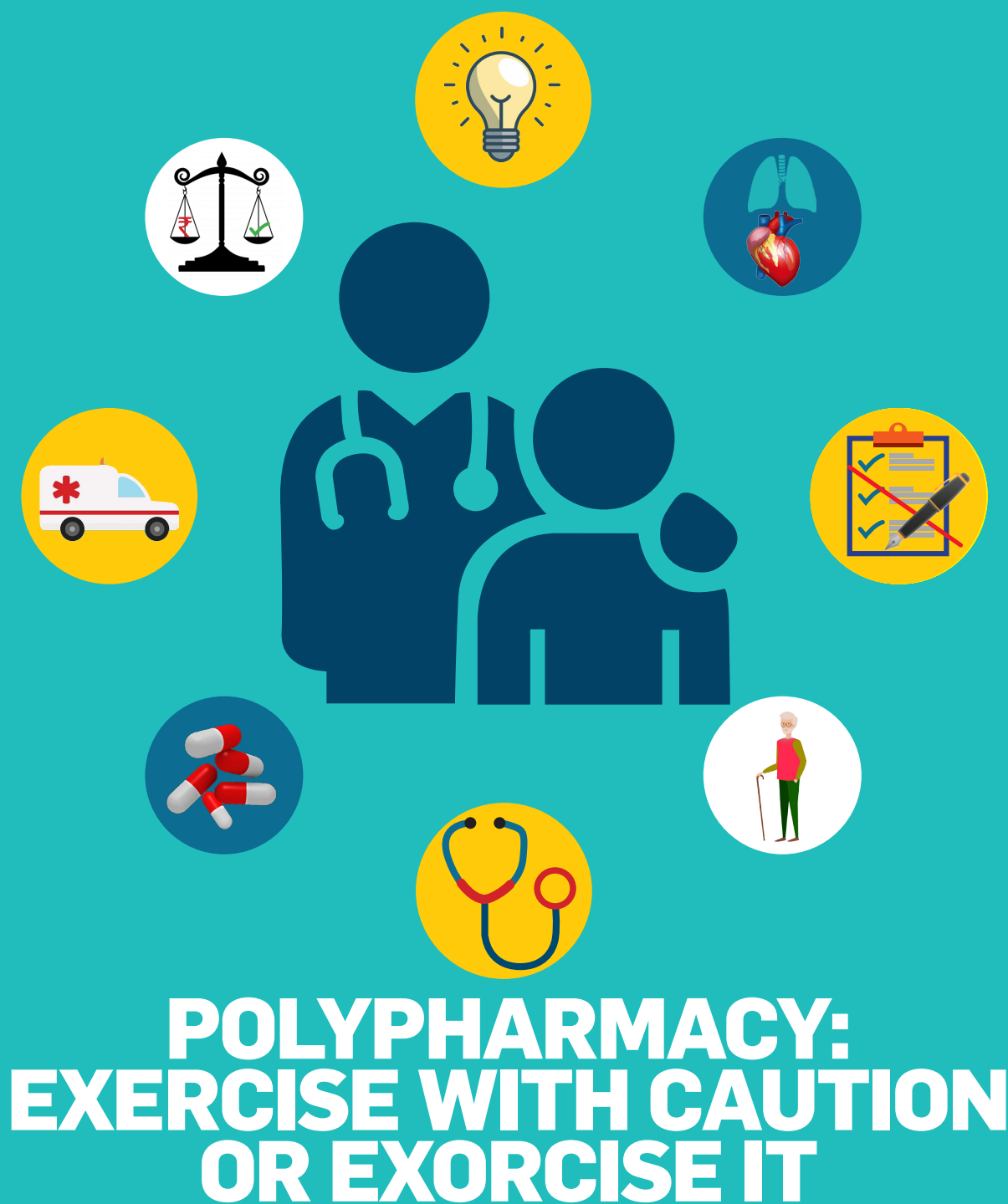




Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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Foreword from Secretary-cum-Scientific Director



Dear Readers,

The ambit of Pharmacovigilance in recent past has acquired a wide spectrum across all strata of clinical practice, ensuring healthcare for the patients with optimization of use of drugs and minimization of risks by any drug or medical device. The self-awareness for safe medication among the masses in the present day information age has been on the rise, and as such the healthcare providers especially physicians are under constant scrutiny to prescribe drugs with a safety-cautious approach. The growing curve of the safety aspect of drugs among the populace has given an impetus to, as also placed the onus on, the Pharmacovigilance Programme of India (PvPI) for adoption of cutting-edge knowledge-evidence and technology-based tools to assess and decipher the risk-prone potential of any medication in use.

The electronic tech tools aimed at enhancing the instant outreach of the PvPI to the public include the toll-free helpline 1800-180-3024, mobile App 'ADR PvPI' which patients/consumers or stakeholders can use to report ADRs. One of the essential features to sensitize the healthcare professionals about the suspected hazards of drugs includes sharing of Drug Safety Alerts through SMS by PvPI which is gradually taking momentum.

Healthcare centres and hospitals across the country have been urged by IPC to display PvPI helpline number on IPD/OPD slips to popularize the facility of ADR-reporting by the public at large.

One of the endeavours of the PvPI has been to equip the Pharma sector with the necessary tools, updates and guidelines for adherence vis-à-vis reporting ADRs in a manner satisfying the

parameters on the ICSR quality and completeness score. The MAH representatives are also provided with need-based training at NCC-PvPI as well as across different regions of the country. All this is aimed at monitoring safety of drugs under the eagle's eye of PvPI so as to eventually avert the probability of any harm to a patient. As such, the sole responsibility of a medical product lies with its manufacturer.

The Indian Pharmacopoeia Commission (IPC) through PvPI and MvPI has been bringing under its purview as many healthcare centres and superspecialty hospitals as possible AMCs to cater to the needs and tasks of Pharmacovigilance (PV) at the grassroot level. The efforts to strengthen and streamline the PV system across all arenas of healthcare have been more intense by regularly imparting hands-on training for skill development in PV to all stakeholders to meet the challenges posed to patient safety by broad-spectrum drug use.

To further widen the scope of Pharmacovigilance among the masses, especially in the rural areas, a small caption in Hindi is being published in IPC Newsletter.

I am sure that the stakeholders will continue to provide their active support for the success and effectiveness of this programme for the ultimate benefit of the patient by monitoring, reporting and analyzing the Adverse Events due to medicines.

Dr Jai Prakash
Secretary-cum-Scientific Director (I/c)
Indian pharmacopoeia Commission



Polypharmacy: A challenge to patient safety

Prescribing of multiple medicines, or polypharmacy, is more evident in clinical practice, particularly affecting the geriatric population. The two major factors that contribute to polypharmacy are population longevity and increase in the incidence of multimorbidity.

There are variable definitions of polypharmacy but it is generally understood as the concurrent use of multiple medicines by one individual. While in many instances the use of multiple medicines or polypharmacy may be clinically appropriate, it is important to identify patients with inappropriate polypharmacy that may place patients at an increased risk of adverse events and poor health outcomes.

Appropriate Polypharmacy is defined as prescribing multiple medicines for an individual when:

- All medicines are prescribed for the purpose of achieving specific therapeutic objectives that have been agreed with the patient
- Therapeutic objectives are actually being achieved or are achievable
- Optimized medicine therapy to minimize the risk of Adverse Drug Reactions (ADRs)
- Patient is well informed and able to take medicines as intended

Inappropriate Polypharmacy is defined as prescribing multiple medicines inappropriately, or where:

- there is no-evidence based indication, or unnecessarily high dose is prescribed
- one or more medicines have failed to achieve the therapeutic objectives
- one or more medicines cause ADRs
- patient is not willing or able to take medicine/s as intended

PREVALENCE OF POLYPHARMACY

Polypharmacy is a worldwide public health concern which is on the increase among all health care settings. The issue is well explained in literature from countries in North America, Europe and West Pacific. In India, a nation-wide literature survey of data between 2010 and 2018 conducted by Sharma et al 2019 shows Uttaranchal, Karnataka and Telangana reported a higher level of polypharmacy with 93.14%, 84.6%, and 82.8%, respectively, while Andaman and Nicobar Islands (2%) and West Bengal (5.82%) registered the lowest polypharmacy.

It is, therefore, essential to take necessary stringent measures in terms of raising awareness and enforcing a change in healthcare practices to curb the risks associated with inappropriate polypharmacy.

CAUSES OF INAPPROPRIATE POLYPHARMACY

- Comorbidities in ageing population requiring several medications
- Inappropriate self-medication of over-the-counter

medicines inviting drug interactions and adverse drug reactions

- A “prescribing cascade” which occurs when patients take a medication and develop side-effects that are misinterpreted by the healthcare practitioner as symptoms of a disease, requiring additional medication
- Multiple consultations by patients for same disorder inviting chances of overdosing and drug-drug interactions
- Ineffective communication and coordination between healthcare practitioners

KEY CHALLENGES

- Lack of systematic approach that incorporates age-related complexities into routine decision-making
- Meagre assessment of medication appropriateness and discontinuation in elderly patients
- Lack of targeted guidelines tailored to clinical care models for patients with multimorbidities
- Poor coordination among healthcare providers in a multi-level, open-ended healthcare setting like India
- Paucity of patient education campaigns on issues such as medication adherence, inappropriate use of alternative/traditional therapies as concomitant medicines

GOALS OF POLYPHARMACY MANAGEMENT

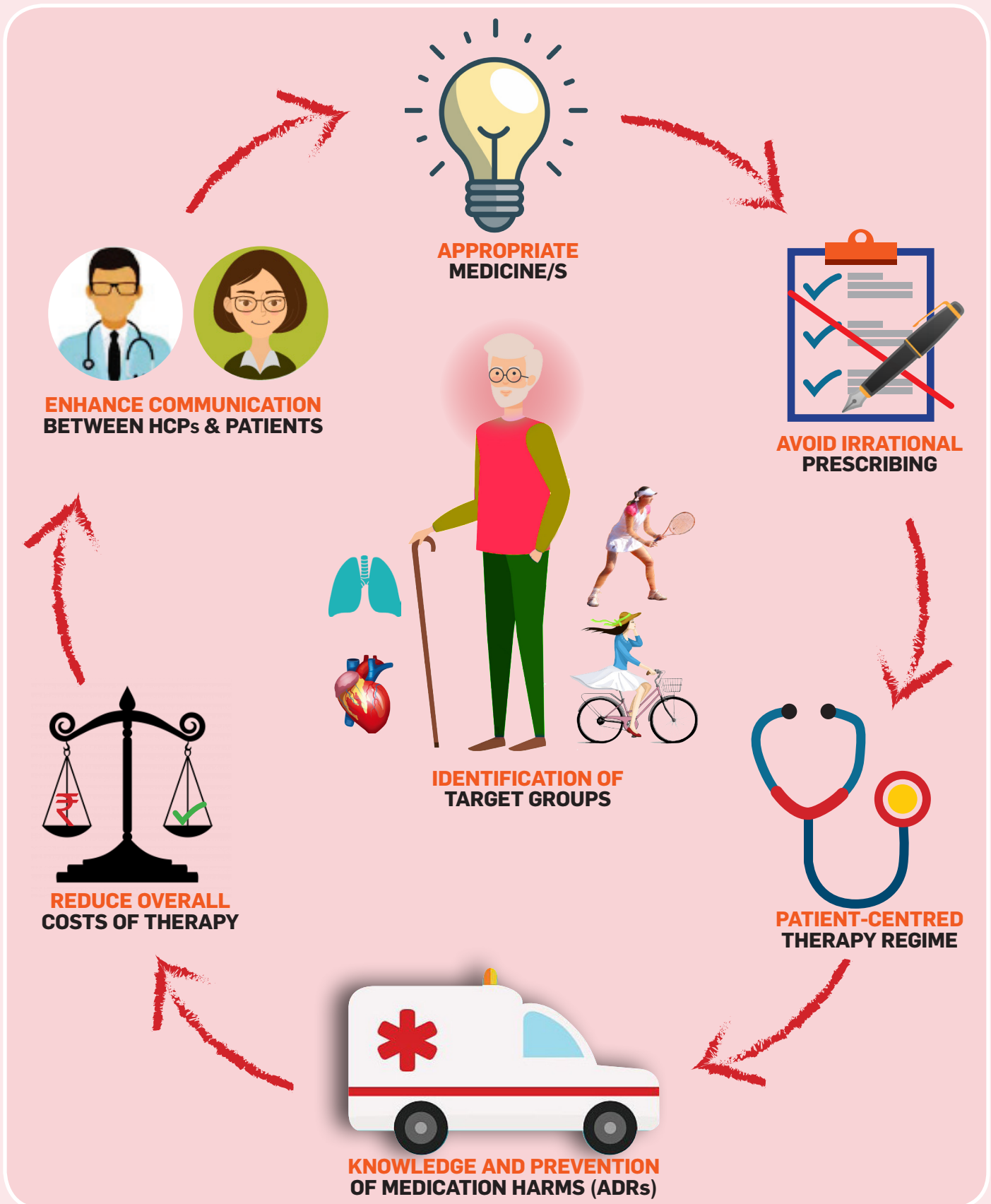
The evidence for the need to address polypharmacy is compelling. It requires efforts by all stakeholders, including policymakers, healthcare professionals, managers as well as caretakers and patients. The goal of a systemic approach in polypharmacy management is to ensure optimal and sustainable use of medicines in patients with multimorbidities, ensuring the quality of care and reducing medication harms.

These goals may be inclusive of but not limited to:

- Nurturing a culture that encourages and prioritizes the safety and quality of polypharmacy
- Raising awareness about the problems with polypharmacy (Adverse Drug Reactions, Drug-drug interactions) and non-adherence by healthcare professionals and patients
- Encouraging partners in Pharmacovigilance to address polypharmacy-related harms among general public
- Advocating policy-level changes to influence rational prescribing and use of appropriate polypharmacy



Polypharmacy Management Sequel



Pharmacovigilance in Special Population: Pregnancy and Lactation

Medications are commonly used by all sections of populations as required for their disease management. Special populations are no exception when it comes to use of medicine except for their safety concerns. Pre-marketing studies have always been associated with certain limitations that weaken the information of predictability of effects on humans on the basis of effects observed in animal models, long-term adverse effects, drug-drug and drug-food interactions, drug-effects in specific ethnic groups. And, more importantly, information about drug effects in special populations involving pregnancy and lactation, pediatrics, elderly, and renal and hepatic diseases. Thus, Pharmacovigilance becomes inevitable in strengthening medication safety in these special populations.

In reality, pregnant women are rarely included in clinical trials at the time of marketing authorization. As such the assessment of potential risks associated with use of medicinal products in pregnancy usually relies on extrapolation from non-clinical data and the knowledge of adverse embryo/foetal reactions of other products with similar pharmacological properties. In 1961, the observations of McBride WG and Lenzin in *The Lancet* titled “Thalidomide (Distaval) and congenital abnormalities” sparked the urgency for intense drug safety monitoring, and subsequently thalidomide was withdrawn. Around the same time, Frances Oldham Kelsey, a Canadian-American pharmacologist, physician, and reviewer for the Food and Drug Administration (FDA), rejected the thalidomide authorization in the United States of America for six times due to paucity of safety studies data and saved many from the thalidomide disaster. A decade from then, in 1971, vaginal clear cell adenocarcinoma was found in girls and young women who had been exposed to diethylstilbestrol in-uteri of their mothers.

This has necessitated the need for intensive pregnancy exposure registries in modern times. In 1990s, European Network of Teratology Information Services (ENTIS) began its journey to collect and evaluate data in order to contribute to the primary prevention of birth defects and developmental disorders in the European region. This led to the creation of various regulations such as Guidance for Industry: establishing pregnancy exposure registries (FDA,



Dr M Ramesh, Professor & Head, Department of Pharmacy Practice, JSS College of Pharmacy, JSS Academy of Higher Education & Research, Mysuru and Coordinator, AMC- PvPI, JSS Medical College & Hospital, Mysuru

2002), Reviewer Guidance: evaluating the risk of drug exposure in human pregnancies (FDA, 2005), Content and format of labeling for human prescription drug and biological products, requirements for pregnancy and lactation data (FDA, 2008), and guideline on the exposure to medicinal products during pregnancy: need for post-authorization data (EMA, 2005).

Tools have been developed to grade the risk of medications in causing teratogenicity during pregnancies. One such is United States Food and Drug Administration's (US-FDA) pregnancy risk categories. These categories are A, B, C, D, and X. Where Category A drugs are safe to be used in pregnancy (controlled studies have shown no risk) while Category X drugs are known to possess the risk of adverse reactions in humans and animals, and the drug is contraindicated in pregnancy. However, Ramozet al. denounced this

system as it lacked information for accidental exposures of medicines, the nature, severity, timing, incidence rate, and/or treatability of potential foetal injury. Furthermore, the lack of lactation risk categories of these drugs makes it further vulnerable.

There are several examples where the mechanism of action of the medication is often associated with the mechanism of teratogenicity and/or adverse embryo/foetal reactions. However, evidence of absence of teratogenicity and/or adverse embryo/foetal reactions for one substance cannot be generalized to other medicines of the same class. Therefore, the assessment of potential risks for any active substance that has known adverse pregnancy outcomes for another substance of the same class of medicinal products should be carefully considered. The physiological changes that occur during pregnancy may also result in changes in the drug plasma levels and associated dose-related adverse reactions or under-treatment, either of which could have negative consequences on the pregnancy through their impact on maternal health.

The evidence of risk in clinical practice exposure to teratogen in the embryo or foetus through semen is limited and we should be warned of highly teratogenic substances that are transmitted into semen. On the other hand, nursing women are also usually excluded from clinical trials for similar reasons, which has led to underestimation of risks for breast-fed infants at the time of marketing authorization. Therefore, any notification of the risk category of the drug may be based on pharmacokinetic (PK) data, coupled with data about the severity of potential adverse outcomes to the medicine in the user population.

Ultimately, the safety of the drug is determined by its dose, and therefore, the primary objective during clinical development of a drug should be to form a safe dose. As it is difficult for the special populations to participate in



pre-marketing clinical research due to the procedures involved in the studies, the safety profiles of the drugs in real clinical practice must be monitored by the post-marketing surveillance (PMS) instead. Furthermore, factors causing adverse drug reactions such as individual variations in pharmacogenetic profiles, drug metabolic pathways, the immune system and drug-drug interactions must not be ignored. Thus, the safety of a drug is a major clinical consideration before and after it is marketed. Owing to the fact that we are far from precision medicine, clinical trials must include a multidisciplinary approach to enhance the safety profile of drugs at all stages of development, including PMS activities. Safer therapeutics in a wider spectrum of patients can be delivered by extensive use of drug pharmacokinetics in special populations coupled with pharmacogenetics, which provides the possibility of genotype-specific therapeutics. Given the complex nature and unpredictability of adverse reactions, strengthening the PMS activities remains the crux of managing the risks of drugs. The study of adverse outcomes of drug exposure in pregnant women remains the most challenging and, therefore, intense surveillance of every new moiety should be mandated at least for a year along with strict implementation of pregnancy drug registries.

NOTABLE EVENTS

National AEFI meet

National AEFI meeting was held at the Conference Hall in the National Documentation Centre of the National Institute of Health and Family Welfare (NIHFW), Munirka, New Delhi on September 10, 2019. Dr Shashi Bhushan, Senior Scientific Officer, IPC and Dr R S Ray, Scientific Assistant, IPC represented PvPI-IPC. The meeting was attended by other members of National AEFI committee and various subject experts across the country.

MOOT POINTS:

- Discussed accomplishments of the last meeting
- Updates on Causality Assessment of reported AEFI cases, AEFI surveillance activities -- West zone and East zone.
- Discussed procedures to procure IP Reference Substances (IPRS) from IPC for testing possible contamination in vaccines/vaccination
- AEFI surveillance update
- Updates on literature review process and SAFE-VAC

Interactive meet with MAHs on ICSR quality

To keep MAHs abreast of the latest updates on Individual Case Safety Reports (ICSRs) aimed at improving the quality of ICSR, PvPI holds regular interactive sessions, inviting representatives of Pharma companies to IPC, Ghaziabad. For the Index Period -- July 2019- September 2019, PvPI has conducted two such meetings:

- ICSRs' grading scores of last year
- Quality parameters such as drug information, adverse drug reaction, patient details, etc, were defined with scoring
- Lack of information in the ICSRs received
- Weightage for each field of ICSR and its impact on overall quality

S. No.	Date	Company Name	Representative/s
01.	August 09, 2019	Baxter India Pvt Ltd	1. Dr Isha Aumta, Manager PV APAC(PVOI)
02.	September 17, 2019	Roche Products (India) Pvt Ltd	1. Dr Samir Sangitrao, Associate Director-RA 2. Ms Nidhi Vaish, Manager Drug safety

DISCUSSION:

During these interactive sessions PvPI officials presented a summary report on ICSR quality of both the companies. The presentation provided following inputs:

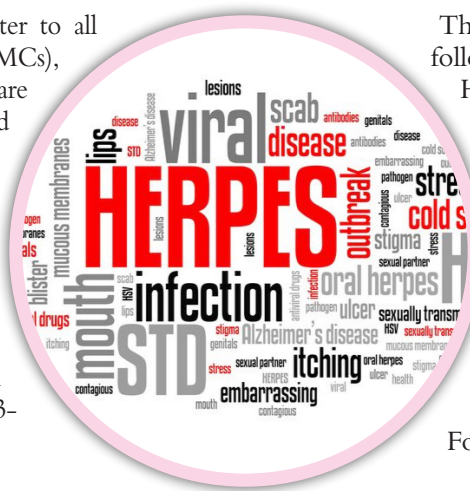
RECOMMENDATIONS:

Following points were suggested to improve the quality of ICSRs:

- Mandatory fields must be provided to consider the case valid
- Adverse event should be coded appropriately
- Information on time onset, outcome and action taken of adverse event
- Narrative must cover all the information filled in the ICSR
- Communication through emails be sent within a stipulated timeframe to expedite case processing

Sensitization on SGLT₂ inhibitors-related Genital Infections

In a July 15, 2019 official letter to all ADR Monitoring Centres (AMCs), PvPI has sensitized healthcare professionals (HCPs) concerned to closely monitor incidence of Genital Infections associated with use of Sodium-Glucose Co-transporter-2 (SGLT2) inhibitors. This formal communication was issued following a warning letter issued by the Central Drugs Standard Control Organization (CDSCO) vide its letter 12-74/13-DC dated March 25, 2019.



The above-safety communications following the delayed announcements by Health Canada and US Food and Drug Administration (USFDA) on July 20, 2018 wherein Health Canada addressed the potential risk of inflammation of the pancreas (acute and chronic pancreatitis), and USFDA on August 29, 2018 issued a warning of serious rare infection called necrotizing fasciitis of the perineum also referred to as Fournier's gangrene.

5th Quality Review Panel meeting

The fifth meeting of Quality Review Panel was convened at IPC, Ghaziabad on September 4, 2019. Chaired by Prof Y K Gupta, National Scientific Adviser, PvPI, the meeting was attended by Dr Rubina Bose, DCG (I) nominee, Dr Jai Prakash, Senior Principal Scientific Officer & In-charge PvPI, IPC, Dr Shashi Bhushan, Senior Scientific Officer, IPC, Mr Rishi Kumar, Scientific Assistant, IPC and Dr R S Ray, Scientific Assistant, IPC.

SALIENT FEATURES

- Reconstitution of QRP
- New SOPs and Revised SOPs
- Need to train MAHs for improving the quality of ICSRs received from Pharma industries
- Raise ADR-reporting awareness in the Pharma sector
- Corrections to ADR-reporting in Pharmacovigilance Guidance Document for MAHs
- Progress in development of indigenous software for adverse drug reaction monitoring system (ADRMS), Prof Y K Gupta suggested corrections to improve features of the software
- Dr Rubina Bose clarified that reporting of SAE to licensing authority concerned is mandatory for all Pharma industries as per Schedule M guidelines

15th Signal Review Panel meet

The 15th Signal Review Panel (SRP) meeting was held at IPC, Ghaziabad on August 21, 2019. Chaired by Prof Urmila Thatte, the meeting was attended by SRP members, including Dr G N Singh, Dr Mita Nandy, Dr Jai Prakash, Dr Shashi Bhushan, Dr R S Ray, Mr Vipin

Kumar, Ms Shivangi and Dr V Lokesh Reddy. The meeting was conducted with an objective to detect signal(s) from Indian safety database for ensuring patient-safety. SRP recommended to CDSCO new signals, drug-safety label change and drug alerts for the following pharmaceutical products marketed in India:

S. No.	Action Plan
01	Risperidone and Rabbit Syndrome Signal Review Panel suggested PvPI to continue close monitoring for Risperidone-associated Rabbit Syndrome
02	Itraconazole-associated Symmetrical Drug-Related Intertriginous and Flexural Exanthema (SDRIFE) SRP recommended PvPI to collect more information on diagnostic clarification from dermatological experts for further discussion on Itraconazole-associated SDRIFE
03	Metronidazole –Vasculitis Signal Review Panel suggested to PvPI that no action is required at this time as it is not a signal
04	Olanzapine-associated Tracheo-eosophagial Fistula SRP suggested PvPI to continue close monitoring for Olanzapine-associated Tracheo-eosophagial Fistula
05	Teneligliptin-associated Arthralgia SRP suggested PvPI to issue a drug safety alert to healthcare professionals for sensitization to Teneligliptin-associated Arthralgia
06	Amlodipine-associated Lichenoid Keratosis SRP recommended PvPI to collect more information on diagnostic clarification from dermatological experts for further discussion on Amlodipine-associated Lichenoid Keratosis.
07	Chloroquine – Toxic Epidermal Necrolysis (TEN)/Stevens Johnson Syndrome (SJS) SRP recommended to incorporate Toxic Epidermal Necrolysis (TEN) and Stevens Johnson Syndrome (SJS) as Adverse Drug Reactions into the PIL of Chloroquine marketed in India.
08	Proton Pump Inhibitor-associated Acute Kidney Injury SRP recommended to incorporate Acute Kidney Injury as an Adverse Drug Reaction into the PIL of Proton Pump Inhibitors marketed in India.

Regional Workshop on enhancing PV in Pharma sector

The Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India organized two regional workshops, one each in Chandigarh and Hyderabad region, during Index Period July 2019–September 2019. The workshop based on “**Pharmacovigilance and**

Establishment of Pharmacovigilance System in Pharmaceutical Industries — Way Forward” was tailored to address regional needs and challenges unique to Pharmacovigilance and its setup in Pharmaceutical industries. Experts from CDSCO, IPC, Industries and academia attended the workshop.

S. No	Date	Venue and Address	No. of Participants	Resource Persons and Designation
01.	July 12, 2019	Council of Scientific & Industrial Research (CSIR) - Institute of Microbial Technology (IMTECH), Chandigarh	14	Guest of Honour Dr Rajender Soni, Acting Director & Head, PTM, Dr Suresh Korpole, Sr Scientist, MTCC, Dr Venkat Raman, Senior Scientist, MTCC, IMTECH, Chandigarh, Dr Bikash Medhi, Professor & AMS, PGI, Chandigarh, Mr Amit Duggal, In-charge, Drugs Control Wing, CDSCO, Chandigarh, Dr Shaunik Singh, Drug Safety Physician, PARAXEL Int. Services Pvt Ltd, Chandigarh, Dr Vijit Agrawal, Ms Swati Thaplial and Mr Kapil Negi, Pharmacovigilance Associates
02.	August 28, 2019	CSIR - Centre for Cellular & Molecular Biology (CCMB), Hyderabad	46	Guest of Honour Dr Rakesh K Mishra, Director CCMB, Dr Y Venkata Rao, Professor & Head, Dept of Pharmacology, KIMS, Hyderabad, Ms A Visala, DDC, CDSCO Zonal Office, Hyderabad, Dr Sridhar Yeshamaina, General Manager, CMA-PV, Hetero-Hyderabad, Dr Jai Prakash, Principle Scientific Officer, IPC, Dr Shashi Bhushan, Senior Scientific Officer, IPC, Dr Vijit Agrawal, Ms Swati Thaplial and Ms Savya Singh, Pharmacovigilance Associates, PvPI



OUTCOME:

- Participants were sensitized to basic concepts of PV& implementation of effective PV system in Pharmaceutical Industries
- Stress on importance of ADR-reporting in patient safety
- Awareness of PV Guidance Document with focus on submission of E2B XML ADR-related files to PvPI
- Essence of training for marketing professionals to collect adverse events direct from physicians at hospitals

NABH training-cum-workshop @Yashoda Hospital, Kaushambi

National Coordination Centre (NCC)-Pharmacovigilance Programme of India (PvPI), Indian Pharmacopoeia Commission (IPC) organized a day-long “Workshop-cum-Training Programme on Pharmacovigilance

for NABH-accredited hospitals of Delhi-NCR and Kolkata region” on July 26, 2019 and September 27, 2019, respectively. The participants were healthcare professionals, including doctors, pharmacists and nurses. Details of the training are given in the table below:

S. No.	Date	Venue and Address	No. of participants	Resource Persons and Designation
01.	July 26, 2019	Yashoda Superspeciality Hospital, Kaushambi, Ghaziabad	33	Dr G N Singh, Secretary-cum-Scientific Director, IPC, Dr Jai Prakash, Sr Principal Scientific Officer, Dr Prashant, Assistant Director NABH, New Delhi, Dr R S Ray, Scientific Assistant, Mr Bharat Vijay Kumar, Ms Gunjita Belwal, and Mr Kapil Negi, Pharmacovigilance Associates
02.	September 27, 2019	Institute of Postgraduate Medical Education & Research, Kolkata	45	Dr. Somnath Basu, Assistant Drug Controller, CDSCO, New Delhi, Prof Suparna Chatterjee, Coordinator, AMC, IPGMER, Kolkata, Dr R S Ray, Scientific Assistant, Ms Manjari Bhat-tacharya and Ms Satavisa Mukherjee, Pharmacovigilance Associates

DEBATABLE TOPICS:

- Basics of Pharmacovigilance & updates on Pharmacovigilance Programme of India
- Importance of ADR-reporting for NABH-accredited hospitals in India
- Monitoring & reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting up of a Pharmacovigilance system in hospitals
- Causality Assessment: Logics & Methods

OUTCOME:

- Sensitization to ways of enhancing ADR-reporting and setting up a Pharmacovigilance system in hospitals
- Participants suggested that such workshops be conducted with the sole aim of sensitizing healthcare professionals to report ADRs and resolve their PV-related issues
- Participants learned the process of performing causality assessment
- Awareness on documentation practices at AMCs





Induction-cum-Training Programmes

The National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) conducted two Induction-cum-Training programmes for Coordinators of newly-recognized AMCs and Pharmacovigilance Associates appointed under PvPI, IPC, Ghaziabad during the Index Period. The Secretary-cum-Scientific Director, Dr G N Singh expressed gratitude to individuals and representative institutions for attending the programme. The programme was organized by a team comprising Dr Jai Prakash, Senior Principal Scientific Officer & Officer-in-Charge PvPI, Dr

Pooja Gupta, Coordinator, AIIMS, New Delhi, Dr Nidhi Gupta, Senior Programme Officer-AEFI, AEFI Secretariat, MoHFW, Govt of India, Dr Ajay Sachan, ADC, CDSCO, Mr Kapil Negi, Ms Shavya Singh, Mr Tarani Prakash, and Dr Lokesh Reddy, Pharmacovigilance Associates, PvPI.

The five-day each training programme covered basics of Pharmacovigilance, Quality Management System, and monitoring/ADR-reporting, collation of ADR reports, hands-on training on Vigiflow and in-depth knowledge of Causality Assessment, Signal Detection, Regulatory Intervention/ outcome in a systemic manner. The training also included field visits to recognized AMCs.



Advance Level Training cum Coordinators Meeting

With intent of active and interactive learning for existing professionals in PvPI, Regional Training Centre (RTC), AIIMS, Rishikesh organized Advance-level Training-cum- Coordinators meeting on September 14 2019. The agenda was to share the experiences of various AMCs & discuss ways to improve ADR reporting by individual AMCs. The training programme also served as a platform to discuss areas of collaboration between the different AMCs in the field of Pharmacovigilance.

TOPICS DISCUSS

Dr. Jai Prakash, Senior Principal Scientific Officer, PvPI, IPC, Ghaziabad discussed on herbal drug safety said, that the herbal drugs enjoy mass appeal and faith among users of the traditional system of medicine which are labelled as both safe and effective without any adverse effects. Hence, there is a need to uproot this natural

fallacy by setting up a system for creating awareness and monitoring the safety considerations of herbal drugs. Also the topic of AEFI update from Uttarakhand was taken by Dr. Mayank Badola Addl. Chief Medical Officer, Dehradun. He demonstrated the current scenario of AEFI reporting in the state of Uttarakhand by showcasing the regions which were actively involved in AEFI reporting. Districts of the Kumaon region actively contributed to the system while reporting figures from districts of Garhwal region were quite low.

OUTCOME:

- It was an open discussion among Coordinators & PV Associates regarding strengthening of PV related activities in the state of Uttarakhand & Uttar Pradesh and some of the issues concerning PvAs working in different AMCs
- It was an overall fruitful conversation between Coordinator & PV Associates

CME-cum-Workshop @Greater Noida



A two-day CME-cum-Workshop on “Current Challenges and Future Prospects of Pharmacovigilance” was organised by Government Institute of Medical Sciences, Greater Noida on September 26-27, 2019. Dr Jai Prakash, Senior Scientific Officer, IPC invited as Guest of Honour inaugurated the workshop on September 26, 2019. He addressed the participants on the current status of PvPI and the challenges India faces in raising awareness among healthcare professionals to enhance PV practices. Mr Tarani Prakash Shrivastava, Pharmacovigilance Associate, PvPI also attended the workshop. As many as 35 participants from the NCR region were sensitized to Basics of Pharmacovigilance, ADR-reporting Tools and Regulatory Perspective of PV in India.

Approved New Drugs in India

New drugs approved by CDSCO during July- September 2019

S. No	DRUG	INDICATION
1.	Rifapentine 150mg film-coated tablet	Latent tuberculosis infection caused by Mycobacterium tuberculosis in adults, and children 2 years and older who are at high risk of progression to tuberculosis, (including those in close contact with active tuberculosis patients, recent conversion to a positive tuberculin skin test, HIV-infected patients, or those with pulmonary fibrosis on radiograph)
2.	FDC of Bictegravir, Emtricitabine and Tenofovir alafenamide 50mg/200mg /25mg tablets	Human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per ml) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to Bictegravir, Emtricitabine and Tenofovir alafenamide
3.	Levomilnacipran ER capsules 20mg/40mg/80mg/120mg	Major depressive disorder
4.	Bosutinib bulk and Bosutinib tablets 100mg/400mg/500mg	For treatment of adult patients with: 1) Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive Chronic Myelogenous Leukemia (Ph+CML) 2) Chronic phase, accelerated phase (AP), or blast phase (BP) Ph+CML with resistance or intolerance to prior therapy
5.	Safinamide methane sulphonate bulk drug and Safinamide tablets 50mg/ 100mg	For treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (Ldopa) alone or in combination with other Parkinson's disease (PD) medicinal products in mid to late stage fluctuating patients
8.	Droxidopa bulk drug and Droxidopa capsules 200mg/300mg	For treatment of orthostatic dizziness, light headedness or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease multiple system atrophy (MSA) and pure autonomic failure), dopamine beta-hydroxylase deficiency and non-diabetic autonomic neuropathy
<ul style="list-style-type: none"> Healthcare professionals are urged to closely monitor the safety of these drugs. ADRs, if any, to be reported to PvPI. 		

Source: on https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDk2NA==

Drug Safety Alerts for July-September 2019

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

Suspected Drug: Febuxostat

Indication: Chronic Hyperuricemia in conditions where urate crystal deposition has already occurred

ADR: Toxic Epidermal Necrolysis/Stevens Johnson Syndrome

Suspected Drug: Netilmicin

Indication: Septicaemia, including neonatal sepsis and other severe systemic infections

ADRs: Tetany

Suspected Drug: Metronidazole

Indication: Amoebiasis, Urogenital trichomoniasis, and giardiasis

ADRs: Vasculitis

Suspected Drug: Risperidone

Indication: Bipolar-1 disorder (Monotherapy or as adjunctive therapy in lithium or valproate)

ADRs: Rabbit Syndrome

Suspected Drug: Tenzeligliptin

Indication: Type-2 Diabetes Mellitus

ADRs: Arthralgia




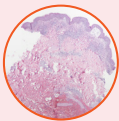
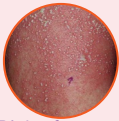

Suspected Drug: Atorvastatin

Indication: Primary hypercholesterolemia & Mixed dysbetalipoproteinemia (Type IIa & IIb)

ADRs: Vitamin-D deficiency

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/medicine side-effect reporting form for consumer (<http://ipc.gov.in>) via PvPI tollfree **Helpline #1800-180-3024**

Comparative status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS	REFERENCE
NALTREXONE / BUPROPION	 Risk of dizziness / Somnolence/ Seizure	Global – 8496 India – 21	21 ICSRs reported in PvPI database	Drug safety update, MHRA 19, August 2019 (www.gov.uk/mhra)
MONTELUKAST	 Associated with the Neuropsychiatric reaction including nightmares, insomnia, agitation, aggressive behaviour, depression	Global – 4588 India – 11	11 ICSR reported in PvPI database	Drug safety Newsletter, HPRA, August 2019 (www.hpra.ie)
TOCILIZUMAB	 Rare risk of hepatic injury such as acute liver failure, Hepatitis and Jaundice	Global – 102 India – 01	01 ICSR reported in PvPI database	Drug safety Newsletter, HPRA, August 2019. (www.hpra.ie)
AMOXICILLIN	 Drug reaction with Eosinophilia and systemic symptom	Global – 315 India – 12	12 ICSR reported in PvPI database	Product Safety Alerts, HSA, 14 September 2018 (http://www.hsa.gov.sg).
BETA-LACTAM ANTIBIOTICS	 Risk of severe cutaneous adverse reaction (SCAR).	Global – 152 India – 19	19 ICSR reported in PvPI database	Summary Safety Review, Health Canada, 7 September 2018 (www-hc-gc-ca)
ZOLEDRONIC ACID	 Risk of Hypocalcaemia	Global – 841 India – 25	25 ICSR reported in PvPI database	Prescriber update, medsafe, time 2018 (www.medsafe.gov.nz/)

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

PV System @Belagavi Institute of Medical Sciences

Belagavi Institute of Medical Sciences (BIMS), Belagavi was set up in year 2005-06 as one of the six newly-established government medical colleges in Karnataka. Spread over a 36-acre area, the college includes a 740-bed BIMS hospital with an average attendance of more than 1,000 OPD patients daily. BIMS hospital has 30 major and 21 minor OT units, a dialysis unit, six clinical laboratories, ICU/ICCU for all clinical departments, ICU for burns unit and a 24-hour Accident and Emergency Department.

BIMS, Belagavi was recognized as an AMC in 2014 by NCC-PvPI, Indian Pharmacopoeia Commission, Ghaziabad under the stewardship of Assistant Professor Dr Pankaj Kumar Masare as Coordinator and Dr B C Kotinatot, Prof & HOD, Pharmacology as deputy coordinator.

ACTIVITIES

- Sensitization of doctors, staff nurses, MBBS

students through regular seminar sessions to ADR-reporting

- Conducting ADR reporting and awareness sessions at ART & RNTCP civil hospital
- Coordination and conduct of awareness sessions on ADR-reporting with nearby peripheral hospitals such as KLE medical college and hospital, and Vijaya Ortho & Trauma Centre (VOTC) hospital
- Dissemination of information related to ADR reporting, displaying tollfree helpline number 1800-180-3024, ADR awareness posters at different departments
- Sessions on “ADRs reporting via ADR reporting mobile application” in different departments
- Distribution of ADR forms and ADR collection boxes at different departments
- Circulation of monthly drug alerts and other information related to drug safety among HCPs via WhatsApp group.

PV highlights @Madras Medical College, Chennai

Madras Medical College (MMC) is a government medical college, which was established by Sir Fredrick Adams in 1835, and rechristened as Madras Medical College (MMC) on October 1, 1850. It is attached to 3,000-bed Government General Hospital also known as Rajiv Gandhi Government General Hospital (RGGGH) and is one of the premier institutions in the country. Set up in Madras by Sir Edward Winter on November 16, 1664 as a small hospital to treat the sick soldiers of the East India Company, Government General Hospital is first British hospital.

Institute of Pharmacology, Madras Medical College was designated as an AMC under Pharmacovigilance Programme of India in November

2010 under the supervision of Dr R Nandhini, former director and professor of Pharmacology. At present the AMC is functioning under Dr K M Sudha, Coordinator-PvPI and Director in-charge, Institute of Pharmacology, MMC. Mrs Siddiraju Devipriya is the PSPvA at MMC.

AMC ACTIVITIES:

- Contribution of more than 13,000 ICSRs to PvPI since its inception in November 2010 to September 2019
- Organised 5 CMEs, 2 workshops and 42 sensitization and training programmes on Pharmacovigilance with emphasis on spontaneous ADR reporting for clinicians, CRRIs, staff nurses,

- Pharmacists and various medical and paramedical students of MMC and nearby medical and Pharmacy colleges
- Follow-up of product quality issue of medicines such as Bupivacaine
- Active involvement in base line studies of medical devices and medical device recalls/alerts as per the Medical Device Programme of India (MvPI) and CDSCO
- Promotion of PvPI helpline number (1800-180-3024) with ADR posters in vernacular language at 44th National Industrial Trade Fair held at Island Grounds, Chennai
- Contribution of unlabelled ADRs such as Lichenoid dermatitis: Imatinib, Lichenoid skin lesion: Rifampicin, Drowsiness: Telmisartan
- Dissemination of PvPI-Drug Safety alerts via WhatsApp to healthcare professionals

Government Medical College, Nagpur excels PV

Government Medical College and Hospital (GMCH), Nagpur was founded at Nagpur, Maharashtra, in 1947. This tertiary care hospital has 1,700-bed occupancy, providing speciality health facilities. GMCH Nagpur was enrolled as a regional Adverse Drug Reaction Monitoring Centre (AMC) under Pharmacovigilance Programme of India (PvPI) in 2013. Pharmacovigilance activities of AMC are effectively carried out under the leadership of Dr Ganesh Dakhale, Coordinator and Professor, Dr Smita Sontakke Deputy Coordinator & Associate Professor, Department of Pharmacology. The programme has gained pace since the deputation of Mr Piyush Nama, Patient Safety Pharmacovigilance Associate, NCC-PvPI, IPC, Ghaziabad. The institute has constituted a CAC (Causality Assessment

Committee) and Pharmacovigilance committee for strengthening pharmacovigilance and sensitizing healthcare professionals to Pharmacovigilance.

AMC ACTIVITIES:

- Contribution of more than 2,000 ICSRs (including common, rare & very rare ADRs) to PvPI database since 2013
- CMEs/Orientation Programme on PV for all faculties, consultants and resident doctors with updates on recent advancements
- Regular sensitization of nurses, medical, paramedical and pharmacy staff by seminars and workshops on ADR-reporting in GMCH
- Coordination with other government hospitals for active ADR-reporting as well as receiving ADRs Reports from Govt Medical College, Chandrapur, GMC Akola, Govt Mental Hospital, PHCs (Primary Health Centres) & ESIC Hospital, Nagpur
- Coordination with Private Sector hospitals for active ADR-reporting, including Wockhardt Superspeciality Hospital, Seven Star Superspeciality Hospital, Shrikrishna Superspeciality Hospital, Lotus Hospital, Columbia Hospital, HCG- Nichri Cancer Hospital, Nelson Mother & Child Care Hospital, Nagpur
- Dissemination of information through PvPI awareness posters and pamphlets at all OPD wards and ICUs
- Active vigilance of medical devices
- Inclusion of more than 150 mobile numbers of HCPs into national database to receive drug safety SMS alerts
- Demonstration of Android mobile app for ADR-reporting during sensitization programmes





Dr B C KOTINATOT

**Professor & HOD, Department of Pharmacology
BIMS, Belagavi**

We have a well established PV centre at BIMS, Belagavi where we encourage and sensitize healthcare professionals to report ADRs to drugs, vaccines for promotion of rational drug use. The mission of PV here is bolstered to safeguard the population by ensuring that benefits of use of medicine outweigh the risks associated with its use. Our reporting has been increasing constantly over time and we shall continue to contribute the same in future for the betterment of public health.

Dr GAJANAN PISE
**Senior Resident, Department of Dermatology
BIMS, Belagavi**

"Anything not reported is not done" is an age old saying. Living up to this experience, the department of dermatology has taken reporting of ADRs very seriously, we are precise and pedantic in pinpointing the culprit drugs. We hope to continue this legacy and thoroughly imbibe this in our PG teaching so all clinicians inculcate this habit wherever they practice.



Dr GIRISH DANDAGI

**Professor & HOD, Department of Chest & TB, Medical Superintendent
BIMS, Belagavi**

Identification and reporting of suspected adverse drug reaction or pharmacovigilance process is important for patient safety which is the primary responsibility of all clinicians and Pharmacists. Pharmacovigilance is particularly important for newer drugs as rate of drug-related adverse effect is not always identified in clinical trials and prescribing medication in the real world often entails new safety concerns.

Dr J A NAGALIKAR
**Medical Officer, RNTCP
BIMS, Belagavi**

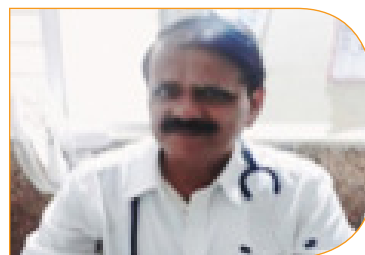
Reporting of ADRs is a critical and important parameter for ensuring patient safety and it is the responsibility of all healthcare professionals to report suspected ADRs.



Dr RAJENDRA BALIKAI

**Medical Officer, Department of NCD
BIMS, Belagavi**

Getting information about adverse drug reactions (ADRs) helps in better management of not only the disease a patient suffers from but also provides first-hand information about the efficacy or otherwise of the drug. This information on ADRs related to drugs makes us think objectively about the acceptance of newer alternative drugs for disease management – a good initiation for patient safety.



Dr PANKAJ KUMAR MASARE

**Assistant Professor/Coordinator-PvPI, Department of Pharmacology
BIMS, Belagavi**

Recognizing and reporting of ADRs is a critical step towards better drug safety. Pharmacovigilance has become the most effective and extensive tool for drug safety monitoring globally. We have a well established ADR monitoring centre at BIMS, Belagavi where we sensitize doctors, staff nurses, MBBS students, interns through regular seminar sessions on ADR-reporting. Our reporting has been consistently on the increase and we will continue to contribute to drug safety in future.

Dr JAYESH MUKHI

**Associate Professor, Department of Dermatology
GMCH, Nagpur**

PvPI is an essential tool for all healthcare professionals when deciding rational use of medicines for better patient-care. It helps in assessing the interactions and adverse drug reactions thereby reducing morbidity and mortality.



Dr SMITA SONTAKKE

**Deputy Coordinator & Associate Professor, Dept of Pharmacology
GMCH, Nagpur**

Pharmacovigilance Programme of India (PvPI) has helped increase awareness and importance of reporting adverse drug reactions among clinicians, circulating drug alerts through SMS. PvPI Newsletter, too, is praiseworthy as it alerts healthcare professionals to rare adverse effect of drugs.

Dr VIJAY MOTGHARE

**Professor & Head, Department of Pharmacology
GMCH, Nagpur**

The Pharmacovigilance Programme of India (PvPI) is a very useful tool for all healthcare professionals in routine monitoring of ADRs and drug interactions. It has helped raise awareness about ADR and drug safety among healthcare professionals as well as the consumer.





Dr K M SUDHA, Coordinator-PvPI & Director I/c, Institute of Pharmacology Madras Medical College, Chennai

Congratulations to NCC-PvPI, IPC for being the "WHO-Collaborating Centre for Pharmacovigilance in public health programmes and regulatory services". With the growing trend of new diseases and new drugs in the market, Pharmacovigilance Programme of India (PvPI) has been pivotal to collecting ADRs from AMCs as well as consumers, besides exploring drug alerts to all stakeholders of PvPI for patient safety and rational use of medicines in clinical practice. The extended activities of ADR/AE reporting of vaccines and medical devices have helped achieve new milestones in Pharmacovigilance at national level. It has been a great pleasure to work with PvPI and I look forward to its further growth.

**Dr N GOPALAKRISHNAN
MD, DM, FRCP, Director, Institute of Nephrology
Madras Medical College & RGGGH, Chennai**

PvPI is a great initiative. Pharmacovigilance is of utmost importance, but as yet continues to be neglected. Of late, there has been a remarkable surge in Pharmacovigilance, thanks to the impetus given by PvPI. We at Madras Medical College & Rajiv Gandhi Government General Hospital have initiated a host of AMC activities involving medical and paramedical personnel. Adverse drug reactions are collected from different departments and collated. "I wish Pharmacovigilance becomes part and parcel of the undergraduate curriculum itself."



**Dr R JAYANTHI, DEAN
Madras Medical College & RGGGH, Chennai, Chairman, Pharmacovigilance Committee
MMC & RGGGH, Chennai**

The Pharmacovigilance Programme of India is a landmark and a coveted programme, too. It ensures not only the implementation of Pharmacovigilance but also paves the way for rich and useful database of ADRs to the benefit of all stakeholders, clinicians and patients including. My appreciation to the team at Madras Medical College for the robust Pharmacovigilance and ADR activities aimed at enriching our knowledge as also ensuring the quality of healthcare delivery in our institution.

**Dr NIRMALA, Professor & HOD, Department of Dermatology
Madras Medical College & RGGGH, Chennai**

In recent years, we have come across an increased incidence of adverse reactions following drugs prescribed by doctors and self-medication by patients. After the setting up of Pharmacovigilance Committee, doctors are sensitized to adverse drug reactions and reporting of these events. When such incidents are reported and monitored it helps avoid unsafe medications. Hence, safer drugs are prescribed, and the process has reduced drug reactions and medication errors in our institution. We also educate patients in our outpatient and inpatient departments not to go in for self-medication. I appreciate the active involvement of Pharmacology department in preventing adverse drug reactions, thus enhancing patient safety in our practice.

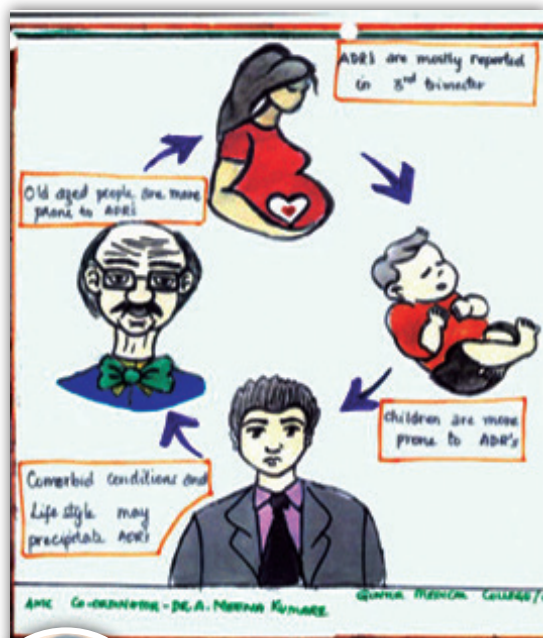


**Dr S SEKAR
Senior Medical Officer, ART Centre
Madras Medical College & RGGGH, Chennai**

Nowaday Pharmacovigilance plays an important role in patient safety. With the rapid growth of speciality care, a whole lot of new issues have arisen with new and old drugs which were not mentioned in the textbooks. PVPI is an informative forum to learn a lot from. We have been giving vent to our experiences and challenges in Pharmacovigilance through a proper mechanism. With the growing trend of diseases Pharmacovigilance is much needed for all.

Winners of Poster Competition Held on Independence Day 2019

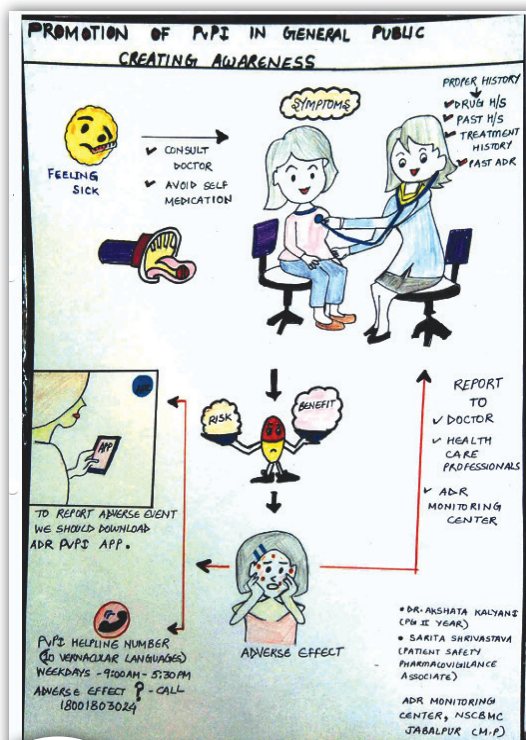
FIRST



Dr. PAWAN KUMAR KANDULA,

PS-PvA
Guntur Medical College,
Guntur, Andhra Pradesh

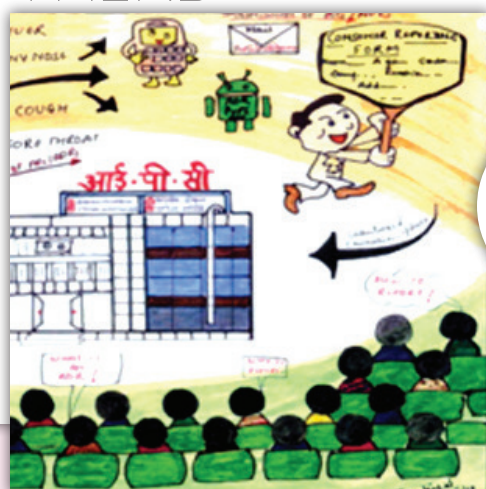
SECOND



Ms. SARITA SRIVASTAVA,

PS-PvA
NSCB Medical College
Jabalpur,
Madhya Pradesh

THIRD



Ms. SWATI THAPLIYAL,

PS-PvA
National Coordination Center,
Pharmacovigilance Programme
of India,
Ghaziabad

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 आँकलन 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 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 स्वास्थ्यकर्म 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, pvpi@ipcindia.net
Website: www.ipc.gov.in

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