raipur, Chhattisgarh on April 27, 2018

## PvPI, IPC-NABH Meet

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As per the MoU between NABH and NCC-PvPI, IPC, the second meeting of the Working Group was held at National Accreditation Board for Hospitals and Healthcare Providers (NABH), New Delhi on April 4, 2018. At the meeting, NABH and PvPI officials discussed the ways and means of strengthening patient safety by strict adherence to PV and following Good Pharmacovigilance Practices (GvPs) at all NABH-accredited hospitals across the country.

### SALIENT FEATURES:

- PvPI to ensure availability of ADR reporting forms at all NABH hospitals
- Dr Harish Nadkarni, CEO, NABH agrees to inclusion of PvPI's "Chapter 3 – Management of Medication" into the NABH "Accreditation Standards Guidebook for Hospitals"
- NABH to train their assessors on "ADR Reporting and Pharmacovigilance System" by inviting a trainer from PvPI
- The latest version of National Formulary of India (NFI) to be made available at all NABH hospitals
- PvPI will help promote PV at NABH hospitals, providing resource materials such as videos, posters and pamphlets, etc

# 9<sup>th</sup> Skill Development Programme

## Basics and Regulatory Aspects of PV



The objective of the bi-monthly, 10-day Skill Development Programme (SDP) is to enhance Pharmacovigilance skills of healthcare professionals (HCPs) and other stakeholders, including those from Pharma industry and academia, to promote patient safety by ensuring safe use of medicines in India.

**The 9<sup>th</sup> SDP was held between May 7, 2018 and May 16, 2018** at the National Coordination Centre, Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad. Sixteen participants from Maharashtra, Madhya Pradesh, Kerala, Tamil Nadu and Delhi participated

in the training programme. The 10-day training includes Technical/Practical sessions with field visits AMC at Guru Teg Bahadur Hospital, Dilshad Garden, Delhi.

### MvPI PRESENTATION AT SDP

The Materiovigilance Programme of India made a presentation at SDP on May 14, 2018. More than 17 participants were imparted training on “what, where and how to” report an adverse event following the implant/use of a medical device and also provided with hands-on training for reporting an MDAE.



The 9<sup>th</sup> SDP was inaugurated by Dr Y K Gupta, former dean and professor, AIIMS, New Delhi. He appreciated the interest and aspiration of the participants to choose Pharmacovigilance as a career. On behalf of PvPI, he stressed the importance and need for young professionals in the field of Pharmacovigilance.

### DETAILS OF PARTICIPANTS

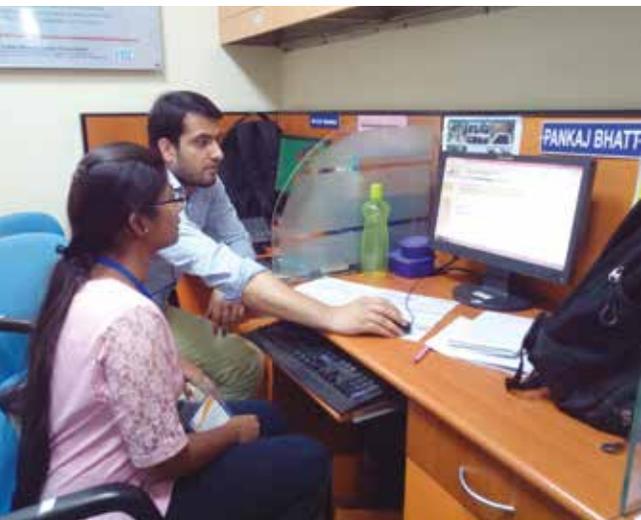
Participants with the medical & pharmacy background participated in this training programme.

9 <sup>th</sup> BATCH	NO. OF PARTICIPANTS
<b>State/Union Territory</b>	
Madhya Pradesh	03
Tamil Nadu	03
Delhi	01
Kerala	05
Maharashtra	04
<b>Total no.</b>	<b>16</b>
<b>Participants' Professional background</b>	
Clinicians	01
Students	10
Junior Residents	04
Academicians	01

### TECHNICAL SESSIONS

- Pre-assessment test for participants
- More than 30 Technical sessions, including nine practical sessions, were conducted

- Workshop on ADR reporting forms of CIOMS, Med Watch and PvPI
- Clinical relevance and judgement, Literature search and its importance
- Hands-on training for VigiFlow



# Approved New Drugs in India

**New drugs approved by CDSCO during April-June 2018**

S. No	DRUG	INDICATION
1	<b>Ulipristal Acetate bulk &amp; 5mg tablets</b>	For pre-operative and intermittent treatment of moderate-to-severe symptoms of uterine fibroids in adult women of reproductive age
2	<b>Riociguat bulk &amp; 0.5mg/1.0mg/1.5mg/2.0mg/2.5mg tablets</b>	For treatment of persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) following surgical treatment or inoperable CTEPH to improve exercise capacity
3	<b>Baricitinib 2mg/4mg film-coated tablets</b>	For treatment of moderate-to-severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modification anti-rheumatic drugs. Baricitinib may be used as monotherapy or in combination with methotrexate
4	<b>Vortioxetine Hydrochloride 5mg/10 mg/15mg/20mg film-coated tablets</b>	For treatment of major depressive disorder in adults
5	<b>Vardenafil Hydrochloride Trihydrate bulk &amp; Vardenafil 2.5mg/5mg/10mg/20mg tablets</b>	Treatment of erectile dysfunction in adult men
6	<b>Trientine Hydrochloride bulk &amp; 250mg capsule</b>	For treatment of Wilson's disease (hepatolenticular degeneration) in patients intolerant to Penicillamine. It should be used when continued treatment with Penicillamine is no longer possible because of intolerable or life-endangering side-effect
7	<b>Apremilast bulk &amp; Apremilast 10mg/20mg/30mg film-coated tablets</b>	Indicated for treatment of patients with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy
8	<b>Gadoteridol - 279.3mg/ml for injection Pack size - 10ml/15ml/20ml</b>	Lesions with abnormal vascularity in the brain (intracranial lesions), spine and associated tissues in adults and paediatric patients over 2 years of age. Lesions in the head and neck in adults
9	<b>Emtricitabine 200mg and Tenofovir alafenamide 25mg tablets</b>	In combination with other antiretroviral agents for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35kg) infected with Human Immunodeficiency Virus type I (HIV-I)

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

Source: [https://cdsco.gov.in/opencms/opencms/en/Approval\\_new/Approved-New-Drugs/index.html](https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/index.html)

# Drug Safety Alerts for April-June 2018

Preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from the PvPI database reveals that the following drugs are associated with the risks as given below:

**Suspected Drugs: DEXAMETHASONE**

**Indication:**

Adjunct in the emergency treatment of anaphylaxis; short term suppression of inflammation in allergic disorders; adrenocortical insufficiency, ocular inflammation, autoimmune disorders, rheumatic disorder, cerebral oedema, unresponsive shock, bacterial meningitis along with antibiotics

**ADR: Peripheral Neuropathy**

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above-mentioned adverse events while prescribing /consuming above quoted suspected drugs and report to the NCC-PvPI either by filling up suspected adverse drug reactions reporting form/medicines side-effect reporting form for consumer (<http://ipc.gov.in>) via PvPI **Helpline # 1800-180-3024**.

## Comparative status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS
QUININE	 <p>Dose-dependent QT-prolonging effects and interactions with other medicines</p>	<p>The UK, Medicines and Healthcare Products Regulatory Agency (MHRA), UK, has reminded HCPs as Dose- dependent QT-prolonging effects associated with quinine use, quinine should be used with caution in patients with QT-Prolongation risk factors (eg. Pre-existing cardiac diseases) or in those with AV block</p>	<p>One ICSR of QT- Prolongation reported in PvPI database</p>
CLOZAPINE	 <p>Agranulocytosis</p>	<p>From 1991 to the time of the review in 2017, Health Canada received 92 Canadian reports of low numbers of white blood cells (i.e. agranulocytosis) in patients using Clozapine. Health Canada issued a safety communication to inform healthcare professionals that the patients must be enrolled in a patient registry programme to monitor their white blood cell levels before their next prescription can be filled</p>	<p>20 ICSRs of Agranulocytosis reported in PvPI database</p>

Healthcare professionals are sensitized to carefully monitor the above mentioned alerts, if any event related to these drugs is to be reported to NCC-PvPI.

# KMC-Manipal excels in ADR-reporting



Kasturba Medical College (KMC) is a private institute affiliated to deemed university Manipal Academy of Higher Education (MAHE), a deemed university located in Manipal, Udupi, Karnataka. MAHE has been accorded the status of Institute of Eminence by MHRD (Ministry of Human Resource and Development), Government of India. Manipal is a name synonymous with quality medical education and tie-up with national and international universities of repute. The college has consistently been ranked among the top 10 medical colleges in the country.

Dr TMA Pai established the KMC at Manipal on June 30, 1953. Today, Kasturba Hospital is a 2,032-bed, speciality and super-speciality medical and surgical centre. KMC Manipal was recognized as an AMC under PvPI in June 2011. The Department of Pharmacology has been actively running the programme with Dr Shalini Adiga as Coordinator and Mrs Nitha Vayoth as Pharmacovigilance Associate.

## PHARMACOVIGILANCE ACTIVITIES

- Regular awareness classes and sensitization



of healthcare professionals to inculcate ADR reporting culture during their clinical practice

- Seminars on importance of ADR reporting at all departments of the hospital
- Awareness drive at Ayurveda faculty on reporting of ADRs due to herbal drugs
- CME on 'Antimicrobial Resistance, Need for Pharmacovigilance'
- Drug Alert Cards provided to patients who are allergy-prone to certain drugs
- Display of Pharmacovigilance posters at all in-patient and out-patient departments
- Display of ADR reporting form with the department contact number and the associate's number at all nursing stations and OPDs
- ADR reporting included in the curriculum for both undergraduate and post-graduate students of Pharmacology department
- A news column was placed in The Times of India, The Hindu and Udayavani, a local newspaper, to raise public awareness on reporting ADRs to the AMC concerned or PvPI Tollfree # 1800-180-3024



# Govt Medical College, Bhavnagar at its PV best

**G**ovt Medical College at Bhavnagar in Gujarat was established in 1995. Affiliated to Shri Maharaja Krishnakumar Singhji Bhavnagar University, Bhavnagar, the institute has an annual intake of 150 students for MBBS and 70 for post-graduation. It also offers B.Sc Nursing and Laboratory Technician courses. On an average daily it has 1,200 OPD and 600 IPD patients. GMC, Bhavnagar was designated as an Adverse drug reaction Monitoring Centre (AMC) by PvPI in 2011. However, it was functional in 2018 with Dr Bhargav Purohit, I/C

Head of Pharmacology, as Coordinator and Mr Bhavesh Chavada as Pharmacovigilance Associate.

## PHARMACOVIGILANCE ACTIVITY

- ADR reporting by android Mobile app at Govt Medical College, Bhavnagar
- 40 ADR drop boxes at clinical ward of Sir Takhsinghji General Hospital, Bhavnagar
- Sensitizing medical students to GVPs as practised by Pharmacovigilance Programme of India (PvPI)
- Regular sensitization to PV for doctors and clinicians through Email and WhatsApp messenger groups of GMC, Bhavnagar
- Pharmacovigilance Cell monitors on monthly basis ADRs reported by different departments of Sir Takhsinghji General Hospital, Bhavnagar
- Inclusion of special clause in IRB (Institutional Review Board) form which stipulates that every resident doctor will report 100 ADRs during their three-year residency
- Five Pharmacovigilance workshops held yearly for local IMA branch, faculty and residents of medical, dental and nursing colleges and pharmacists



## STAKEHOLDERS' FEEDBACK

It is heartening to see Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) generate drug-safety data for Indian population. Pharmacovigilance centre at GMC Bhavnagar relentlessly promotes PV at its medical college as also at its dental, nursing and pharmacy colleges. Making Pharmacovigilance Programme of India a true success is the shared responsibility of all the stakeholders, including clinicians, paramedical staff, patients, health administrators and regulators. This programme will go a long way in generating safety data and safeguarding the Indian population.



**Dr HEMANT MEHTA**

Dean , Govt Medical College,  
Bhavnagar, Gujarat

Sir Takhtsinghji General Hospital is one of the largest government hospitals in Gujarat, hence the need for strengthening Pharmacovigilance. Indian Pharmacopoeia Commission (IPC) with its Pharmacovigilance Programme of India (PvPI) has done us all proud. Under this programme we are able to generate robust indigenous drug-safety data for Indian population. India due to its large patient population, diverse food and cultural practices, being home to myriad treatment models and heterogenous genetic pool owes its natural responsibility to generate robust drug safety data not only for itself but for the entire world. We wish this programme fills the void in terms of lack of Indian data. I wish PvPI all the best!



**Dr VIKAS SINHA**

Medical Superintendent,  
Sir Takhtsinghji  
General Hospital,  
Bhavnagar, Gujarat

I feel privileged to be associated with a cardinal component of Indian healthcare system that is Pharmacovigilance. In a country like India where lax regulations regarding sale of drugs, rampant polypharmacy, variety of alternative therapies are practised with modern medicine and lack of formal prescription audit, drug safety is a serious issue. It is, therefore, necessary to sensitize clinicians across the length and breadth of the country to the paramount need for Pharmacovigilance, methods of reporting ADRs, the impact of ADRs and what happens to the reported ADRs. We should drive home the message that a formal Pharmacovigilance structure is in place in India.



**Dr BHARGAV PUROHIT**

I/C Head of Pharmacology and Coordinator, Adverse Drug Reaction Monitoring Centre (AMC), Bhavnagar, Gujarat

Pharmacovigilance Programme of India (PvPI) plays a key role in finding out the offending drug in adverse cutaneous drug reactions. It has reduced polypharmacy which will go a long way in minimizing drug interactions and ADRs. Monitoring and reporting of ADRs will help clinicians improve their prescriptions and counselling of patients. The database generated by this programme will, indeed, lend a helping hand to Indian drug regulators.



**Dr SATHISH PAI B**

Professor & HoD, Dermatology KMC, MAHE (Manipal Academy of Higher Education), Manipal

## STAKEHOLDERS' FEEDBACK

Pharmacovigilance is an important tool to ensure marketed drugs are safe for patients. Our AMC since its inception has been involved in the process of reporting ADRs and encouraging implementation of PvPI activities. Under-reporting of ADRs due to lack of obligation and indifference to its importance is a challenge. PvPI directives to strengthen the safety monitoring of medicines are commendable.



**Dr SHALINI ADIGA**

Professor & HoD,  
Pharmacology  
KMC, MAHE (Manipal  
Academy of Higher  
Education), Manipal

The Pharmacovigilance Programme of India is a good initiative by the Govt of India to raise awareness among clinicians and people at large about drug safety by reporting Adverse Drug Reactions and better management of patients with safe drugs.



**Dr AVINASH SHETTYA**

Medical Superintendent  
KMC, MAHE (Manipal  
Academy of Higher  
Education), Manipal

PvPI plays a key role in patient care. ADR reporting and monitoring lead to better management of disease, thus improving the quality of life for patients. KMC has been doing a wonderful job as an AMC and has improved clinicians' awareness on ADR reporting.



**Dr M MUKHYAPRANABHUA**

Professor Dept. of Medicine  
KMC, MAHE (Manipal Academy  
of Higher Education), Manipal

Pharmacovigilance Programme of India is very useful and important for nurses in routine monitoring of ADRs. It makes a marked difference by ensuring the health-safety of patients and also improves the nursing practices and quality of care.



**Mrs DEENA PRABHAVATHI**

Nursing Superintendent  
KMC, MAHE (Manipal  
Academy of Higher  
Education), Manipal

# दवाईयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

## फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

जैसा कि हम सभी जानते हैं कि दवाईयों (टैबलेट्स, कैप्सूल्स, सीरप, इंजेक्शन, टीके इत्यादि) के उपयोग से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की सम्भावना रहती है इसको ध्यान में रखते हुए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया को नवीकृत किया, जिसका राष्ट्रीय समन्वय केंद्र भारतीय भेषज संहिता आयोग, राजनगर, गाज़ियाबाद, उत्तर प्रदेश में स्थित है। इस समन्वय केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए.डी. आर. मॉनीटरिंग सेंटर के द्वारा एकत्रित करके उसका ऑकलन एवं विश्लेषण करना है जिससे किसी भी दवा के फायदे एवं नुकसान की जानकारी अग्रिम कार्यवाही हेतु केन्द्रीय औषधि मानक नियंत्रण संगठन, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार को प्रेषित की जा सके।

“फॉर्माकोविजिलेंस का अर्थ है औषधि सतर्कता”, यदि किसी मरीज या व्यक्ति को दवाई लेने के बाद कोई प्रतिकूल प्रभाव/दुष्प्रभाव जैसे कि त्वचा संबंधित परेशानी, डायरिया, जी मिचलाना, उल्टी, बुखार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

राष्ट्रीय समन्वय केंद्र फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया, में दवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुवधाजनक माध्यम उपलब्ध हैं, जैसे कि:

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024 (सोमवार से शुक्रवार प्रातः 9:00 बजे से सायं 5:30 बजे तक)
- मोबाइल ऐप (ADR PvPI)

- ए.डी.आर. मॉनीटरिंग सेंटर
- ए.डी.आर. रिपोर्टिंग फॉर्म

(ए.डी.आर. मॉनीटरिंग सेंटर एवं फॉर्म की जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट [www.ipc.gov.in](http://www.ipc.gov.in) पर उपलब्ध है)

अगर आपको पहले किसी दवा से किसी भी प्रकार की कोई असुविधा हुई हो तो अपने चिकित्सक को इसकी सूचना अवश्य दें, जिससे चिकित्सक को आपका उपचार बेहतर ढंग से करने में सहायता मिले।

यदि कोई चिकित्सक, फॉर्मासिस्ट, नर्स या अन्य कोई स्वास्थ्यकर्मी प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी देता है तो उनके विरुद्ध किसी प्रकार की कार्यवाही नहीं की जाती है बल्कि इससे दवाईयों के प्रभाव को बेहतर ढंग से समझने में एवं रोगी के उचित उपचार में सहायता मिलती है इसलिए अपने मन से इस प्रकार के समस्त डर व भ्रमों को दूर करके जनहित में स्वास्थ्य संबंधित इस महान कार्य में अपना सहयोग दें।

वर्तमान में भारत के अधिकतर राज्यों में ए.डी.आर. मॉनीटरिंग सेंटर कार्यरत हैं एवं राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजिलेंस विषय पर वर्ष भर कौशल विकास कार्यक्रम का आयोजन किया जाता है। इस कार्यक्रम की पूर्ण जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट पर उपलब्ध है।

राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजिलेंस प्रोग्राम ऑफ़ इंडिया आप सभी से अनुरोध करता है कि दवाओं के सेवन से हुए सभी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी अवश्य दें जिससे कि दवाओं का सुरक्षित उपयोग सभी के लिए सुनिश्चित किया जा सके।



**Indian Pharmacopoeia Commission**  
National Coordination Centre,  
Pharmacovigilance Programme of India  
Ministry of Health & Family Welfare, Govt. of India,  
Sector-23, Raj Nagar, Ghaziabad- 201002  
Tel.: 0120-2783400, 2783401, 2783392  
Fax: 0120-2783311

**For any other Information/Suggestions/  
Query contact:**  
Officer Incharge  
Pharmacovigilance Programme of India  
**Email:** [ipclab@vsnl.net](mailto:ipclab@vsnl.net), [pvpi@ipcindia.net](mailto:pvpi@ipcindia.net)  
**Website:** [www.ipc.gov.in](http://www.ipc.gov.in)

*Let us join hands with PvPI to ensure patient safety*  
**ADR reporting Helpline (Toll Free): 1800-180-3024**