



Pharmacovigilance Programme of India (PvPI)

Vol 5
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11

Newsletter



**“I am proud of my job,
humbled by my responsibility**

**I am a PHARMACIST,
I am a PHARMACOVIGILANTE in
Pharmacovigilance Programme of India”
(PvPI)**

**My minuscule contribution by reporting
Adverse Drug Reactions helps voluminosly to
promote the safety of more than**

1.2 billion population

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Indian Pharmacopoeia Commission

National Coordination Centre, PvPI, Ministry of Health & Family Welfare
Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201002

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Secretary-cum-Scientific Director's Message



Dear Colleagues,

I am pleased to share with you the 11th issue of PvPI newsletter which has become one of the most progressive programmes in the past four years. The Ministry of Health & Family Welfare (MoHFW), Government of India (GoI) with technical support of National Coordination Centre (NCC)-PvPI has taken important decisions which were brought under implementation to ensure benefits to the patients' safety. The decisions pertain to almost all spheres including training & education, data gathering & collation, establishment of networks etc. I hope this process of development will gain further momentum in the coming years with the firm determination. Dr. Jagdish Prasad, DG, DGHS, MoHFW, GoI appreciated the role of Indian Pharmacopoeia Commission (IPC) in public health on the 6th Foundation Day Commemoration of IPC. To strengthen the patient safety of Indian population, PvPI has included a branch of Materiovigilance Programme of India (MvPI) to regulate the usage of medical devices. Currently PvPI initiated the process to integrate periodic safety update reports (PSURs) submitted by pharmaceutical companies to assured medicine safety data of the country. PvPI extends joint monitoring mission of the National Health Programmes of our country to monitor the ART & anti -TB drugs' adverse reactions to strengthen the treatment.

I am pleased to announce that IPC-PvPI are hosting the 38th Annual Meeting for Program for international drug monitoring (PIDM) in India in collaboration with WHO (Country Office) India. This will be a great opportunity for IPC-PvPI to strengthen the pharmacovigilance system in our country and also it will exhibit our achievements in the international forum. I hope you will enjoy reading this newsletter and learn more about numerous initiatives and achievements of PvPI to enhance the patients safety in a short span of time.

Best Wishes & Regards
Dr. G.N. Singh

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Important Events of PvPI

API Textbook: A Chapter on Pharmacovigilance

Shri J.P. Nadda Hon'ble Minister of Health & Family Welfare, Government of India released the 10th edition of API Text book of Medicine on 3rd February 2015 at New Delhi. This book contains the chapter on Pharmacovigilance: "Safety monitoring of medicines" for educating medical professionals the concept of Pharmacovigilance.



Shri J.P. Nadda, Hon'ble Minister, Minister of Health & Family Welfare, along with Dr. Jitendra Singh Hon'ble Minister of state, PMO & DOPT, Government of India releasing the 10th edition of API Text book of Medicine on 3rd February, 2015 at New Delhi. This book includes a chapter on "Pharmacovigilance: Safety monitoring of medicines" to educate medical professionals in Pharmacovigilance

Indian Pharmacopoeia Commission (IPC) plays key role in promoting public health in India: *Dr. Jagdish Prasad*

Padmashree Dr. Jagdish Prasad, DG, DGHS, MoHFW, GoI visited IPC on 2nd January 2015. While addressing Scientists of IPC, occasion of 6th foundation day, he mentioned that Commission is playing a key role in promoting public health not only in India but also globally. He also emphasized that IPC is a unique organization in the country engaged to ensure both quality and safety of medicines. He congratulated IPC Scientists for their tremendous contribution to promote public health which is reflected in national and international arena. He asked healthcare professionals to give equal



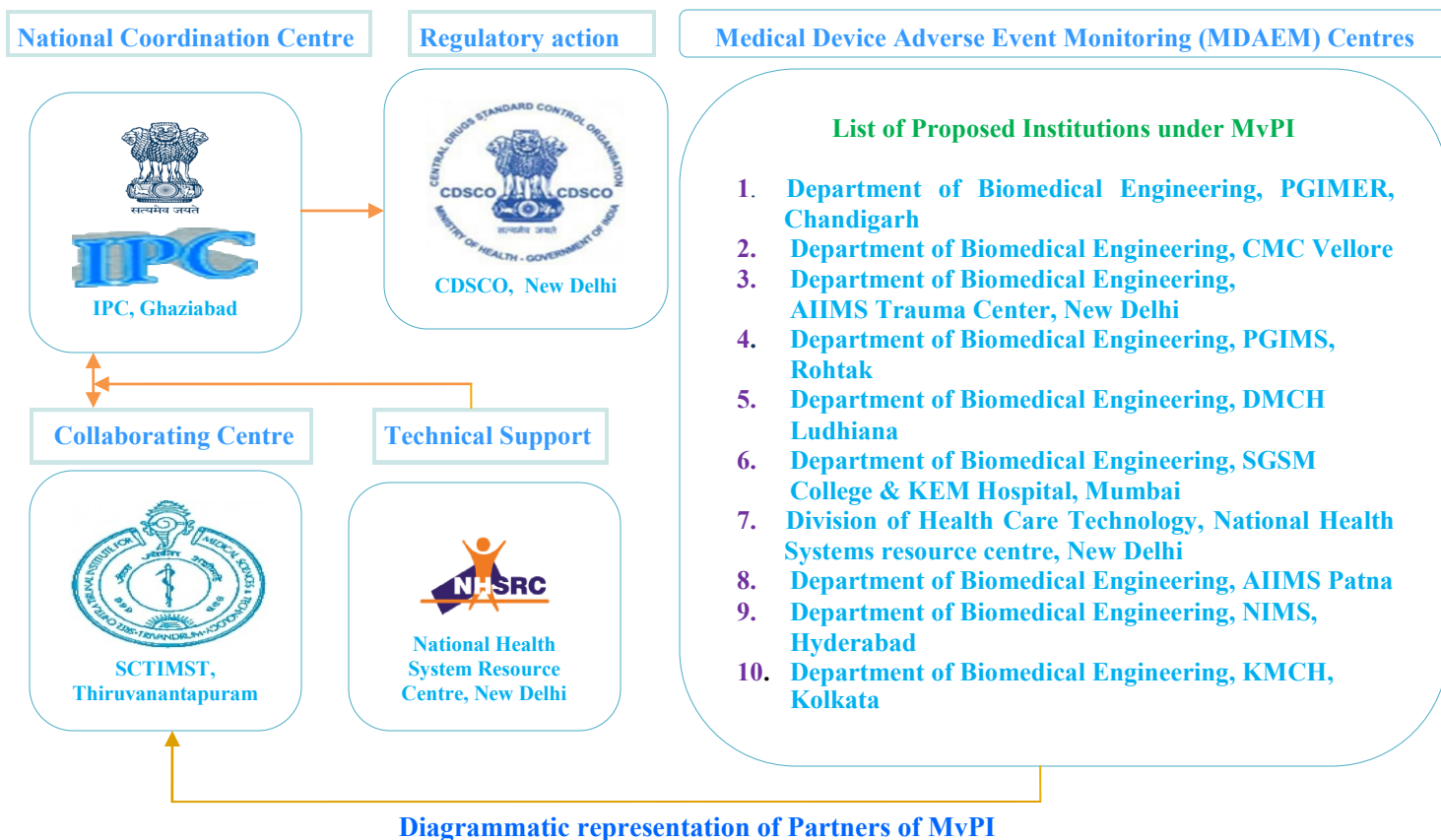
importance in monitoring of antimicrobial resistance which is very much needed to promote patients' safety.

One month later, again on 3rd February 2015, Dr. Jagdish Prasad convened a meeting at his office, exclusively to review the progress of PvPI. The main objective of the meeting was PvPI recommendation to CDSCO for regulatory intervention on certain drugs. After review of progress, he extended his support and commitment to PvPI since Pharmacovigilance is one of the pillars of patient's safety .

Padmashree Dr. Jagdish Prasad , DG, DGHS MoHFW, GoI, addressing Scientists of IPC on the foundation day on 2nd January 2015.

Materiovigilance Programme of India – *monitoring of adverse events related to usage of medical devices* –

Materiovigilance is monitoring the safety of medical devices (Invasive & Non Invasive) to outweigh the risk and ensure patient safety. It enables unsafe devices to be withdrawn from the market and to eliminate faults in medical devices with the intention of constantly improving the quality and providing patients/users with increased safety. Currently, over 75 percent of medical devices sold in India are imported and India is one of the top twenty markets for medical devices in the world. Policies, strategies and action plans for health technologies, specifically for medical devices, are required in any national health plan. In this context a robust health system must ensure access to safe, effective and high-quality medical devices that prevent, diagnose, treat disease and injury and assist patients in their rehabilitation. Government of India has constituted a national level committee to formulate a system of reporting of medical devices related adverse events under Materiovigilance Programme of India (MvPI) to ensure safety in usage of medical devices. Proposed MvPI envisages a



nationwide programme involving district hospitals, corporate hospitals and Medical Colleges. The programme will be coordinated by IPC, Ghaziabad with the technical support of National Health System Resource Centre (NHSRC) New Delhi. The Biotechnology wing of Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram will be the National Collaborating Centre for MvPI.

The MvPI is meant to enable safety data collection in a systematic manner so that regulatory decisions to be taken and recommendations suggested for safe use of medical devices could be based on data generated in India.

Goal

To ensure that the benefits of use of medical devices outweighs the risk and thus safeguard the health of the Indian population.

Objectives

- To monitor Medical Devices Associated Adverse Events (MDAEs) in Indian Population.
- To create awareness amongst healthcare professionals about the importance of MDAE reporting in India.
- To evaluate risk benefit profile of Medical Devices.
- Generate independent evidence based recommendations on the safety of Medical Devices.
- Support CDSCO for formulating safety related regulatory decisions pertaining to Medical Devices.
- Communicate findings with all key stakeholders eg. - manufactures, regulators, prescribers.

Quality ICSRs Facilitates Indisputable Signal

Quality reporting strengthens signal detection process in PvPI. To improve the quality of report, Quality Review Panel (QRP) Members discussed certain issues regarding causality assessment, completeness score and documentation grading of reports on 19th Feb, 2015 at IPC, Ghaziabad. In this meeting, main stress was on the constitution of Causality Assessment Committee (CAC) at the level of AMCs. The composition of Causality Assessment Committee will include the AMC Coordinator as Chairman, One clinician as Member and One Pharmacologist/ Pharmacist as Member. The panel reviewed the check list of SOPs, documentation Grading and Completeness score of PvPI to monitor the functioning of AMCs.

PSUR to be linked with PvPI

The evaluation of PSURs is a part of overall pharmacovigilance activity and also one of the important sources for signal detection. Thus it is only natural and appropriate to consider the review and analysis of such reports as a part of PvPI. This strategic decision was taken during a high level meeting organized in Delhi between the CDSCO and IPC officials on 30th March 2015. During the meeting, DCG (I) stressed that the PSURs submitted by the pharmaceutical industries should be made accessible to the PvPI for further enhancing the drug safety monitoring process. Currently, the PSURs are not linked to the PvPI and are submitted to the CDSCO only. IPC is already working on this matter. In fact, IPC is soon planning to set up a dedicated Committee or Cell to start the work on reviewing the PSURs.

PvPI to Integrate with ICMR for Rural Pharmacovigilance

Dr. G. N. Singh, DCG (I) and Chairman Steering Committee of PvPI, urged PvPI to integrate with the Indian Council of Medical Research (ICMR) to outreach PvPI into rural community of the country. Also this would widen the scope of PvPI and strengthen the evidence based information. Dr. Singh, Chaired the second Steering Committee Meeting held on 9th April 2015 at CDSCO and emphasized that though many laudable progresses have been made in PvPI, the need of the hour is to work with ICMR to gather the scientific information of ICMR sponsored projects on pharmacovigilance and to make it available at NCC-PvPI as a rational approach. He asked CDSCO and IPC to prepare a road map for expanding PvPI in urban and rural area of the country. The DCG (I) extended CDSCO's support and commitment for ensuring safety of medicines.

Dr. Rajani Kaul, a renowned Scientist, ICMR said that the steps would be taken to integrate pharmacovigilance data gathered by concerned department of ICMR with PvPI. She also added that AMCs in PvPI would be given preference to carry out the ICMR projects on tribal, rural and urban pharmacovigilance.

Applauding the NCC initiative, President, Pharmacy Council of India (PCI) and Member of Steering Committee, Prof. B. Suresh said, "What is being established today is a path-breaking initiative." He agreed to revise the pharmacy curriculum by incorporating pharmacovigilance in Under Graduate and Post Graduate level which was one of the agenda of the meeting.

PvPI and Pharmaceutical Industries to Harmonize PSUR Reporting

Pharmaceutical industries are one of the vital stakeholders of the pharmacovigilance. PvPI coordinates with industries for their active participation into the programme. IPC organized a round table meeting for “Challenges and Issues for the Pharmaceutical Industries in Reporting ADRs to PvPI” held on 29th April, 2015. The main objective of this meeting was to discuss the issues with the NCC-PvPI in handling industry data such as harmonization of ADRs reporting and better coordination among CDSCO, NCC-PvPI and pharmaceuticals industries. This meeting also aimed to discuss the challenges in linkages of PSUR with PvPI.



Participants of round table meeting held on 29th April, 2015

The major outcomes of the meeting are as under :

- Submission of ADR data in XML format to NCC-PvPI to facilitate import into Vigiflow,
- Coordination among NCC-PvPI, CDSCO & Pharmaceutical Industries,
- Review of drug guidance document for reporting of PSURs.

- Medical representatives are to be trained on the concept of Pharmacovigilance
- Pharmaceutical Industries to consider Pharmacovigilance as priority area of concern.

Indian Medical Association and PvPI to Collaborate for Training on Pharmacovigilance

Since the clinician's community is an important partner in pharmacovigilance, PvPI structured a meeting with high level members of the Indian Medical Association (IMA) on 30th April, 2015 at IPC, Ghaziabad.

The meeting was chaired by Dr. G. N. Singh, DCG (I). During his speech, he emphasized that IMA could play a major role in expanding activities of the PvPI and its outreach to the rural and urban population. He also emphasized that IMA can ensure the reach of the program to private practitioners and hospitals alike. He highly appreciated the IMA for coming forward to join hands with PvPI.

Dr. J. A. Jayalal, National Coordinator, academic wings of IMA, remarked that he was impressed with the work of PvPI in pharmacovigilance. He added that every clinician should come forward to involve himself in this programme as a national cause. He stated that the IMA College of General Practitioners (CGP) would be glad to extend its technical and operational support to PvPI. It was proposed in the meeting that IMA - CGP headquarters at Chennai will be recognized as 'PvPI Collaborating Centre' for Advocacy and Training on Pharmacovigilance.



Dr. G. N. Singh, DCG (I) addressing the IMA & PvPI Officials on 30th April, 2015

The major recommendations of the meeting are as under :

- Collaboration between NCC-PvPI and IMA to be initiated
- Android mobile Application for ADRs reporting to the database
- Pharmacovigilance cell in corporate hospitals, medical colleges including dental colleges to be set up

Active Surveillance on *Bedaquiline* all set to roll out soon in India

Bedaquiline

For the first time in over 40 years, a new anti-TB drug with a novel mechanism of action – Bedaquiline is introduced for clinical practice. It inhibits mycobacterial ATP (adenosine 5' triphosphate) synthase, an enzyme that is essential for the generation of energy in *Mycobacterium tuberculosis*. Although the drug is active against many different bacteria, it has been registered specifically for the treatment of MDR-TB. DCG (I) approved SIRTUORO® (Bedaquiline) for use in adults (>18 years) as a part of combination therapy of pulmonary tuberculosis due to multidrug-resistant *Mycobacterium tuberculosis* (MDR-TB) in January, 2015. This approval is an exciting milestone in the fight against TB, and specifically MDR-TB which poses

a significant treatment challenge and major public health concern in India.

DCG (I) instructed on 18th April 2015 that only Revised National Tuberculosis Control Programme (RNTCP) centres are allowed to prescribe Bedaquiline. World Health Organization (WHO) estimates that there are more than 2,800,000 cases of TB in India, and amongst them, approximately 64,000 (2.28%) cases are suspected to be multidrug-resistant.

***Bedaquiline* - need for active surveillance**

Safety monitoring should be stronger for Bedaquiline because of the introduction of the new drug in the context of complex regimens for drug-resistant TB, the concomitant use of antiretroviral treatment in patients with HIV-associated TB, or other drugs in case of comorbidities. Furthermore, the complete safety profile of *Bedaquiline* has to be developed as it

is a new drug to Indian population. Hence, it is important that adverse drug reactions be routinely monitored for patients suffering from TB on treatment. Thus active Pharmacovigilance is needed to help identify any rare adverse drug reactions that may be associated with the use of *Bedaquiline*.

Active pharmacovigilance is a more systematic and proactive form of safety surveillance. It is essential while introducing *Bedaquiline* to record in a reliable way the evidence of adverse drug reactions or drug-drug interactions and to use this information to formulate policy decisions, clinical guidelines and treatment recommendations. It provides the most complete and comprehensive data and in accordance with WHO interim guidance recommendation, Cohort Event Monitoring (CEM) is the recommended approach to active pharmacovigilance for introduction of *Bedaquiline*.

Vigibase Data

The data of *Bedaquiline* was extracted from the WHO Global ICSR database (VigiBase) on 19th April 2015 and it was found that 8 ICSRs of *Bedaquiline* have been reported till date. The number of ICSRs received at WHO Global ICSR

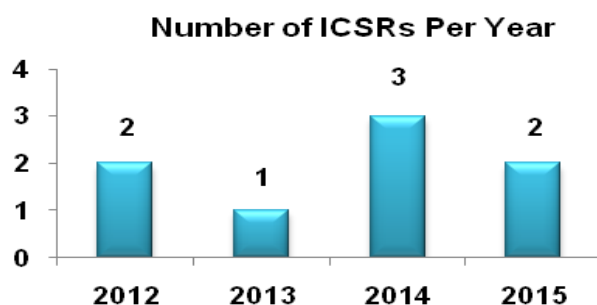


Figure 1: Number of ICSRs of Bedaquiline per year (Global)

All cases were of serious categories and one death case was reported. The types of reported ADRs were classified according to the WHO-Adverse reaction terminology (WHO-ART) System Organ Class (SOCs). Adverse events attributed with the use of *Bedaquiline* are shown in table 1.

Table 1 : SOC of *Bedaquiline*

| System Organ Class | Reaction in preferred term |
|-------------------------------------|--|
| Body as a whole-general disorder | Fever (1) Death (1) |
| Cardiovascular disorder | QT prolonged (2) |
| Endocrine disorder | Hypothyroidism (1) |
| Gastrointestinal disorder | Nausea (1) Diarrhoea (2) |
| Metabolic and nutritional disorders | Dehydration (2) |
| Musculoskeletal disorders | Creatine phosphokinase increased (1) |
| Neoplasms | Non-Hodgkin's lymphoma (1) |
| Neurological disorders | Neuropathy peripheral (1) |
| Immune disorders and infections | Infection bacterial (1) |
| Respiratory disorders | Coughing (1) Dyspnoea (1) |
| Secondary terms-events | Overdose (1) Medicine ineffective (1) |

Patient Monitoring

It is an important part of active surveillance patients receiving *Bedaquiline* should be monitored on weekly basis as given below and should have the following baseline tests done: liver function, thyroid function, CBC and electrolytes (including serum potassium, calcium and magnesium), and ECG.

- Monitoring for Cardiac Toxicity
- Monitoring for Hepatotoxicity and Renal Toxicity

- Therapeutic Drug Monitoring
 - Microbiologic Monitoring
 - Monitoring for Additional/New Side Effects
- Treatment should be modified as clinically indicated.

Proposed AMCs for Active Surveillance (Cohort Event Monitoring) on Bedaquiline

- Guwahati Medical College, Guwahati
- Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, New Delhi
- Lala Ram Swarup Institute, New Delhi
- B J Medical College, Ahmedabad
- DPS KEM GTB Hospital, Mumbai
- Government Hospital Thoracic Medicine, Tambaram, Chennai.

Only RNTCP centres are instructed for prescribing Bedaquiline

PvPI as a core component of Joint Monitoring Mission of RNTCP

The Joint Monitoring Mission (JMM) took position in a situation characterized by the recent adoption of the 'End TB strategy' by the Member States to end the TB epidemic in the world and India's experience with implementation of its ambitious strategies. Central TB division, MoHFW, Government of India and WHO recognized PvPI by including as a member of review team of JMM for RNTCP. The programme was held from 10-23th April 2015 at New Delhi, to evaluate the functioning of the programme and interacting with the DOTS providers at the field level which strengthened the mutual activities between PvPI and RNTCP. NCC-PvPI recommended to focus and to provide training to the DOTs providers on Pharmacovigilance.

Drug Safety Information

Intussusception due to Rota Vaccine: A matter of risk concern

Rotavirus is highly contagious virus causing severe acute gastroenteritis with diarrhea and vomiting in children. It is resistant and regardless of water quality and available sanitation, nearly every child in the world is at risk of infection. Diarrhea can be severe leading to dehydration and may also cause vomiting and fever. To protect children from Rota virus infection, Rota virus vaccine has been approved by the National Regulatory Authority in India. WHO also recommends this vaccine to be included in the National Health Programmes.

To ensure the safety of Rota vaccine, it is also equally important to protect the vulnerable population's health. Intussusception (part of the intestine folds in to another portion of intestine) is considered to be one of the risk concern due to the administration of Rota virus vaccine from day 1 to 4 months post vaccination. In India, out of 15 ICSRs on Rota vaccine; 10 suspected cases of intussusceptions were reported from 2011 till April 2015. Out of 10 cases, the male and female ratio was 4:3 and remaining 3 cases were Unknown. These cases were communicated to Immunization Technical Support Unit of Universal Immunization Programme, MoHFW for further

follow up with the patients and for causality assessment. To intensify the vigilance in this aspect NCC-PvPI is closely working with CDSCO and often with stakeholders to review the cases.

- NCC-PvPI received 10 ICSRs on Intussusception due to the administration of Rota vaccine
- NCC-PvPI holds regular coordination meeting with AEFI division of Universal Immunization Programme, MoHFW and CDSCO to review the cases
- Healthcare professionals and patients are advised to report-intussusceptions due to Rotavaccine to AMCs under PvPI or district immunization office or PvPI helpline (1800 -180-3024).

Artemether/Lumefantrine: Stevens Johnson Syndrome

This is preliminary evaluation report based on ICSRs received from different AMCs under PvPI in which Artemether/Lumefantrine is associated to cause Stevens Johnson Syndrome. *Artemether/Lumefantrine* is a regularly prescribed combination for malaria. Till April, 2015 a total of 2 ICSRs were reported to NCC-PvPI in which *Artemether/Lumefantrine* is suspected to induce Stevens Johnson Syndrome. These reports were received from KEM Mumbai and HIMS, Dehradun. Both the reports were considered as serious due to the hospitalization of the patients. The time of onset of reaction varies from one day to one month. In both the cases the reaction was either recovering or recovered. In one of the cases it was mentioned that the patient had a history of epilepsy and was on phenytoin. The

drug was withdrawn in one of the cases while the details are not known in the other case.

In conclusion, *Artemether/Lumefantrine* may cause severe Stevens Johnson Syndrome which is a serious life threatening reaction. Since this is a new ADR associated with Artemether/Lumefantrine use, healthcare professionals are advised to keep close monitoring of Stevens Johnson Syndrome with artemether/lumefantrine, which will help in early recognition and prompt withdrawal of the drug resulting in lesser morbidity.

NCC-PvPI keeps Intensive Monitoring on Stevens Johnson Syndrome of Artemether/Lumefantrine

Piperacillin/Tazobactam: Hypokalemia

This is a preliminary evaluation report based on ICSRs received from different AMCs under PvPI in which use of Piperacillin/tazobactam is associated with hypokalemia.

Piperacillin/tazobactam is a commonly used antibiotic with tolerable side effects and broad antimicrobial activity in general practice. Till April, 2015 a total of 13 ICSRs were reported to NCC-PvPI in which Piperacillin/tazobactam is suspected to induce hypokalemia. The reports were received from different AMCs as shown in figure 2.

Among 13 cases, 10 were reported from male patients and 3 were from female patients. Of all the cases, 10 cases represented the patients of adult age group, 2 cases represented child age group and 1 case was from an infant as shown in figure 3a, 3b.

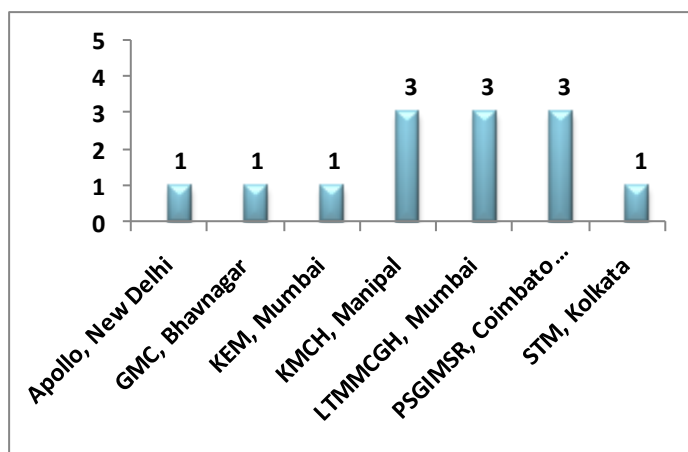


Figure 2 - Number of reports received from different AMCs in PvPI database

Figure 3a - Genderwise distribution of ICSRs

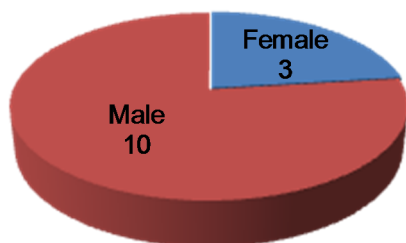
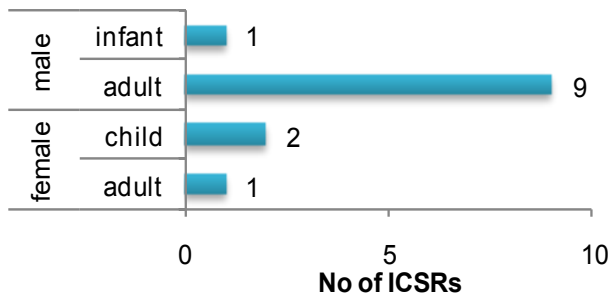
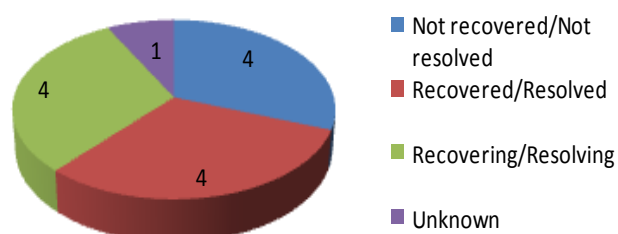


Figure 3b- Distribution of ICSRs based on Age Groups



Out of these 13 ICSRs, 6 reports were considered as serious reports as per the definition of seriousness of the report defined in the ICH E2B. Among these 6 cases, one case was life threatening, 4 were of hospitalization and one case was considered serious for other medical conditions.

Figure 4 - Outcome of Reaction of ICSRs



In 4 cases outcomes mentioned were not recovered while in one case the outcome was unknown. In the remaining cases the outcomes of the reactions were recovered/recovering as shown in Figure 4.

In conclusion we must keep in mind that even in patients with normal renal and hepatic functions, Piperacillin/Tazobactam may cause severe hypokalemia which could cause life threatening complications such as cardiac arrhythmia. Hence periodic electrolyte assessment is ideally recommended for patients who are receiving Piperacillin/Tazobactam.

NCC-PvPI keeps watch on hypokalemia of Piperacillin /Tazobactam

Ambroxol and Bromhexine expectorants - Rare severe skin reactions

Ambroxol and Bromhexine containing medicines have small risk of severe allergic reactions and severe cutaneous adverse reactions (SCARs) which include erythema multiforme and Stevens Johnson Syndrome when used as expectorants in European population. In Indian population no reports of severe cutaneous adverse reactions were found with use of both the drug and their combinations. However some skin related ADRs like erythematous rash, exfoliative dermatitis and urticaria were found in Vigibase. Healthcare professionals are advised to be vigilant while prescribing Ambroxol and Bromhexine expectorants to their patients and report any such ADR to the concerned.

Reference - www.ema.europa.eu

Nitrofurantoin - New advice on use in renal impairment

Nitrofurantoin is used in patients with moderate renal impairment. Recently, use of nitrofurantoin was contraindicated in patients with an estimated glomerular filtration rate (eGFR) less than 60ml/min/1.73m². The latest advice states that the drug can now be used in patients with an eGFR greater than 45ml/min/1.73m². In certain instances nitrofurantoin may also be prescribed for patients with an eGFR of 30 to 44ml/min/1.73m². Use in such patients should be limited to a short course of 3-7 days for the treatment of lower UTI with suspected or proven multidrug-resistant pathogens where the benefits of nitrofurantoin are considered to outweigh the risk of adverse events.

Reference - www.gov.uk Drugs/DrugSafety/

Ziprasidone - Associated with rare but potentially fatal skin reactions

Ziprasidone is an antipsychotic drug used to treat the serious mental health disorders like schizophrenia and bipolar I disorder. It is associated with a rare but serious skin reaction that can progress to affect other parts of the body. A new warning has been added to the Ziprasidone drug label to describe the serious condition known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). FDA required the manufacturer of ziprasidone to add a new warning for DRESS to the Warnings and Precautions section of the drug labels for the capsule, oral suspension, and injection formulations. Healthcare professionals are advised to be alert while prescribing this drug and monitor and forward such reports (DRESS) to the concerned.

Reference - www.fda.gov Drugs/DrugSafety/

Amiodarone with hepatitis C treatment - causes serious slowing of heart rate (containing Sofosbuvir in combination with another direct acting Antiviral drug)

FDA is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug Amiodarone is taken together with either the Ledipasvir/Sofosbuvir/Sofosbuvir taken in combination with other direct acting antivirals for the treatment of hepatitis C infection. FDA recommends that health care professionals should not prescribe Sofosbuvir combined with another direct acting antiviral, such as the investigational drug Daclatasvir or Simeprevir, with Amiodarone. Post marketing reports found

that patients can develop serious and life threatening symptomatic bradycardia with use of antivirals either alone or with combined.

Reference - www.fda.gov/Drugs/DrugSafety

Meropenem induced Tremors

Meropenem is used to treat a wide variety of bacterial infections. Seizures have infrequently been reported during treatment with meropenem. Meropenem induced tremors, 25 ICSRs (Asia 9) were found from Vigibase worldwide. From PvPI database 2 ICSRs, one is meropenem induced convulsions and the other shivering have been reported.

Diclofenac induced decreased lactation

It is a non steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic properties. It has an acceptably low infant dose and considered safe to use. It should not be taken during the last 3 months of pregnancy as it may affect the baby's circulation. Diclofenac should be avoided during breast feeding. Globally, 5 ICSRs were found from Vigibase on Diclofenac induced decreased lactation. However in India, there are no reports till date.

- Healthcare professionals are sensitized to carefully monitor Ambroxol and Bromhexine induced severe skin reactions, Ziprasidone induced fatal skin reactions, slowing of heart induced by Amiodarone with anti virals used for hepatitis C treatment, Meropenem induced tremor and Diclofenac induced decreased lactation.
- These events to be reported to PvPI

National and International status of Suspected Unexpected Serious Adverse Drug Reactions

Suspected Unexpected Serious Adverse Drug Reactions (SUSARs) related to any medicinal product are subjected to expedited reporting. The following are identified as SUSARs as shown in table 2.

| S.No | Name of the Drug | Reported ADR | Indian Status (ICSR Received) | Global Status (ICSR Received) |
|------|------------------|---------------------------|-------------------------------|-------------------------------|
| 1 | Sildenafil | Cyanosis | 1 | 27 |
| 2 | Vecuronium | Cardio Respiratory arrest | 1 | 64 |
| 3 | Oseltamivir | Photophobia | 1 | 5 |

Table 2: National and international status of reported SUSARs

New Drugs Approved in India from January 2015 to March 2015

The following new drugs were approved during the period from January 2015 to March 2015 by CDSCO (Table 3).

Table 3

| S.No | Drug | Indication |
|------|---|---|
| 1. | Lixisenatide Pre-filled solution for injection | Type 2 Diabetes Mellitus |
| 2. | Bedaquiline Tablet 100 mg | MDR-TB |
| 3. | Sofosbuvir Tablet 400 mg | Chronic Hepatitis C |
| 4. | Pazopanib Tablet 200/400 mg (Additional Indication) | Advanced Soft Tissue Sarcoma (STS) |
| 5. | Eribulin mesylate solution for injection 0.88 mg in 2ml vial | Advanced or metastatic breast cancer |
| 6. | Abiraterone acetate Tablet 250 mg (Additional Indication) | Metastatic castration resistant prostate cancer in adult men |

Training and Education Programmes

Induction cum Training Programme for Newly Recruited Technical Associates

NCC-PvPI, Ghaziabad organized an induction cum training programme for newly recruited Technical Associates from 16th to 20th February, 2015 to make them acquainted with the basic and essentials of pharmacovigilance terminologies, standards and processes for ADR reporting and causality assessment.

Five days of induction cum training programme included presentations by eminent speakers, hands on training for filling of "Suspected ADR Reporting Form" and data entry in "VigiFlow Software" for case processing and one-day field

visit to AMC at UCMS & AIIMS, New Delhi. Training session was ended with the distribution of certificates to all the participants and post training assessment.

West Zone Coordination and Training of AMCs- Mumbai

Department of Clinical Pharmacology, Seth G S Medical College (GSMC), Mumbai is one of the ADRs monitoring centre for training and also functions as regional resource centre for training and technical support of west zone under PvPI. This centre is dedicated to perform the responsibility of providing hands on training and

filling the ADRs to newly inducted AMC's in west zone. In total 36 AMC's are functioning in west zone, to provide hands on training to the coordinators and technical associates, GSMC organized a one day training programme on 18th March 2015 at Mumbai. The training covered the basic concept to pharmacovigilance, filling up of ADR forms, VigiFlow hands on training etc.

Pharmacovigilance Awareness at IPC- PvPI

Faculty members and Students of Devaki Amma Memorial College of Pharmacy, Malappuram, Kerala visited IPC on 29th January 2015. They visited different departments of IPC and gained knowledge regarding IPC and PvPI.



Faculty and students of Devaki Amma Memorial College of Pharmacy along with IPC Scientists during their visit to IPC, Ghaziabad on 29th January 2015.

Mini Symposium on "Pharmacovigilance and Pharmacopoeial Education" For Quality Improvement Programme Delegates, DIPSAR

Students and faculty members of DIPSAR and other pharmacy colleges across the countries, visited IPC on 4th March 2015 to update their

knowledge on Pharmacovigilance and Pharmacopoeia during the Quality Improvement Programme (QIP), organized by DIPSAR, New Delhi.



Participants of QIP and Faculty of DIPSAR during their visit to IPC, Ghaziabad on 4th March 2015

Educating Pharmacovigilance to Pharmacy Professionals

International conference on roles and responsibilities of pharmacists on chronic disease management, ADR and therapeutic drug monitoring was held on 24th and 25th April 2015 at PSG College of Pharmacy, Coimbatore. Dr. V. Kalaiselvan, Principal Scientific Officer, IPC, Ghaziabad, attended the conference on behalf of IPC, he explained the details on ADR reporting: Indian experiences in ADR reporting. He emphasized the current status and achievements of PvPI at the national and international level, growing pharmacists would be educated about the importance of pharmacovigilance and PvPI foreground the role of pharmacists including Pharm.D in this field.

Upcoming Event

PvPI to host Programme for International Drug Monitoring

PvPI will be hosting in association with WHO Country Office (India) 38th Annual Meeting of World Health Organization (WHO) Programme for International Drug Monitoring (PIDM) in India from 4-6th November, 2015 at New Delhi. It was decided and declared in the 37th Annual Meeting of WHO, PIDM held on 14-17th October 2014 at Tianjin, China. It is expected that representatives from more than 119 countries will be participating in this meeting. Also experts from WHO, Geneva and Uppsala Monitoring

Centre, Sweden shall be attending this event.

This will be a great opportunity for IPC-PvPI to strengthen the pharmacovigilance system in our country and also it will be the right time to exhibit achievements in the international forum. This annual meeting offers a unique opportunity to discuss the particular topics from different points of view and to share ideas as to how patients' safety could be further improved. The goal of this event is to escalate awareness of drug safety best practices worldwide, by sharing newest information on science based solutions for the stakeholders.

News Digest

Pharmacovigilance Training in Collaboration with Uppsala Monitoring Centre

JSS University, Mysore is an ADR monitoring centre and also acts as regional resource centre under PvPI. JSS University in collaboration with UMC conducted "First Asia Pacific Pharmacovigilance Training Course" from 16th - 28th Feb 2015, at Mysore. Dr. Shanthi Pal and Mr. Sten Olsson were resource personnels of this programme and sixteen participants from different countries of Asia region participated in the training program. In this programme, Consumer Reporting of ADRs – Indian Experience was shared by Dr. V. Kalaiselvan, Principal Scientific Officer, IPC, Ghaziabad.



Dr. Shanthi Pal, Mr. Sten Olsson and other delegates from various countries attending UMC training course from 16th-28th Feb 2015

NCC to set up 30 more AMCs

NCC is proposing to recognize 30 more AMCs in PvPI. In near future these AMCs are best identified based on the existence and non existence of the AMCs in the State and Union

Territories (Preference will be given to the States where there are no or less AMC exists), population ratio of AMCs, outreach of PvPI to urban and rural India, Infrastructure and expertise in pharmacovigilance, current progress/ ADRs reporting to PvPI.

VigiAccess a new tool to Patient Safety

WHO-UMC launched VigiAccess on 17th April 2015 with the aim of improving patient safety, increasing transparency and encouraging the reporting of adverse reactions to medicinal products .

VigiAccess is a new web-based application that will allow anyone to access information on reported cases of adverse events related to medicines and vaccines. VigiAccess (www.vigiaccess.org) allows searching VigiBase and retrieving statistical safety data on medicines' and vaccines' –suspected adverse reactions – reported to the WHO-UMC. VigiAccess allows a quick overview on reported suspected adverse drug reactions for research purposes.

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Indian Pharmacopoeia Commission

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