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IPC

Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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PvPI takes wing

STRIVING FOR EXCELLENCE: A PROFESSIONAL 'SKILL DEVELOPMENT PROGRAMME' FOR HEALTHCARE STAKEHOLDERS

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Secretary-cum-Scientific Director's Message

Dear Readers,

It gives me immense pleasure to delve on developments during the Jan-Mar 2017 quarter that could mark a turning point for drug-use and safety-monitoring among Indian masses.

At the outset, I wish to congratulate Pharmacovigilance Programme of India (PvPI) under the aegis of Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare (MoHFW), for successful assessment by World Health Organization-National Regulatory Authority (WHO-NRA) Global Benchmarking Tool (GBT). PvPI is rapidly gaining momentum in India and has been awarded a coveted maturity level of 4 out of 5.

Another landmark achievement in light of Pradhan Mantri Kaushal Vikas Yojana (PMKVY) is the commencement of Skill Development Programme on 'Basics and Regulatory Aspects of Pharmacovigilance', aimed at enhancing skills of the workforce engaged in the pharmaceutical industry and to effectively meet quality standards. I am happy to note that the first batch of these young Pharmacovigilance professionals has successfully qualified, and is geared for a great journey ahead.

It is noteworthy to mention that PvPI has taken a call to act on antimicrobial resistance (AMR) in the country. PvPI acts by all possible means of interventions like executive orders, educational approach and training aimed at curbing the menace of AMR. To combat AMR, we must strengthen Pharmacovigilance activities at national, regional and district levels to safeguard public health. It is the need of the hour to educate healthcare professionals on rational use of antimicrobials in the country.

I congratulate the entire PvPI team for its relentless efforts aimed at attaining a sustainable system of healthcare for one and all in the country.

Dr G N SINGH
Secretary-cum-Scientific Director,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare,
Government of India.

Strengthening Pharmacovigilance: PvPI Skill Development Programme for Professionals

Skill Development Programme aims at enhancing skills of healthcare professionals in Pharmacovigilance for ensuring patient safety

Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), initiated a Skill Development Programme on "Basics & Regulatory Aspects of Pharmacovigilance" from January 2017 for imparting training to young professionals in the field of Pharmacovigilance. The objective of this skill development programme has been to enhance Pharmacovigilance skills of healthcare professionals for promotion of patient safety.

Renowned national and international experts from various disciplines of Pharmacovigilance served as a trainer/faculty in this training programme.

DETAILS OF PARTICIPANTS

Participants with a medical and pharmacy background underwent the training. The details are mentioned in the table.

Dr G N Singh, Secretary-cum-Scientific Director, IPC, addresses participants during the inaugural session of Skill Development Programme at NCC-PvPI, IPC, Ghaziabad

TECHNICAL OUTCOME

- Provided an opportunity to the participants for enrolling themselves in Pharmacovigilance units of organisations
- Trained participants for Good Pharmacovigilance Practices (GVP) to ensure better patient safety

This training programme also encouraged them to become entrepreneurs in Pharmacovigilance.

The certificate of participation was provided to all participants. On the basis of the performance of participants in the training, top five performers of the training programme may be preferred for any future recruitment at PvPI.

1ST BATCH	NO. OF PARTICIPANTS	2ND BATCH	NO. OF PARTICIPANTS
STATE/UNION TERRITORY		**STATE/UNION TERRITORY**	
Uttar Pradesh	14	Bihar	07
Uttarakhand	11	Madhya Pradesh	21
Maharashtra	05	Tamil Nadu	01
Haryana	06	Jammu & Kashmir	01
Delhi	07	Uttar Pradesh	02
Telangana	01	Kerala	02
Bihar	03	Karnataka	04
Tamil Nadu	01	Maharashtra	01
Karnataka	01		
PARTICIPANTS' PROFESSIONAL BACKGROUND		**PARTICIPANTS' PROFESSIONAL BACKGROUND**	
Clinicians	10	Clinicians	02
Students	10	Students	35
Pharmacists	20	Pharmacists	07
Industry Professionals	03	Industry Professionals	-
Regulators	-	Regulators	04
Academicians	05	Academicians	-

Participants at technical session of Skill Development Programme

MODULES COVERED

- Pv Basics: Objectives & Methods
- Pharmacovigilance Programme of India
- ADR Understanding, Prevention & Reporting
- Causality Assessment & Quality Review
- Role in Public Health Programmes
- Signal Detection & Assessment
- Understanding of Individual Case Safety Reports
- Vaccine Pharmacovigilance
- Optimization of Drug Safety through Research
- Periodic Safety Reports: PSURs/PBRERs
- Pv-based Regulatory Action
- Application of IT Tools

NRA Meets WHO Standards on Vaccine Regulation

The Pharmacovigilance system of India has been declared 'functional' with a maturity level 4 out of 5

A World Health Organization (WHO)-led team of international experts from several countries has affirmed that the National Regulatory Authority (NRA) of India and its affiliated institutions meet the WHO-published indicators for the functional vaccine regulatory system.

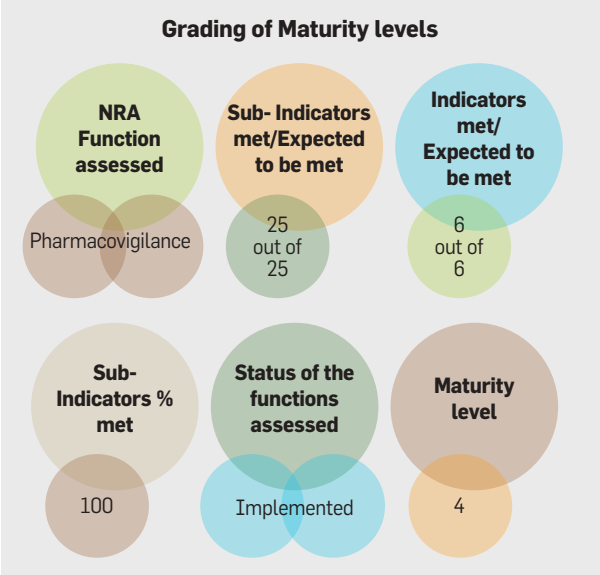
The WHO-NRA exercise – from February 13-17, 2017 – was aimed at assessing and documenting the status of Indian vaccine regulatory system, re-benchmarking the status of the vaccine regulatory system against the WHO-NRA Global Benchmarking Tool (GBT), updating the Institutional Development Plan and measuring maturity of the system.

The NRA includes Pharmacovigilance as one of the indicators for NRA-benchmarking tool. A visit by a team of WHO experts to NCC-PvPI, Ghaziabad, on February 15, 2017, was followed by a two-day field visit by a separate team from February 14-15, 2017, to KEM, Mumbai, an ADR-monitoring centre (AMC) of Maharashtra, for reviewing the Pharmacovigilance system by using the WHO-NRA assessment tool. All sub-indicators of the Pharmacovigilance tool were fulfilled and found satisfactory. The progress was remarkable when compared with the last NRA assessment made in 2012. The assessment has been done in respect of nine different functionalities. A review meeting to this effect was held on February 17, 2017 at MoHFW in Nirman Bhawan, New Delhi. The Pharmacovigilance system of India has been declared 'functional' with a maturity level of 4 out of 5, which is the highest level as per currently-evolved definitions.

RECOMMENDATION

PvPI/AEFI Secretariat

- To extend signal-detection tool for vaccine safety as well



Inaugural session of NRA Assessment 2017 at CDSCO (HQ), New Delhi

Institutional Achievements: A Journey from 2012 to 2016

S.No	SUBJECT	NRA 2012	NRA 2016
1	ADR Monitoring Centres	90	210
2	ICSRs a Drugs b Vaccines	22,935 22768 167	65,198 64,533 665
3	MAH-ICSRs a Drugs b Vaccines	200 185 15	13,513 13,423 90
4	ICSRs Completeness score	0.74	0.82

S.No	SUBJECT	NRA 2012	NRA 2016
1	Channel of ADR reporting	Suspected ADR reporting	a Suspected ADR reporting form b Consumer Reporting form c E2B, XML-MAH d Helpline e Mobile App
2	Resource	Newsletter	a Newsletter b Guidance Document c Performance Report d Quality Manual e Publications f Tool-kit g Pamphlets
3	National Collaboration	—	a AEFI b RNTCP c NACO d NVBDCP e ICMR f NABH g IMA

NRA reviewers during an inspection at NCC-PvPI

Reporting of Adverse Events due to Medical Devices is now PvPI's duty

PvPI has now been assigned ownership of Medical Devices Adverse Events (MDAEs) reporting

In the aftermath of Adverse Events (AEs) due to use of medical devices, the Ministry of Health and Family Welfare (MoHFW), GoI, has laid down stringent mechanisms for identifying and reporting such events throughout India. To monitor any such AEs, the Materiovigilance Programme of India (MvPI) was launched by the Drugs Controller General of India (DCGI), Dr G N Singh, at Indian Pharmacopoeia Commission, Ghaziabad, on July 6, 2015. During the launch, a Steering committee and a Working group committee were constituted to meet the aims and objectives as also the functions of the programme. The committees recommended identification of Medical Devices Adverse Events Monitoring Centres (MDMCs), assignment of coordinators and recruitment of research associates for these centres. The MoHFW nominated Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, as National Collaboration Centre (NCC) and National Health System Resource Centre (NHSRC) for providing technical support.

Following the recommendations by the two committees, 10 government medical colleges across the country, covering various zones, were identified as MDMCs by the NCC-PvPI and coordinators and newly-recruited research associates assigned to these centres. To train the coordinators and research associates in materiovigilance, the NCC-PvPI held a two-day induction-cum-training programme from February 22, 2017.

MEDICAL DEVICE ADVERSE EVENT (MDAE) REPORTS IN PvPI DATABASE

S. No.	Category of Device	Device Name (No. of reports)	Serious/ Non-serious	Adverse Event	Reporter
1.	Non-invasive	Surgical Gloves (2)	Non-serious	Allergic reactions	Surgeon
		Dialysis Machine (1)	Serious	Hypertension and cramps due to low conductivity	Technologist
		Chemotherapy (1)	Non-serious	Swelling,Thrombophlebitis at injection site	Doctor
		Surgical diathermy (1)	Non-serious	Patient developed burning sensation at patient placement position	Research Associate
2.	Invasive	Hip Implants (34)	Serious	Pain associated with limb dystrophy, Difficulty in walking, Osteolysis	Industry
		Copper T (1)	Non-serious	Pelvic Pain	Doctor
		Endoscopy (1)	Non-serious	Fever with chills and rigours, Pain in epigastric region after ERCP	Research Associate
		Cannula (1)	Non-serious	Multiple ecchymotic lesions on forearm with purpuric lesions	Pv-Associate
		Pacemaker (1)	Non-serious	Arrhythmia suspected due to pacemaker programming	Doctor
		Bone Cement (1)	Serious	Patient suffers cardiac arrest during the application of bone cement for total hip replacement in operation theatre	Surgeon

MvPI partners during an induction-cum-training programme for coordinators and research associates, at NCC-PvPI, IPC

During the steering committee's second meeting at IPC, Ghaziabad, on March 21, 2017, Dr G N Singh urged the NCC-PvPI, IPC, to shoulder all MvPI responsibilities with a view to ensuring its smooth functioning.

Dr Singh in his capacity as Secretary-cum-Scientific Director, IPC, has recently issued a circular to 210 Adverse Drug Reactions Monitoring Centres (AMCs) under PvPI, highlighting the following:

- Urgent need for reporting all adverse events due to use of medical devices
- Reporting of adverse events due to medical devices through the specifically-prescribed Medical Device Adverse Event (MDAE) reporting-form
- Need for close coordination by PvPI with cardiology, orthopaedics and dentistry departments of all AMCs to ensure urgent reporting
- PvPI to develop working relations with biomedical engineers, technical partners and healthcare professionals

NCC-PvPI has received as many as 50 Medical Device Adverse Event (MDAE) reports, which included 39 reports due to invasive devices, five reports due to non-invasive devices and six reports related to quality of the medical device.

IPC Signs MoU with NABH for ADR-Reporting

MoU to promote monitoring and reporting of Adverse Drug Reactions (ADRs) by NABH-accredited hospitals to PvPI

Indian Pharmacopoeia Commission (IPC) signed a Memorandum of Understanding (MoU) with the National Accreditation Board for Hospitals and Healthcare Providers (NABH) on January 10, 2017.The objective of this MoU between IPC and NABH is to promote monitoring and reporting of ADRs by NABH-accredited hospitals to Pharmacovigilance Programme of India. Indian Pharmacopoeia Commission is the National Coordination Centre for Pharmacovigilance Programme of India. A Memorandum signing ceremony was organised by IPC at CDSCO headquarters, FDA Bhawan, New Delhi, on January 10, 2017.

Dr G N Singh and Dr B K Rana exchanging MoU, along with other delegates

PvPI & MCI to Strengthen Pharmacovigilance

Dr Jayshree Mehta assures strengthening PvPI by changes in regulations

A meeting between PvPI and officials from Medical Council of India (MCI) was held in New Delhi on March 20, 2017. Those present included Dr Jayshree Mehta, MCI President; Dr Reena Nayyar, MCI Additional Secretary; Dr Arti Sharma, MCI Deputy Secretary; Dr V Kalaiselvan, Principal Scientific Officer, IPC, and Dr Prasad Thota, Scientific Assistant, IPC.

HIGHLIGHTS OF THE MEETING

- To strengthen Pharmacovigilance activities at various medical colleges/hospitals by effective coordination between NCC-PvPI, IPC, Ghaziabad, and MCI, New Delhi
- Incorporation of 'Adverse Drug Reaction (ADR) reporting to PvPI' as a Minimum Standard Requirement (MSR) for Medical Colleges seeking approval of Medical Council of India
- To include Pharmacovigilance and ADR-reporting mechanism topics in medical curriculum
- To motivate non-reporting ADR-monitoring centres into reporting ones

PSUR Expert Committee Recommendations on AEFI-Reporting

Periodic Safety Update Report (PSUR) expert committee recommends vaccine safety through enhanced adverse-event reporting

To assess the PSUR related to vaccines in India a meeting of PSUR Expert Committee was held at FDA Bhawan, New Delhi, for the purpose of examining and reviewing the AEFI data and PSURs pertaining to vaccine products of various manufacturing and importing companies.

RECOMMENDATIONS OF PSUR EXPERT COMMITTEE

- An adequate number of trained staff in Pharmacovigilance System be recruited by the firms
- Marketing Authorization Holders (MAHs) should proactively solicit to collect, collate and carry out a risk-based analysis of all AEFI-reported cases across the country
- The Pharmacovigilance System within MAHs should coordinate with private clinics as well as those in the government sector, institutional purchasers/users for reporting of all AEFI-reported cases (serious, severe and minor as well)
- MAHs should submit an active surveillance plan for the vaccine, ensuring that all cases are collected, collated and analysed with effective conclusions under intimation to CDSCO
- These MAHs should present their vaccine vigilance organogram and list of SOPs for such activities

PvPI Hitech Initiative: Web, Mobile App and Helpline Triad

Developing an Indian web-based Individual Case Safety Report (ICSR) management system & Mobile application for ADR reporting

Stressing the need for developing an indigenous software for collection, reporting, analysis and communication of ADRs in PvPI, NCC-PvPI will undertake the ownership role in handling drug-safety data with a software of its own.

The Drug Controller General (India) suggested the following steps for effective functioning of an indigenous web-based safety tool:

- Plan to develop indigenous software for Pv reporting
- The software will be integrated with CDSCO and other departments of MoHFW.
- A demo-version may be used at 10 AMCs to check the suitability of the new software
- Upgradation of mobile application and Toll-free helpline to efficiently document Drug-safety

PRIORITIES' SYNOPSIS

A. TELECOM SECTOR APPLICATION

i. **Upgradation of Toll-Free Number (1800-180-3024) of NCC-PvPI**
The existing toll-free number has limitations owing to its current single-line operation. It was decided that initially a small call centre will be made operational, manned in one shift with a voice-call recording facility for the remaining hours.

ii. **Mobile Application for ADR Reporting**
The new mobile application will cover reporting from HCPs and patients, or their Legally Accepted Representatives (LARs).

iii. **Mobile Application for Lack of Efficacy (LOE) Reporting**
It would be a new application which will cover all stakeholders such as HCPs, patients or their LAR to report ADR.

B. CLOUD BASED E-REPORTING COMPATIBLE WITH MOBILE PHONES/ DESKTOPS AND LAPTOPS

i. To submit Periodic Safety Update Reports (PSURs) from marketing authorization holders (MAH) to CDSCO/PvPI

ii. To report spontaneous ADRs to PvPI

Enhanced Coordination between PvPI and NVBDCP for Kala-azar Elimination

Road-mapping the Pharmacovigilance of drugs used for vector-borne diseases

Visceral Leishmaniasis (VL) or Kala-azar (KA) is a parasitic disease with anthroponotic infection. Remaining untreated, it has proved fatal in more than 95% of patients. India is one of the six countries which share 90% of global burden of VL. There are four main forms of the disease: visceral leishmaniasis (VL), post-kala-azar dermal leishmaniasis (PKDL), cutaneous leishmaniasis (CL) and mucocutaneous leishmaniasis (MCL). While CL is the most common form of disease, VL or kala-azar is the most serious form and can be fatal if untreated.

Pharmacovigilance Programme of India – in collaboration with National Vector Borne Disease Control Programme (NVBDCP) and World Health Organization (WHO) Country Office for India – organized a two-day 'National Meeting on Accelerated Plan for Kala-azar Elimination 2017 and National Workshop on Pharmacovigilance for Vector-Borne Diseases', in New Delhi from February 2-4, 2017.

The 'Accelerated Plan for Kala-azar Elimination', including a 'Roadmap for Introduction of Pharmacovigilance for Vector-Borne Diseases', was launched during the meeting by Mr Faggan Singh Kulaste, Hon'ble Minister of State, Health & Family Welfare, Government of India. During

Shri Kulaste in his address to the audience says: "Kala-azar elimination is one of the important flagship programmes of Government of India and we at the Ministry of Health are making all our efforts in seeing to it that our long cherished dream of elimination is realized.
After Kala-azar elimination, maintenance of elimination status is a big challenge as it envisages a close and intense monitoring in the field of suspected VL & PKDL cases."

Dr (Prof) Jagdish Prasad, Director General of Health Services (DGHS), in his address to the audience appreciates the efforts by PvPI, NVBDCP and WHO for eradication of Kala-azar, stressing the need for monitoring and minimizing the risks associated with the treatment of Kala-azar

WORKSHOP HIGHLIGHTS

- All stakeholders were apprised of the knowledge on ADR-reporting related to Kala-azar drugs
- Healthcare workers and treatment providers were sensitized on Pharmacovigilance vis-a-vis Kala-azar
- Alignment with ADR-monitoring centres (AMCs) under PvPI for Kala-azar-prone districts in respective states
- Scope for identifying a Kala-azar treatment centre as an ADR-monitoring centre (AMC)

the workshop the members were apprised of customized suspected ADR-reporting form and also provided with hands-on training on VigiFlow® (web-based ICSR management system).

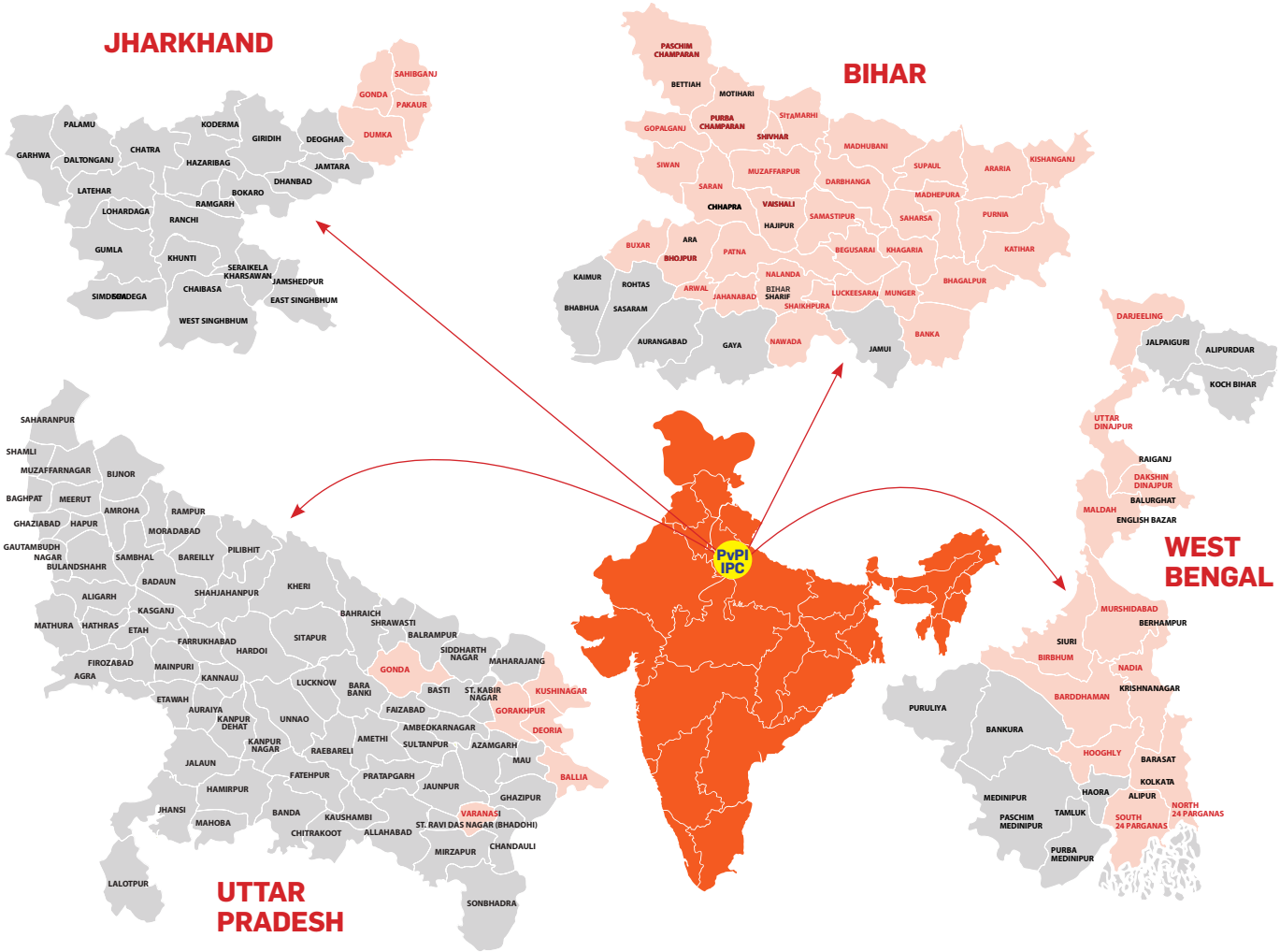
At present **Kala-azar is endemic to 54 districts in the country of which 33 districts are in Bihar, 4 in Jharkhand, 11 in West Bengal with cases of sporadic occurrence reported from 6 districts of eastern Uttar Pradesh.** The state of Bihar alone contributes more than 70% of total Kala-azar cases reported from the four states.

BIHAR SCENARIO: Of 38 districts in Bihar, 33 are affected. The population at risk is 34.65 million, in nearly 12,000 villages spread over 426 blocks. As many as 62% of these blocks have achieved elimination.

JHARKHAND SCENARIO: Of 24 districts in Jharkhand, Kala-azar is endemic to 4 districts – Dumka, Godda, Pakur and Sahibganj. The population at risk is 4.8 million, in nearly 1,507 villages spread over 30 blocks. Only 10% blocks have achieved elimination.

WEST BENGAL SCENARIO: Of 19 districts in West Bengal, 11 districts which include Malda, Murshidabad, Darjeeling, 24-Parganas (North), 24-Parganas (South), Nadia, Hooghly, Burdwan, Dinajpur (North), Dinajpur (South) and Birbhum are endemic to Kala-azar. The population at risk is 4.76 million, in nearly 731 villages spread over 119 blocks. As many as 93% blocks have achieved elimination.

UTTAR PRADESH SCENARIO: Of 72 districts in Uttar Pradesh, 6 districts in eastern part of the state including Kushinagar, Balia, Deoria, Varanasi, Gonda and Gazipur have reported sporadic cases of Kala-azar. The number of cases reported in 2013 was 11. Seven cases have been reported from the state in 2014. The population at risk is 2.35 million. All blocks have reached the state of elimination.



Induction-cum-training Programme for Newly-recognized AMC Coordinators

Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) organised a two-day "Induction-cum-training Programme on Pharmacovigilance" for the coordinators of newly-recognised Adverse Drug reaction monitoring centres (AMCs) under PvPI on February 22-23, 2017 at Indian Pharmacopoeia Commission, Ghaziabad.

This training delved upon the Basics & Concepts of Pharmacovigilance, Good Pharmacovigilance Practices (GVP), Quality Management System (QMS) of PvPI and Regulatory Aspects of PvPI, including practical sessions and hands-on training on VigiFlow.®

S. No.	STATE	CENTRE NAME	PARTICIPANT NAME
1	Karnataka	Mysore Medical College and Research Institute, Irwin Road, Mysore, Karnataka	Dr Basavanna P L
2	Kerala	Aster Medcity, Cheranelloor, Kochi, Kerala	Dr Ameer Shajahan
3	Telangana	Malla Reddy Institute of Medical Sciences, Quthabullapur, Jeedmetla, Hyderabad, Telangana	Dr M Jamuna Rani
4	Uttar Pradesh	Mata Anandamayee Hospital, Pandit Madan Mohan Malviya Road, Shivala, Varanasi, Uttar Pradesh	Dr Amit Kumar Gupta
5	Bihar	Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar	Dr Rahul Mohan

TECHNICAL OUTCOME

This induction-cum-training programme provided the coordinators of AMCs an opportunity to learn Good Pharmacovigilance Practices and Quality Management System of PvPI with a view to implementing the same at their centres for ensuring patient-safety.

Advance-Level Pv Training at B J Medical College, Ahmedabad

B J Medical College, Ahmedabad, which is enrolled as a Regional Training Centre, held a day-long training on Pharmacovigilance on January 20, 2017. This training was organized with the objectives of updating the participants on principles of drug safety, risk assessment and quality management system of PvPI. As many as 96 participants, including AMC coordinators (10), Patient Safety-Pharmacovigilance Associates (08), Medical Faculty (38) and post- graduate students (40), participated in the event. The training was well organized and the participants' knowledge was gauged by pre and post-assessment which assured the usefulness of training. B J Medical College, Ahmedabad, is committed to organizing such events and continuing to fulfil PvPI's objectives of patient safety.

Inaugural ceremony of training programme at B J Medical College, Ahmedabad, on January 20, 2017

Drug Safety Alerts for January-March 2017

A preliminary analysis of Suspected Unexpected Serious Adverse Reactions (SUSARs) from PvPI database reveals that the following drugs are risk-prone

AMISULPRIDE
Indication:
Treatment of acute and chronic schizophrenic disorders in which positive symptoms and or negative symptoms are prominent including patients characterised by predominant negative symptoms

ADR: Tinnitus

LURASIDONE
Indication:
Treatment of patients with schizophrenia

ADR: Thrombocytopenia

DEFERASIROX
Indication:
Treatment of chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes

ADR: Osteoporosis

LEVAMISOLE
Indication:
Treatment of roundworm and hookworm infestations

ADR: Skin exfoliation

CLOMIPRAMINE
Indication:
Treatment of Obsessive-compulsive disorder and panic disorder

ADR: Melasma

AMBROXOL
Indication:
Treatment of all forms of tracheobronchitis, emphysema with bronchitis pneumoconiosis, Chronic inflammatory pulmonary conditions, Bronchiectasis, bronchitis with bronchospasm asthma

ADR: Lacrimation

METOPROLOL
Indication:
Treatment of supraventricular arrhythmia, Angina pectoris, Hypertension, Myocardial infarction, Migraine prophylaxis, Hyperthyroidism and heart failure

ADR: Lichenoid drug eruption

ETORICOXIB
Indication:
Short-term use in acute painful condition

ADR: Skin hyperpigmentation

GLIMEPIRIDE
Indication:
Treatment of Type 2 diabetes mellitus

ADR: Lichenoid drug eruption

CEFEPIME
Indication:
Treatment of serious chronic respiratory tract infection (CRTI), Uncomplicated and complicated urinary tract infection (UTI), Uncomplicated skin & skin structure, Infection acute exacerbation of chronic bronchitis & intra-abdominal infection

ADR: Dermatitis Lichenoid

LOSARTAN
Indication:
Treatment of congestive heart failure, Hypertension (Myocardial infarction along with stroke including reduction of stroke risk in hypertension) with left ventricular hypertrophy and diabetic nephropathy in type II diabetes

ADR: Burning Micturition

CARBAMAZEPINE
Indication:
Treatment of partial seizures with or without secondary generalisation, trigeminal neuralgia and bipolar disorder

ADR: Bruxism

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above adverse events while prescribing/consuming above suspected drugs and report to the NCC-PvPI either by filling of Suspected Adverse Drug Reactions Reporting Form/Medicines Side-Effect Reporting Form for Consumer (http://www.ipc.gov.in) or via PvPI **Helpline No. 1800-180-3024.**

Comparative status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS
CODEINE-CONTAINING PRODUCTS	 Restrictions on use in children and adolescents due to respiratory adverse events	The Health Sciences Authority (HSA), Singapore, has received five reports of respiratory adverse events (AEs) such as dyspnoea and bronchospasm in children between 9 and 16 years of age associated with the use of codeine-containing cough products. Hence, HSA has worked with market authorization holders to update the package inserts of codeine containing products to include the restriction of the use in children and adolescents	One case of Respiratory depression was reported in 1.5 year-old infant
PIOGLITAZONE CONTAINING MEDICINES	 Increased risk of bladder cancer	US FDA has concluded that use of pioglitazone may be linked to an increased risk of bladder cancer and recommended that healthcare professionals should not use pioglitazone in patients with active bladder cancer. Hence, FDA has updated product information for pioglitazone-containing medicines (Actos®, Actoplus Met®, Duetact®, Oseni®) to include an additional description of studies to existing warnings about the increased risk of bladder cancer	One case of bladder cancer was reported
FLUOROQUINOLONES	 Risk of retinal detachment	Two large cohort studies have found a statistically significant increased risk of retinal detachment with use of oral fluoroquinolones. Since retinal detachment is serious and its association with oral fluoroquinolones use cannot be ruled out, HSA has worked with marketing authorization holders to update the package inserts of fluoroquinolone-containing products (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, pefloxacin, ofloxacin and lomefloxacin) to warn of the potential risk of retinal detachment. The need to seek medical attention in the event of visual impairment and disturbances with these products has been highlighted	PvPI has not received any reports of retinal detachment associated with the use of fluoroquinolones, but has received several reports describing visual disturbances such as blurred vision, eye redness, itching and conjunctivitis
LAMIVUDINE	 Decrease in hearing	The WHO international database of suspected adverse drug reactions (VigiBase®) documented 45 cases of lamivudine associated with decrease in hearing and it is not labelled as an adverse drug reaction for lamivudine	PvPI has not received any reports of decrease in hearing associated with the use of lamivudine. But, one report each of ototoxicity and ear ache were documented in PvPI

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

KEM, Boosts Pharmacovigilance Activity in Mumbai

Assures of quality reporting as assessed through WHO-NRA

Seth G S Medical College and KEM Hospital was enrolled as an AMC under PvPI since the very inception of PvPI under the leadership of Dr Urmila Thatte, Professor and HoD, Clinical Pharmacology, as coordinator for NCC-PvPI.

ACTIVITIES AT KEM, MUMBAI

- The centre was assessed by WHO-NRA Global Benchmarking Tool (GBT) and measured the maturity of the system for vaccine Pharmacovigilance.
- PvPI helpline poster put up at OPD and Clinical Pharmacology and Medicine wards.
- Distribution of ADR forms and pamphlets, with contact details, to the public and HCPs.
- Regular audits of ADR reports for quality assessment.
- Audit of ADR reports for the last three years was done to check their completeness. ADRs were scored for their completeness.
- Poster presentation at Indian Society of Clinical Research by Dr Manali Mahajan, SMO, KEM.
- Dr Urmila Thatte sensitized District TB Officers and other healthcare professionals on the importance of ADR reporting.
- Dr Nithya Gogtay conducted an interactive session during "National Conference on Pharmacovigilance", at LTMMC & GH, Sion, Mumbai, on March 17, 2017.
- Vigiflow hands-on training for resident doctors and students.
- Sensitization of paramedical staff, lab technicians, biotechnology students, MSc students on how to fill ADR forms completely.

WHO-NRA assessment team during a field visit at KEM, Mumbai

From the coordinator's desk

"Heartiest congratulations to PvPI for all its success!

The last few years have seen it evolve and make not just a national but also an international impact in the area of ADR reporting. The constant encouragement and motivation provided by the programme have helped improve the reporting scenario in India. Measures like including the private sector, national programmes and also pharma industry into the programme have helped in the growth of the newly emerging branch of Pharmacovigilance.
It has been a pleasure to work with and to see the evolution of PvPI since its embryonic stage. I look forward to working with PvPI for many more years to come."

Pharmacovigilance in Bihar: IGIMS takes a leap in patient-safety

IGIMS, Patna, has the distinction of being the first AMC in Bihar

Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, was established on February 12, 1984, as an autonomous organization of Government of Bihar, with the objectives to provide super-speciality medical facilities in Bihar. IGIMS is a 610-bed tertiary-care hospital with an average daily attendance of more than 2,000 patients in the OPD. More than 50 major and minor surgical procedures are performed daily. Recently, the Annual Inaugural Golden Jubilee Conference of Indian Pharmacological Society (AIGJCONIPS 2017) was organized by Dept of Pharmacology, IGIMS, under the guidance of Prof (Dr) N R Biswas and Prof (Dr) Harihar Dikshit. At a PvPI scientific stall a symposium on Pharmacovigilance was organized by the host institute.

ACTIVITIES AT IGIMS, PATNA

1. Incorporation of toll-free Helpline # 1800-180-3024 in the OPD card.
2. Publication of toll-free Helpline # in regional newspapers to spread awareness
3. Sensitization of healthcare professionals on ADR-reporting through regular meetings and seminars
4. Workshops for JRs, MBBS, Nursing and Paramedical students to update on Pv reporting
5. An exclusive PvPI scientific stall for mass sensitization during the celebration of IGIMS' Foundation Day
6. Collaboration with AEFI, Kala azar-eradication programmes and IMA, Bihar, at the state, district and local level

Pharmacovigilance is the need of today's healthcare system. The most crucial step in ensuring patient-safety is to identify, manage and prevent the occurrence of adverse drug reactions (ADRs), which can be achieved by proper understanding and knowledge of Pharmacovigilance. It will be helpful in identifying spurious drugs. Technical support by NCC-PvPI is of utmost importance for smooth functioning of PvPI at AMC.

Prof (Dr) HARIHAR DIKSHIT
Prof & Head, Department of Pharmacology, IGIMS, Patna

IGIMS, Patna, has proved to be a role model for consumer reporting via toll-free # displayed on footnote of the OPD card. This is reflected in the PvPI annual performance report 2015-16 which mentions Bihar leading among all states.

Dr P K SINHA,
Medical Superintendent, IGIMS, Patna

IGIMS, Patna, has the distinction of being the first ADR-Monitoring Centre (AMC) in Bihar. Pharmacovigilance activities in our AMC are well supported by both non-clinical and clinical departments. Causality Assessment Committee is functional. Spontaneous ADR-reporting is increasing gradually and consistently.

Prof (Dr) N R BISWAS
Director, IGIMS, Patna

AIIMS, Bhopal, Strengthens Pv Role in Madhya Pradesh

As a regional training centre it promotes Skill Development in Pharmacovigilance

AIIMS, Bhopal, is one of the six new AIIMS set up under the Pradhan Mantri Swasthya Suraksha Yojna (PMSSY). It is a tertiary-level healthcare institute with a medical college and a 960-bed hospital, which provides speciality health services to a maximum number of people in central India. On an average, attendance in the outpatient department (OPD) ranges from 1,000 to 1,500 per day. AIIMS, Bhopal, was enlisted as an AMC in March 2014 under the leadership of Dr Balakrishnan S, Prof

& HoD, Pharmacology, as a deputy coordinator and Dr Ratinder Jhaj, Associate Professor, as Coordinator for NCC-PvPI. NCC-PvPI recognized AIIMS, Bhopal, as a regional training centre (RTC) for both Madhya Pradesh and Chhattisgarh in 2015.

ACTIVITIES AT AIIMS, BHOPAL

- Sensitization of doctors, pharmacists, staff nurses, technicians, MBBS and nursing students through training programmes.
- Continuing Medical Education (CME) programme held on July 23, 2016 at AIIMS, Raipur, in collaboration with AIIMS, Bhopal.
- Coordination with the state expanded programme immunization officer (SEPIO) for vaccine ADR monitoring and reporting.
- Coordination with peripheral hospitals such as Jawaharlal Nehru Cancer Hospital and Research Centre (JNCHRC) and Bhopal Memorial Hospital and Research Centre (BHMRC) for active ADR-reporting.
- Guest lecture by Dr Ratinder Jhaj (Coordinator, AMC, AIIMS Bhopal) on November 26, 2016 and November 29, 2016 at Bansal College of Pharmacy and Bhopal Institute of Technology, respectively, for awareness among budding pharmacists.
- Display of ADR awareness visual presentation in Hindi at OPD registration counter and other OPD sections.
- Display of ADR awareness calendars in cabins of different departments.
- Dissemination of information related to ADR reporting, toll-free Helpline #, etc, by displaying posters in various departments.
- Design and distribution of ADR report cards to patients to avoid repetition of reports.
- Advertisement of Helpline # 1800-180-3024 and AMC-AIIMS, Bhopal, contact details in local print media.
- Publication of special case reports in indexed journals.
- Circulation of newsletters released by PvPI.
- Release of in-house newsletter annually, which is circulated among all HCPs.
- Circulation of drug alerts and other information related to drug-safety among HCPs via WhatsApp groups.

"Pharmacovigilance is going to be the most effective and extensive tool for drug-safety monitoring globally, and to make this more successful every citizen of India (especially healthcare professionals) have to play an active role via reporting each and every adverse event so as to ensure patient-safety. I express my gratitude to clinical faculty for their cooperation and support. To ensure patient-safety at AMC-AIIMS, Bhopal, we assure that all our physicians and other healthcare professionals are well sensitized on the issue of reporting & shall continue to update knowledge of Pv through active involvement."

Dr K C TAMARIA
Medical Superintendent
AIIMS, Bhopal

"Recognizing and reporting ADRs is a critical step towards better drug-safety. With the cooperation of our clinical colleagues we have been able to contribute to the national adverse drug reaction (ADR) database and consequently to data worldwide. We would also like to express our appreciation to the state CDSCO for its prompt assistance as regards quality check of drugs when batch-to-batch variation was suspected to be the cause of adverse reaction."

Dr RATINDER JHAJ
Associate Professor
Coordinator, RTC-AMC,
AIIMS, Bhopal

"The efficacy is not only the prime parameter to judge the quality of therapy and treatment but safety issues related to adverse events are equally important. For this pharmacovigilance has now become a globally well-established tool. As regional training and resource centre, AMC-AIIMS, Bhopal, promotes coordination with different stakeholders. to report adverse events in a standardized manner. Our future goals will be focused on sensitizing private practitioners, local chemists/pharmacists for participation in ADR reporting as they have direct interphase with the patient through dispensing and counseling.

Dr BALAKRISHNAN S
Professor & HOD, Pharmacology
Deputy coordinator
RTC-AMC, AIIMS, Bhopal

"We have a well-established Pharmacovigilance centre at AIIMS, Bhopal, where we sensitize HCPs as well as patients attending this tertiary care centre. Our Reporting has been increasing constantly over time."

Dr DINESH ASATI
Associate Professor
Department of
Dermatology, AIIMS,
Bhopal

"Knowledge prevents unnecessary omission and willful commission of medical errors. All clinicians, pharmacists and general public have a role to play in improving medical knowledge and thus the power of prediction by medical sciences. Pharmacovigilance should be practised at all levels."

Dr SANJEEV KUMAR
Assistant Professor
Department of Community
& Family Medicine,
AIIMS, Bhopal

Approved New Drugs in India

The following new drugs were approved from January to March 2017 by the CDSCO

S. No.	DRUG	INDICATION
1	Etonogestrel 68mg implant	For Use by women to prevent pregnancy.
2	Dexlansoprazole Delayed Release Capsule 30/60mg & Bulk	For the treatment of i) Healing of all grades of erosive esophagitis (EE). ii) Maintaining healing of EE and relief of heartburn. iii) Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).
3	Carfilzomib Sterile Lyophilized Powder for Injection 60mg/vial (50ml vial)	Relapsed or refractory multiple myeloma ➔ Carfilzomib for injection is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. ➔ Carfilzomib for injection is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.
4	Dabrafenib 50mg/75mg Capsules (Dabrafenib Mesylate)	As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test. In combination with Trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.
5	Trametinib 0.5mg/2mg Tablets (Trametinib Dimethyl Sulfoxide)	As a monotherapy and in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an appropriate test.
6	Alectinib 150mg Capsules (Alectinib Hydrochloride)	For the treatment of patients with anaplastic lymphoma kinase (ALK)-Positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib.
7	Eliglustat 84mg Capsules (Eliglustat Tartrate or Hemitartrate Salt)	For the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an appropriate test.

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

सत्यमेव जयते

IPC

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Pharmacovigilance Programme of India
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let us join hands with PvPI to ensure patient safety

ADR reporting Helpline (Toll Free): 1800-180-3024