Mission PvPI:
To bolster PHPs into drug monitoring

Public Health Programmes (PHPs) being the nationwide network for the supply of drugs and vaccines to the masses need to be monitored for ensuring health safety.

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Greetings to Readers!

The Pharmacovigilance Programme of India (PvPI) has embarked on a journey from across the country to south-east Asia with a mission to establish and strengthen PV systems in low-and-middle income countries (LMICs) in Asia. This follows the designation and establishment of WHO-Collaborating Centre at PvPI-IPC, Ghaziabad last year. A series of policy-level meetings by PvPI-IPC officials with their WHO counterpart have been conducted to bridge the gaps in drug-monitoring at the grassroot level with a concerted focus on Public Health Programmes (PHPs) in LMICs.

PHPs are the backbone of a national health policy as medicines are dispensed and administered to the common masses through such countrywide programmes. Ensuring the safety of medicines delivered by such vast healthcare networks is the bounden duty of all stakeholders at macro and micro-level.

The awareness drive by the PvPI, IPC to hammer home the paramount need for pharmacovigilance (PV) at all healthcare facilities, including government and private hospitals, primary and district health centres, needs a thrust so as to make the common man aware of the right to report any adverse event related to drug-use.

Compliance by marketing authorization holders (MAHs) to the Guidance Document on PV will eventually raise awareness among them to the regulatory requirements of PV and establishment of a sustainable Pharmacovigilance system in the pharma sector.

“I wish PvPI, IPC success in its consistent efforts to popularise pharmacovigilance among the masses.”

Dr G N Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India
Pharmacovigilance and drug-safety monitoring are of primary importance for ensuring treatment with least harm by the drugs prescribed and consumed. The Pharmacovigilance Programme of India and its integration with public health programmes (PHPs) across the country help build a coordinated and sustainable drug-monitoring system. It is vital that adequate systems and practices for reporting of adverse drug reactions (ADRs) are in place to ensure that the benefit of use of medicine outweighs the attendant risks.

Indian Pharmacopoeia Commission through National Coordination Centre, Pharmacovigilance Programme of India is one of the active member-countries in WHO-Programme of International Drug Monitoring. It also leads the thematic area of Vigilance as part of the South-East Asia Regulatory Network (SEARN). Recognizing its essence and services, NCC-PvPI, IPC has of late been designated as a WHO-Collaborating Centre for Public Health Programmmes and Regulatory Services.

NCC-PvPI has also extended its outreach to various Public Health Programmes (PHPs) in India, encouraging them to participate in, and contribute to, the nationwide drug-safety monitoring programme.
Pharmacovigilance Programme of India (PvPI)

Focus on PHPs

- Ensuring easy access to medicines through PHPs
- Quality supply of drugs and vaccines
- Early collation, analysis and detection of ADRs on a regular basis to avert the probability of an endemic
- Regular updates to stakeholders on drug-safety data

Cohort Event Monitoring:

- Prospective, observational and cohort study of adverse events associated with one or more medicines

Candidate Drugs:

- Bedaquiline
- Delamanid

Tasks Ahead:

- Integration of PvPI with other Public Health Programmes in India
- Integration of E-NIKSHAY with VigiFlow®
- In collaboration with WHO develop relevant tools and guidelines for enhancing Pharmacovigilance (PV) practice in low-and-middle income countries (LMICs) in Asia and beyond
- Support LMICs in Asia for establishing PV at their respective Public Health Programmes
To understand the regulatory changes and compliances with new Pharmacovigilance-risk management and adverse event reporting initiatives from organizations such as European Medical Agency, USFDA, PMDA and WHO, the Pharmaceuticals and Medical Devices Agency (PMDA)-Asia Training Centre (ATC), Tokyo organized a seminar at PMDA, Tokyo in Japan from February 5, 2018 to February 8, 2018. The four-day seminar was attended by Dr Prasad Thota, Scientific Assistant, IPC, NCC-PvPI. The objective of the seminar was to review the risk-management plan, including risk-minimizing activities, the means of risk communication & Pharmacovigilance-based methods to conduct studies and surveillances.
USFDA-PvPI venture on PV policy, capacity-building

PvPI in collaboration with USFDA held a policy-level meeting at IPC, Ghaziabad to deliberate on challenges and issues in effective implementation of PV system, PV audits and inspections. It also discussed the need for an effective risk-management plan and benefit-risk assessment of medicines. The meeting was convened in three different phases:

**Phase-I**
March 12, 2018, NCC-PvPI, IPC.

**Participants**
USFDA, CDSCO, PvPI, IPC officials.

**Outcome**
- Participants gained knowledge on regulatory aspects of USFDA and CDSCO.
- Compulsory evaluation of drugs after 18 months of approval can be adopted by the CDSCO.

**Phase-II**
March 13, 2018, AIIMS-NDDTC & Yashoda Hospital, Ghaziabad.

**Participants**
USFDA, CDSCO, PvPI and AMC officials.

**Outcome**
- Mutual exchange of information between USFDA, CDSCO & PvPI on ADR-reporting.
- Interaction of USFDA officials with AMC team to apprise of AMC activities and documentation.

**Phase-III**
March 15-16, 2018, SciTech Centre, Jogeshwari (West), Mumbai

**Participants**
USFDA, CDSCO, PvPI officials, Drugs Inspectors, MAHs, Importers and Distributors

**Outcome**
- Participants gained knowledge on regulatory aspects of USFDA and CDSCO.
- Participants trained on setting up a good PV system at their organizations and following the process of collecting & reporting ADRs to PvPI.
Sri Lanka hosts 2nd SEARN annual meet

Second Annual Meeting of South-East Asia Regulatory Network (SEARN) was held at Movenpick hotel in Colombo, Sri Lanka on March 21-23, 2018. Dr V Kalaiselvan, Principal Scientific Officer, IPC attended the three-day meeting as its chairperson. The other members included Mr Imran from Indonesia, Ms Aurus Kondphanich from Thailand, Mr Gopi Krishantha from Sri Lanka and Mr Pelden Chejor from Bhutan.

The meeting reviewed the progress made since 2017 and chalked out the work plan for the next two years.

- SEARN provides a platform for India to play a lead role in Vigilance for medical products
- Mutual exchange of information – for better results and good decision-making process
- Mapping of resources – scope for ensuring cost-effectiveness
State & UT Regulators: Key to promote IPC services

A meeting was held at IPC, Ghaziabad on February 2, 2018 with a view to ensuring the optimum utilization of services provided by Indian Pharmacopoeia Commission (IPC) to all healthcare stakeholders. The meeting was attended by State & UT Drugs Controllers, CDSCO and IPC officials and AMC Coordinators.

The DCG(I) stressed that IPC has a pivotal role in bringing out the National Formulary of India (NFI) and promoting the rational use of generic drugs. He also emphasized the need for enhancing ADR reporting by all stakeholders, including the poor masses as patients or their attendants/family.

JDC(I) addressed the need for compliance to Drugs & Cosmetics Act 1940 & Rules 1945, emphasizing the role of NCC-PvPI in promoting patient safety. PSO, PvPI highlighted the need for implementation of PV guidelines developed for the Marketing Authorization Holders (MAHs) in all the States/UTs.

During the meeting, DCG(I) released IP Reference Substance (IPRS)-Teriparatide, the first biological reference standard developed by the IPC.

PV in Undergraduate Pharmacy Curriculum

A meeting was convened at NCC-PvPI, IPC, Ghaziabad on February 16, 2018. Chaired by Dr MGR University vice-chancellor Prof (Dr) Geeta Lakshmi, the meeting was attended by Pro-VC Nagaland University Prof Ramesh C Gupta. Prof Geeta Laxmi in her opening remarks stressed the need for introducing PV in UG pharmacy curriculum at all universities in the country.

Salient Features:

- Exhort Pharma students to opt for Pharmacovigilance (BP805ET) as an elective subject in the 8th semester of B Pharm course
- Pharmacy Council of India (PCI) may prompt pharmacy institutions to sign a Memorandum of Understanding with regional AMCs
- Identifying five nodal States as a pilot project under PvPI, inviting pharma students for clinical services at the hospitals
- PCI to ensure hands-on training on PV for faculty
- Universities to ensure PV is made mandatory in Quality Improvement Programmes for faculty
Notable Events

PvPI set to address Delamanid safety in India

After the induction of Deltaba® (Delamanid) by the CDSCO on August 2, 2017 for pulmonary MDR-TB in adults, Programmatic Management of Drug-Resistant Tuberculosis (PMDT) convened a “capacity building meeting for master trainers” at JW Marriot hotel, Aerocity, New Delhi on February 1, 2018. The meeting also addressed the issues such as supporting states to develop their district-wise expansion plans and to roll out newer drugs and shorter MDR-TB regimen as per PMDT guidelines 2017. PvPI officials at the meeting assured all concerned that monitoring and reporting of Delamanid-induced adverse drug reactions by all the ADR Monitoring Centres (AMCs) in the respective states would be ensured.

At present, seven states have been identified as initial sites for the use of Delamanid in MDR-TB and the AMCs in these states shall report the ADRs to NCC-PvPI, which will be regularly communicated to the regulatory authorities.

PvPI shoulders National Deworming Day 2018

Under the flagship of National Health Mission run by Govt of India, the National Deworming Day 2018 (NDD 2018) was observed on February 10, 2018 to combat STH (Soil-Transmitted Helminthiasis) infections in preschool and schoolchildren aged between 1 and 19 years. During the day-long event Albendazole Oral Tablet (400mg) was administered. PvPI as a counterpart participated in the event to spread awareness and collect adverse events following the use of Albendazole. PV-Associates of AMCs in different states visited the government-aided schools and Anganwadi centres before and after the event.

Officials, teachers and Anganwadi workers received training and educational material pertaining to the deworming programme.
MvPI partners review progress

A meeting to review the progress of Materiovigilance Programme of India (MvPI) was held at PvPI, IPC, Ghaziabad on January 19, 2018. During the meet, Dr Pawan K Saini, SO, IPC, welcomed the MvPI partners and briefed them on the final draft documenting the roles and responsibilities of the partners. The participants focused on the following topics:

- Finalization of roles and responsibilities of MvPI partners
- Formation of Causality Assessment Group (CAG)
- Review of MDAE Reports for root-cause analysis of the adverse events
- Revision of MvPI Guidance Document & MDAE Reporting Form
- Data compiling methods and SOPs for MvPI

MDAE Reporting Status:

During the index period, NCC-MvPI received as many as 75 MDAE reports from AMCs/MDMCS/Medical Device industries, etc. The reported cases are under assessment for completeness and clinical relevance. Lack of quality/incomplete reports will be reverted to the reporter/sender for further necessary action.

Awareness Drive

- Sensitization Programme on MDAE reporting conducted at PGIMER, Chandigarh and Dental Department, Punjab University
- Lecture on MvPI at Hindurao Hospital, New Delhi on February 21, 2018
- Presentation on MvPI during Annual Sri Ramachandra University Pharmacology Insight and Review Course ASPIRE-2018
IPC Library and Information Centre is the leading Pharmacopoeial Library in the country. The library has an excellent collection of Pharmacopoeia of different countries, reference books, WHO publications, scientific journals, national and international substance standards, non-book materials and e-resources to regularly improve the standard of drugs used by health professionals, patients and consumers. IPC Library also provides technical services to the users in the field of Drugs & Pharmaceuticals, Pharmacovigilance and other related areas.

IPC focus on herbal drug standardization

A three-day international conference on “Challenges for Global Competitiveness of AYUSH and Natural Products and IASTAM Oration and Award Function” was held at Delhi Pharmaceutical Sciences and Research University (DPSRU), New Delhi from February 2-4, 2018. Inaugurated by Delhi Lt Governor Shri Anil Baijal, the conference was attended by IPC officials Dr Jai Prakash (Sr PSO), Dr Sushma Srivastava (Sr Consultant), Ms Ritu Tiwari (Scientific Assistant) and Dr R S Ray (Scientific Assistant).

The conference focused on traditional systems of medicine and the challenges faced by AYUSH and natural products. The conference was followed by a brainstorming session on development of AYUSH pharmaceuticals for creating new academic and research interest and opportunities. A pre-conference workshop on “HPTLC Analysis of Materials of Botanical Origin” sponsored by Anchrom India Ltd was attended by IPC staff.

Dr Jai Prakash delivered a lecture on the “Role of Indian Pharmacopoeia Commission in Ensuring Quality of Herbal Drugs” during the conference. Scientific deliberations were made by experts from India and abroad in the area of herbal drug standardization.
**Pharmacovigilance Programme of India (PvPI)**

# NFI for rational prescription of medicine

The irrational use of medicines is a matter of grave concern worldwide. The irrational use could be in the form of overuse, underuse and misuse of medicine leading to wastage of scarce resources and widespread health hazards. Examples of irrational use of medicines include practice of poly-pharmacy, inappropriate use of antimicrobials, preference of injectables over oral formulations, non-compliance of clinical practice guidelines wherever available, self-medication habits, pressure from patients/attendants, irrational combinations/formulations, non-compliance by patients and so on.

The National Formulary of India (NFI) is a book of reference for healthcare professionals. It contains a wide spectrum of information and advice on rational prescribing of medicines. It covers the medicines listed in National List of Essential Medicines (NLEM) of India and National Health Programmes of the country. Each specific monograph of NFI provides comprehensive information on indications, contraindications, adverse effects, dose, route of administration, pregnancy category, and other relevant information for prescribing medicines.

Information on drugs in NFI is collected and collated from the available medical and pharmaceutical literature, and through inputs from regulatory authorities and professional bodies, which is further reviewed by the Expert Committees of NFI comprising physicians, specialists etc from various healthcare organizations from all over India.

<table>
<thead>
<tr>
<th>Criteria for inclusion of drugs in NFI</th>
<th>Criteria for exclusion of drugs in NFI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs listed in National List of Essential Medicines, India</td>
<td>Drugs banned in India</td>
</tr>
<tr>
<td>Drugs used in National Health Programmes</td>
<td>Obsolete Drugs</td>
</tr>
<tr>
<td>Drugs listed in Indian Pharmacopoeia</td>
<td>Drugs considered inappropriate by IPC</td>
</tr>
<tr>
<td>Drugs not covered but recommended by panel of experts</td>
<td></td>
</tr>
<tr>
<td>Any drug (s) considered appropriate by the IPC</td>
<td></td>
</tr>
</tbody>
</table>

**NFI 2016: Salient Features**

- NFI 2016 comprises 33 chapters by therapeutic categories, 521 drug monographs including 33 fixed-dose combinations, 20 immunologicals and 12 vitamins
- The specific monographs within a chapter are arranged in an alphabetical order
- NFI 2016 contains a list of banned drugs in India since 2008
- NFI 2016 incorporates 22 appendices with special emphasis on reporting of adverse events/experience and their causality assessment, list of common drugs causing severe allergic reactions, domiciliary care of seizures, drugs banned in India, drugs listed in NLEM 2011, and tips for healthy life style
- Drugs for oral health, medicines banned in sports are newer inclusion
Training and Education

Honing Skills of HCPs

Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) conducted its serial skill development programme on “Basics & Regulatory Aspects of Pharmacovigilance” 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. During the index period two such training sessions of 10 days each were held – the first between January 15-24, 2018 and the second between March 5-14, 2018.

The training covered four modules of pharmacovigilance such as theory, practical, hands-on training and information technology (IT) applications. Renowned national and international experts from various disciplines of Pharmacovigilance served as trainer/faculty in the training programme. The training opened up career avenues for budding pharma students/professionals. Participants with a medical and pharmacy background underwent the training. The graphs depict the details:
Workshop-cum-training on PV for NABH hospitals

In a series of trainings for NABH-accredited hospitals as per the MoU between IPC and NABH, regular workshops are being organized by PvPi. These trainings not only provide a platform for the NABH-accredited hospitals of the region to understand the system and procedures involved in ADR-reporting but also help sensitize the healthcare professionals to monitoring and reporting AEs/ADRs.
Three such workshops were held during the index period:

- **Odisha**
  - Apollo Hospital, Bhubaneswar
  - Participants: 50

- **Punjab**
  - Dayanand Medical College and Hospital, Ludhiana
  - Participants: 43

- **Uttar Pradesh**
  - Vivekanand Polyclinic and Institute of Medical Sciences, Lucknow
  - Participants: 50

Participants during a workshop-cum-training programme on ADR-reporting at Dayanand Medical College and Hospital in Ludhiana

**Topics Covered:**

- Basics of Pharmacovigilance and mandates and activities of NCC-PvPi
- Monitoring & reporting AEs/ADRs (Methodology, Forms & Formats)
- Setting up of a PV system in Hospitals
Integrated Institute of Technology-Dwarka pupils visit IPC

Integrated Institute of Technology, Dwarka, New Delhi staff with 64 students visited Indian Pharmacopoeia Commission on March 9, 2018. IPC scientific staff briefed them on career prospects for students in Pharmaceutical Sciences, Monograph development, cutting-edge analytical instruments and development of Reference Substances.

QIP delegates, DIPSAR students at IPC

As many as 12 teachers from various parts of the country participating in the AICTE sponsored XXVI Quality Improvement Programme (QIP) visited Indian Pharmacopoeia Commission, Ghaziabad on March 15, 2018. The QIP delegates and students were accompanied by DIPSAR faculty, including Mrs Manju Vyas (Co-coordinator & Associate Professor), Mrs S Latha (QIP Coordinator & Assistant Professor) and Mrs Sakshi Bajaj (Lecture).

Dr Jai Prakash (Sr PSO, IPC) welcomed the delegates and delivered a lecture on theoretical and practical aspects of High Performance Thin layer Chromatography. The delegates were provided hands-on training on High Performance Thin Layer Chromatography and Bacterial Endotoxin Test by the IPC scientific staff.
# Approved New Drugs in India

The following new drugs were approved by the CDSCO during January-March 2018

<table>
<thead>
<tr>
<th>S No</th>
<th>Name of drug</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tenofvir Alafenamide Hemifumarate Bulk &amp; Emtricitabine 200mg/200mg + Tenofvir Alafenamide 10/25mg Tablets</td>
<td>In combination with other antiretroviral agents for treatment of Human Immunodeficiency Virus type-1 (HIV-1) infection in adults and adolescents aged 12 years and older</td>
</tr>
<tr>
<td>2</td>
<td>Clofarabine Bulk &amp; Injection 20mg/20ml vial</td>
<td>For the treatment of patients 1 to 21-year old with relapsed or refractory acute lymphoblastic leukemia after at least two prior regimens. This indication is based upon response rate</td>
</tr>
</tbody>
</table>
| 3    | Netupitant 300mg + Palonosetron 0.5mg Capsule                                 | • For the prevention of acute and delayed nausea and vomiting associated with highly emetogenic Cisplatin-based cancer chemotherapy  
• For the prevention of acute and delayed nausea and vomiting associated with moderate emetogenic cancer chemotherapy in adults |
| 4    | Cadexomer Iodine Bulk & Powder 100% w/w (contains 0.9% w/v Iodine) or Cadexomer Iodine Ointment 500mg (contains 0.9% w/v iodine) | For the treatment of chronic exuding wounds such as leg ulcers, pressure ulcers and diabetes ulcers, infected traumatic and surgical wounds |
| 5    | Dalfampridine Bulk & Film-coated extended release tablet 10mg                 | To improve walking in patients with multiple sclerosis (MS)                                                                                           |
| 6    | Ulipristal Acetate 5mg tablets                                                 | For the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age |
Drug Safety Alerts

Drug Safety Alerts for January-March 2018

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

<table>
<thead>
<tr>
<th>S No</th>
<th>Suspected Drug</th>
<th>Indication</th>
<th>Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Levetiracetam</td>
<td>For treatment of myoclonus generalised epilepsy with photosensitivity, idiopathic epilepsy - control of generalised tonic clonic seizures, post-anoxic and post-encephalitic myoclonic epilepsy, absence seizures; rolandic epilepsy</td>
<td>Hypokalaemia</td>
</tr>
<tr>
<td>2</td>
<td>Dapsone</td>
<td>For treatment of leprosy, acne vulgaris, dermatitis, pneumocystic pneumonia</td>
<td>Erythema nodosum</td>
</tr>
<tr>
<td>3</td>
<td>Cefixime</td>
<td>For treatment of Otitis media, respiratory tract infections, uncomplicated UTIs, effective against infections caused by enterobacteriaceae, H. influenza species</td>
<td>Skin Hyperpigmentation</td>
</tr>
</tbody>
</table>

Healthcare professionals, patients/consumers are advised to closely monitor the possibility of above-mentioned adverse events while prescribing/consuming above-quoted suspected drugs and report to the NCC-PvPI either by filling up Suspected Adverse Drug Reactions Reporting Form/Medicines Side-Effect Reporting Form for Consumer (http://www.ipc.gov.in), or reporting to PvPI Helpline # 1800-180-3024 or mobile app ADR PvPI.

Comparative Status of Global Drug Alerts with PvPI Database

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Risk</th>
<th>International Status</th>
<th>India Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine</td>
<td></td>
<td>The Pharmaceuticals and Medical Devices Agency (PMDA), Ministry of Health, Labour and Welfare (MHLW), Japan has announced that the package insert for Chlorhexidine-containing products, including over-the-counter preparations (Hibitan®, Acesclean®, Despakowa® and others) updated to include the risk of anaphylaxis as a clinically significant adverse reaction</td>
<td>One case of Anaphylaxis reported</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>Risk</td>
<td>The Pharmaceuticals and Medical Devices Agency (PMDA), Ministry of Health, Labour and Welfare (MHLW), Japan has announced that the package inserts for Teriparatide preparations (Teribone and Forteo) updated to include the risks of cardiac arrest, respiratory arrest and loss of consciousness accompanying seizures</td>
<td>Two cases of risk of cardiac arrest reported</td>
</tr>
</tbody>
</table>

Healthcare professionals are sensitized to carefully monitor the above-mentioned alerts. Any event related to these drugs has to be reported to NCC-PvPI.
SVMC-Tirupati excels in PV

Located at the foothills of the revered Tirumala, Sri Venkateswara Government Medical College (SVMC) is a renowned institute in Tirupati, Andhra Pradesh. SVMC with a 1,032-bed hospital provides speciality health services under the leadership of Dr N Venkataramaniah, Principal. It was recognized as an AMC under PvPI in 2014. Dr B Vasundara Devi, Professor and head, Pharmacology, and Dr K C Radhika Rani, Professor, Pharmacology, are the nominated Coordinator and Deputy Coordinator, respectively. Mrs R Rajalakshmi is the PV-Associate at SVMC.

Salient Features

- Display of PvPI posters at all IPDs and OPDs
- Regular sensitization programmes for healthcare professionals, including faculty, senior/resident doctors, MBBS and Pharm D students
- Periodic Knowledge, Attitude and Practice (KAP) analysis on PV for nurses
- Demonstration of Android mobile app during sensitization programmes
- Zonal CMEs for PG doctors and faculty of Pharmacology
- Installation of 30 ADR drop-boxes at key places
- PV awareness programmes at peripheral colleges/peripheral hospitals (ESI, RHCS, etc)
- Coordination with NABH-accredited hospitals for spontaneous ADR reporting
- Embossing PvPI Tollfree number on OPD slip
- Regulatory PV to ensure supply of quality medicines at SVMC
BRDMC-Gorakhpur adapts to PV practices

Baba Raghav Das (BRD) Medical College is in Gorakhpur, Uttar Pradesh. A government of Uttar Pradesh medical college, it has a 700-bed Nehru hospital with an additional 108-bed Epidemic Ward. This region has seen severe annual encephalitis outbreaks, and the hospital attracts a large number of poor patients from Uttar Pradesh, Bihar and Nepal.

The department of Pharmacology has been carrying out Pharmacovigilance activities following approval by the Indian Pharmacopoeia Commission and has been functioning effectively since 2014 with Dr Jamal Haider, Associate Professor, Pharmacology, as the coordinator. Mr Sanjiv Srivastav has been working as the Patient-Safety Pharmacovigilance Associate at this centre since February 2014.

Activities

- Sensitization of healthcare professionals to ADR-reporting through regular meetings & seminars
- Maintains highest ADR reporting status in eastern Uttar Pradesh for the last four years
- ART centre sending Highly Active Antiretroviral Therapy (HAART)-induced ADRs to NCC-PvPI
- Coordination with PHCs (Primary health centres), CHCs (Community health centres), Urban PHCs and other peripheral hospitals for active ADR-reporting
- Display of Pharmacovigilance posters at all IPD & OPDs
- Awareness on Pharmacovigilance during indradhanush Vaccination Programme at Dharania Pandey village, Bhatparani, District Deoria, UP on December 18, 2017
GMERS-Vadodara follows GVPs

Established in 2009, Gujarat Medical Education & Research Society (GMERS) Medical College is a 650-bed tertiary-care teaching hospital at Gotri in Gujarat. The department of Pharmacology has been carrying out pharmacovigilance activities since 2011 and was recognized as an ADR Monitoring Centre (AMC) by Indian Pharmacopoeia Commission in 2014. With Dr Prakash Bhabhor, Associate Professor, as the coordinator, the AMC is headed by Dr Manoj Kumar Saurabh, Professor & Head, Department of Pharmacology. Mr Ankit Soni has been the Patient Safety Pharmacovigilance Associate at this centre since September 2016.

Activities
- Sensitization of clinicians & Nursing staff to ADR-reporting
- Sensitization of undergraduate students to pharmacovigilance through e-learning modules devised by GMERS faculty
- Pharmacology department has introduced ADR reporting in practical curriculum for undergraduate students
- Active drug surveillance of Iohexol by Pharmacovigilance Associate in collaboration with radiology department of GMERS Medical College
- Active drug safety monitoring of Albendazole during National Deworming Day 2018 at Govt & Private schools
- Distribution of Newsletter and drug safety alerts issued by NCC-PvPI through SMS/WhatsApp to all faculty members
- PvPI posters and charts pasted in different areas of the main hospital building as well as in peripheral hospitals to raise PV awareness among patients and attendants
- Meeting with Chief District Health Officer (CDHO) to raise awareness on pharmacovigilance in rural health settings
Stakeholders’ Feedback

Dr N Venkataramaniah, Principal
SVMC, Tirupati

Heartiest congratulations to NCC-PvPI, IPC for being designated as WHO Collaborating Centre. Prompt recognition, early detection and intervention of ADRs can be achieved by proper understanding and knowledge of Pharmacovigilance. PvPI fulfills its objectives as PV is the need of the hour in today’s healthcare system to improve patient safety. I appreciate the entire team of AMC-SVMC for its excellent performance in PV promotion.

Dr B Vasundara Devi
Coordinator-AMC
Prof & HOD, Pharmacology
SVMC, Tirupati

Spontaneous reporting by clinicians is a challenging task in the field of Pharmacovigilance. Our AMC moves with a positive approach to inculcate the culture of ADR reporting. PV activities are effectively carried out and further focus is to improve ADR reporting among all healthcare professionals and consumers by regular sensitization programmes. We would like to appreciate the state CDSCO for its assistance in quality check of drugs when a particular batch is suspected to be the cause of the ADR. Technical support by NCC-PvPI plays a vital role in carrying out PV activities.

Dr T Muneeshwar Reddy
Associate Professor, General Medicine
Nodal Officer ART Centre SVMC, Tirupati

Pharmacovigilance is a key component of effective drug regulation system, clinical practice, and public health programmes. PV improves the safety profile of drugs that helps avoid drug-related disasters. I congratulate all stakeholders of PvPI for its excellence at global level.

Dr Sejal Thakkar
Associate professor, Dermatology
GMERS Medical College, Gotri,
Vadodara

PvPI is an excellent program which helps clinicians in generating insight to look for ADRs on wider horizons. It helps in sensitizing them at basic entry level, that is, during undergraduate training. This will eventually help them to use drugs with better safety profile.

Dr Manoj Kumar Saurabh
Professor & Head, Pharmacology
GMERS Medical College, Gotri, Vadodara

Pharmacovigilance Programme of India (PvPI) has been doing incredible work since 2010 in the area of drug safety with various measures such as education, training and technical assistance. It has created awareness about ADR and drug safety not only among health professionals but also among consumer. Doctors are prescribing more rational prescription due to untiring efforts of PvPI.
Pharmacovigilance Programme of India (PvPI) helps track and improve the quality of medical equipment/devices, ensuring safety of the patient and healthcare professionals. PvPI improves medical services by providing a feedback mechanism between healthcare facilities (hospitals/clinics) and manufacturers. It helps the regulator in tracking the quality and safety of medical devices.

Dr Jamal Halder
Coordinator-AMC
BRD Medical College, Gorakhpur

“Pharmacovigilance is an essential component of patient care and rational use of medicines. It helps in assessing, monitoring and detecting adverse effects of drugs and their interactions. This measure will help maximize benefits and minimize risks associated with drugs in India.”

Dr Nimisha Desai
Associate professor, Psychiatry
GMERS Medical College, Gotri, Vadodara

Pharmacovigilance program of our institute is very useful as it gives us great insight regarding rational choice and use of drugs/combinations/interactions. It improves our role as clinician/researcher/teacher as well. We become more and more aware of ADRs and thereby helping a lot our patients/participants and improve our practice day by day.

Dr Prakash Bhabhor
Associate professor & Coordinator,
Pharmacology
GMERS Medical College, Gotri, Vadodara

PvPI is a very useful tool for all healthcare professionals in determining pros & cons of each & every drug for better cost-effective treatment & providing better healthcare facilities to patients by reducing morbidity & mortality caused by adverse effects of drugs.

Dr Minoo Patel
Dean
GMERS Medical College,
Gotri, Vadodara

Pharmacovigilance Programme of India (PvPI) is a great tool for routine monitoring of ADRs in a hospital. It gives an opportunity to every clinician to report drug-related problems to the monitoring agency for further action. Apart from sensitization of healthcare professionals, our Pharmacology department prepared E-learning modules for better understanding of PvPI & ADR reporting for undergraduate students and also implemented ADR reporting in their practical curriculum (Future Clinicians)
दवाइयों से होने वाले प्रतिकूल/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फॉर्मकोविजिसीज़ प्रोग्राम ऑफ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनाहित में जारी

जैसा कि हम सभी जानते हैं कि दवाइयों (टेबलेट्स, कैप्सूल, सीपी, इंजेक्शन, टाइपे इट्साइडी) के उपयोग से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की समस्याओं की होती हैं इसका प्रभाव में तहत हुए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्मकोविजिसीज़ प्रोग्राम ऑफ इंडिया को नीतीश्रुत किया, जिसका राष्ट्रीय सम्मेलन केंद्र, भारतीय भेजज सहित आयोग, राजनायक, ग्रामीण सरकार, उच्च प्रदेश में सम्मेलन है। इस सम्मेलन केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए. डी.आर. मॉनिटरिंग सेंटर के द्वारा एकजुट करके उपक्रम ऑफिस एवं विशेष विभाग करना है जिससे किसी भी दवा के फायदे एवं नुकसान की जानकारी अभियान का कार्यवाही हेतु राष्ट्रीय औषधीय मानक नियमानुसार संगठन, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार की नीतियों के अनुसार हो।

"फॉर्मकोविजिसीज़ का अर्थ है औषधि सहकर्ता", यदि किसी मरीज का प्रतिकूल प्रभाव/दुष्प्रभाव जानने के लिए तथा संबंधित परेशानी जानने के लिए, तो यह हमारी वादियों, मान्यता, उच्च, विवरण, कृतियों (उच्च/लोक), लघुदर्शन एवं अन्य कोई दुष्प्रभाव प्रतिकूल प्रभाव जानने का प्लान है। इसके लिए हम चिकित्सकों के साथ सहभागिता करेंगे।

राष्ट्रीय सम्मेलन केंद्र, फॉर्मकोविजिसीज़ प्रोग्राम ऑफ इंडिया, में दवाइयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकजुट करके बेस्राइट वेबसाइट www.ipc.gov.in पर उपलब्ध है।

- निगम स्वरूप 2000-180-3024 (सोमवार से शुक्रवार प्रति 9.00 बजे से 5.30 बजे तक)
- एडबीआर (ADR PvPI)
- ए.डी.आर. मॉनिटरिंग सेंटर
- ए.डी.आर. थिरिटिंग पॉल्यूशन (PvPI)

ए.डी.आर. मॉनिटरिंग सेंटर एवं प्लान के जानकारी भारतीय भेजज सहित आयोग के वेबसाइट www.ipc.gov.in पर उपलब्ध है।

अगर आपको पहले किसी दवा से किसी भी प्रकार की कोई असुरक्षा हुई हो तो अपने चिकित्सक को उसकी स्थूलता अवडार दें जिससे चिकित्सक को आपका उपयोग विशेष डाटा से करने में सहायता मिले।

यदि कोई चिकित्सक, फॉर्मसिस्ट, नर्स या अन्य कोई स्वास्थ्यकर्मी प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी देता है तो उनके विरुद्ध किसी प्रकार की जानकारी नहीं की जाती है बल्कि इससे दवाइयों के प्रभाव को वैज्ञानिक डाटा से समझने में एवं रोगी के उपचार पर आधारित उपचार में सहायता मिलती है।

वह सरोकार में भारत के अधिकारी राज्यों में ए.डी.आर. मॉनिटरिंग सेंटर कार्यालय हेतु एवं राष्ट्रीय सम्मेलन केंद्र के फॉर्मकोविजिसीज़ प्रोग्राम पर वर्तमान के बारे में स्वीकृत जानकारी का आयोजन किया जाता है।

राष्ट्रीय सम्मेलन केंद्र, फॉर्मकोविजिसीज़ प्रोग्राम ऑफ इंडिया आप सभी से अनुरोध करता है कि दवाओं के सेवन से हुए सभी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी अवडार दें जिससे कि दवाओं का सुरक्षित उपयोग सभी के लिए सुनिश्चित किया जा सके।

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