SENTINEL OF SEVEN SISTERS

Arunachal Pradesh
Assam
Meghalaya
Nagaland
Manipur
Tripura
Mizoram

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Dear Readers,

I once again emphasize the obligatory mission of the various programmes undertaken under the aegis of Indian Pharmacopoeia Commission (IPC) is by and large two-fold. One, to raise mass awareness among the Indian populace about the primary need for reporting adverse reactions to the drugs they consume. And, two to ensure the immaculate quality and safety of the medical devices they are implanted with. To meet this twin objective, the two flagships of IPC – Pharmacovigilance Programme of India (PvPI) and Materiovigilance Programme of India (MvPI) – have to be broad-based, functionally streamlined, instrumentally well-equipped, hence institutionalized.

To this end, PvPI and MvPI have been conducting regular time-bound technical workshops, information-sharing symposia, training sessions and orientation programmes – all aimed at honing the healthcare stakeholders’s skills at monitoring, collating and reporting ADRs/AEs to the NCC database with linkage to its global counterpart at Uppsala in Sweden. This acts in furtherance of our objective and commitment as a WHO-CC partner to the health community worldwide.

However, the task of reaching out to a humongous mass of people in every nook and corner of the Indian healthscape is quite a challenge which needs to be met squarely. Efforts need to be redoubled by the PvPI in conjunction with Public Health Programmes and with an oversight on MAHs to ensure the risk-optimization of the drugs post-marketization.

The systemic calibrated approach of PV with an all-encompassing outreach to the bad pockets of the country, including the far-flung areas of the Northeast, has been an initiative worth commendation. I felicitate the Pharmacovigilance Programme of India for its team-effort to inculcate Good Pharmacovigilance Practices among the tribal masses of the northeast India.

Dr. G. N. SINGH
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India
uucked majestically in the lap of the snow-capped Himalayas, the northeast India comprises eight states — Arunachal Pradesh, Assam, Meghalaya, Manipur, Mizoram, Nagaland, Tripura and Sikkim. Proverbially referred to as “Seven Sisters”, access to the region with its inhospitable terrain is arduous yet adventurous. Replete with scenic beauty, bountiful nature and mountainous expanse, the Northeast is bestowed with glacial lakes, exotic flora and fauna, unique ethnic culture, diverse lifestyles and varied healthcare practices. A well-developed healthcare infrastructure is, however, critical to ensuring safety of health for the people of the region at large. With the exception of Assam the rest of the region is usually snow-bound most of the year though modern means of communications are fast catching up and bridging the disconnect between urban, rural and tribal areas.

**PV at Northeast: Chill and thrill uphill**
Several studies have identified the spread of communicable diseases such as malaria, dengue, tuberculosis. However, major non-communicable diseases such as cardio-vascular ailments, diabetes and various types of cancer have also been noticed over the last decade. Besides AIDS had once been quite prevalent in the region. The Pharmacovigilance Programme of India (PvPI) since its inception in 2010 has gained pace in the region though Govt Medical College, Guwahati, Assam was designated an Adverse drug reaction Monitoring Centre (AMC) in Assam prior to 2010. To fulfill the aim of patient safety by effective ADR reporting, the NCC-PvPI has joined hands with most states in the region with 10 AMCs effectively functional.

CONTRIBUTION BY NORTHEAST

- AMCs: Assam (4), Tripura (2), Manipur (1), Meghalaya (1), Arunachal Pradesh (2)
- Regular increase in number of ICSR submitted to NCC
- As many as 1,500 stakeholders trained during 2017-18
- PV training for MAHs recently conducted in Sikkim with 20 participants in attendance
- Govt Medical College, Guwahati recognized for active surveillance of Bedaquiline and Delamanid
- Silchar Medical College, Silchar recognized as Regional Training Centre (RTC) for PvPI in Northeast

CHALLENGES

- Extending PvPI outreach to all states of the northeastern region
- Coordination with National Health Programmes aimed at tackling malaria, dengue, etc
- Enhancing ADR-reporting by MAHs in northeastern states

FUTURE PROSPECTS

- New AMCs in Nagaland, Sikkim & Mizoram
- Posters in the regional languages
- PV promotion by conducting trainings and workshops
- Pharmacovigilance of traditional and herbal medicines
PvPI progress as WHO-CC

After the recognition of IPC in July 2017 as a WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services for SEARN countries, PvPI, IPC during the last one year has initiated many a programme aimed at capacity building and strengthening of PV systems in SEARN countries.

Following the launch of WHO-CC at Indian Pharmacopoeia Commission, Ghaziabad in October 2017, a synopsis of the events is represented herein:

<table>
<thead>
<tr>
<th>EVENT: VENUE AND DATE</th>
<th>ACTIONS AND OUTCOME</th>
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</table>
| Meeting of Working Group-3 (Vigilance of Medical Products) of SEARN countries conducted via WebEx on December 12, 2017 | • Need for mapping of the existing PV capacity through a questionnaire  
• Formation of a steering committee and working group to assess among SEARN countries the current regulations for PV, and how to bolster their practice and training needs  
• 10 SEARN countries provided response to the questionnaire |
| Orientation Programme on Regulatory Services held at CDSCO, New Delhi on December 15, 2017 | • Aimed at appraising Indian Drugs Regulators on PV audits and inspections tools  
• Stakeholders such as WHO, AEFI, healthcare professionals and MAHs provided valuable inputs |
| National Meet with State & UTs Drugs Regulators held at IPC on February 2, 2018 | • Ensuring effective monitoring & reporting of SAEs by MAHs with the implementation of Schedule M  
• Expansion of training outreach for retailers and community health workers for effective ADR reporting |
| Two-day National Workshop on “Good Pharmacovigilance Practices (GvPs)” held at Mumbai on March15-16, 2018 | • Held in technical collaboration with USFDA to identify challenges in implementation of GvPs  
• Speeding up decision-making in signal detection  
• Regular workshops for training MAHs on GvPs |
| 2nd Annual Meet of SEARN Countries held at Colombo, Sri Lanka on March 21-23, 2018 | • SEARN to enhance information-sharing, collaboration and convergence of the regulatory practices across the region to guarantee access to quality medical products  
• PvPI proposed the support/services action plan to the SEARN member countries |
| Four-day PV Training-cum-Workshop for “DRA Officials, Royal Govt of Bhutan” held at IPC on June 11-14, 2018 | • Conceptual training on basic, technical and regulatory aspects of Pharmacovigilance (PV) and its procedures in India  
• Delegates trained on ICSR processing (E2B-XML format), quality management system (QMS), Causality Assessment, Materiovigilance Programme of India (MvPI), hands-on Vigiflow exercise etc |
1st National Workshop on Medical Devices’ quality/safety

First national workshop on “Ensuring Quality and Safety of Medical Devices” was organized by Indian Pharmacopoeia Commission (IPC) at its premises in Ghaziabad on July 19 and July 20, 2018. The two-day workshop was attended by experts such as NIB Director Dr Surinder Singh, ICMR ADG Dr Chander Shekhar, CDSCO JDC(I) Dr V G Somani, BIS scientist Dr Prakash Bachani and NHSRC adviser Dr S B Sinha. Aimed at seeking the active participation of medical devices’ manufacturers, the workshop provided a platform for the delegates to assimilate the need for quality standards of medical devices with the end-aim of promoting patient safety and strengthening the Materiovigilance Programme of India (MvPI).

SALIENT FEATURES
• Seeking inputs/comments by the pharma industry on upcoming Guidance Document for Medical Devices
• Raising awareness among stakeholders for strict adherence to quality and safety standards for medical devices with paramount need for reporting Medical Devices Adverse Events (MDAEs)
• Ensuring effective AE reporting culture among MDMCs, clinicians, biomedical engineers, hospital biotechnology staff and other HCPs

OUTCOME
• Such workshops are designed to help decision-making for medical device manufacturers, users, regulators and other stakeholders by disseminating information on how to report, when to report and what to report to IPC, NCC-MvPI
• Strengthening of effective Materiovigilance system across the country
Workshop on ‘IP standards for phytopharmaceuticals’

First national workshop on “Best Practices and Compliance of Indian Pharmacopoeia standards for herbal drugs and phytopharmaceuticals” was organized at IPC, Ghaziabad on September 18, 2018. Aimed at providing a platform to update the herbal drugs and phytopharmaceuticals’ standards and their compliance, this workshop was attended by representatives of phytopharmaceutical industries. The expert panel included the chief guest Dr Chandrakant Kokate, former Vice-Chancellor, KLE University, Belgaum, Karnataka, Dr G N Singh, Secretary-cum-Scientific Director, IPC, Dr S K Barik, Director, CSIR-NBRI, Lucknow, Dr Ramachandra Reddy, Director PCIM, Ministry of AYUSH, Mr A K Pradhan, Deputy Drugs Controller, CDSCO and Dr Anantha Narayana, Head, Herbal Research, Hindustan Lever Research Centre, Bangalore.

KEY POINTS

- Sensitization of participants to effective implementation and compliance of IP standards as prescribed in monographs for quality control of herbal medicines
- Identify and understand challenges in improving compliance of herbal drugs monographs
- Best practices to be followed for ensuring safety and efficacy of herbal products
- Promotion of worldwide use of herbal medicines and a rapid expansion of the global herbal medicines’ market
- Improvement of standards for herbal drugs and phytopharmaceuticals
- Utilization of advanced techniques such as DNA bar-coding for herbal drug authentication

Chief Guest Dr Chandrakant Kokate during his address to the workshop on ‘Compliance of Indian Pharmacopoeia standards for herbal drugs and phytopharmaceuticals’ at IPC, Ghaziabad on September 18, 2018
LIC seminar on Health Information Resources

For the enrichment of library resources and facilitating library as a global platform for knowledge-sharing and a powerful searching tool for research and development in the scientific organizations, the Library and Information Centre (LIC), IPC at Ghaziabad organized a national seminar on “Health Information Resources and Searching Techniques” on July 27, 2018. The national-level seminar served as a platform for professionals and researchers to delve upon the challenges and problems faced while setting up an information research gateway. As many as 64 participants, including library professionals, academia, scientists and students across the country, attended the event. Technical sessions during the event covered emergent topics such as Deep web-search engines, information searching tools, newer coding systems for fast retrieval of health information and e-resources and copyright compliance in pharmaceutical research, etc.

Dr K R Reddy, Director, PCIM&H Ghaziabad, Dr R C Gaur, Director (Lib & Info Sciences) IGNCA, New Delhi, Prof (Dr) Shilpi Verma, BBA University, Lucknow, Dr M Madhusudhan, Associate Professor, Department of Lib & Info Sciences, University of Delhi, Dr S Siva Chidambaram, Chief Librarian, AIIMS, New Delhi, Dr A K Suman, President, CGLA, Indira Gandhi National Forest Academy, Dehradun, Dr G N Singh, Director, IPC, and other IPC officials delivered lectures during the event.

The programme highlighted issues related to digital health information access, preservation and its privacy. Eminent professionals in the field exhorted the need for mobile application and QR Code in libraries, by providing the visitors with journals, documents, e-books as also encouraging paperless culture. With the help of information services, library should support evidence-based medicine and practices focused at patient safety.
NOTABLE EVENTS

13th Signal Review meeting

The 13th Signal Review Panel (SRP) meeting was held at CDSCO, New Delhi on August 21, 2018. The meeting was chaired by Prof Urmila Thatte, Head of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai. Dr Jai Prakash, Senior Principal Scientific Officer, IPC, briefed the panel on the action taken on the recommendations of the 12th SRP meeting and provided updates on the implementation of recommendations made by SRP to the Central Drugs Standard Control Organization (CDSCO).

In view of the strong causal relationship and published literature, the SRP members recommended to include the adverse drug reactions (ADRs) to the corresponding prescriber information changes of the following medicinal products:

- Cefotaxime – Angioedema
- Ofloxacin – Stevens-Johnson Syndrome
- Tranexamic Acid – Sizure/Convulsion
- Quetiapine – Urinary Incontinence
- Sulfasalazine – Drug Rash with Eosinophilia and Systemic Symptoms (DRESS)

SALIENT FEATURES

- SRP recommended that each member of the panel may henceforth act as a primary reviewer for one of the Drug-ADR combinations and present it during the meeting
- PvPI to share all necessary information at least a month ahead of the meeting
- Develop a format/template for presentation to maintain uniformity
- Recommendations of five drugs prescribing information change in view of the strong causal relationship and published literature
- Develop a protocol/SOP for identifying Drug-ADR combination that required review by the SRP

Indian Pharma Expo 2018

A three-day “Pharma and Healthcare Conference” was held at Hall 12 A, Pragati Maidan, New Delhi, from August 7-9, 2018 (check date). The conference also known as Indian Pharma Expo was organised by CIMS Medica, India. Senior Pharmacovigilance Associate, Dr Vijit Agrawal, represented NCC-PvPI, IPC at the expo, apprising the participants of the essence of PV

- PvPI’s role in safeguarding health for all
- Liaising between PvPI and various National Health Programmes (NHPs)
- Importance of reporting ADRs – how and whom to report ADRs
- Acts and rules for Marketing Authorization Holders (MAHs) on ADR-reporting

The programme was attended by healthcare professionals, MAHs, academia and students of pharmacy colleges across the country.
OPPI Annual Summit 2018

Organization of Pharmaceutical Producers of India (OPPI) Annual Summit 2018” was held at Durbar Hall, Taj Diplomatic Enclave, New Delhi, on July 13, 2018. The programme was attended by drug manufacturers, policy-makers, healthcare professionals and other eminent persons in the field of Drugs and Pharmaceuticals. Union Commerce and Industry minister Mr Suresh Prabhu, who was the chief guest for the day-long summit, emphasised the value of innovation and economic growth in the pharmaceutical sector. Minister of state for Health and Family Welfare, Mrs Anupriya Patel, reiterated the Union government’s commitment to promoting access of quality medicines through its flagship programme “Ayushman Bharat”.

OPPI Director General T K Kanchana and its president A Vaideesh stressed the need for use of cutting-edge technology such as drones for delivery of medicines to the remote and inaccessible areas of the country. Dr R S Ray, Scientific Assistant and Mr Abhinav Paliwal, Pharmacopoeia Editor, represented IPC at the summit.

PV partners’ monthly meet

Pharmacovigilance partners’ monthly meeting was held at Deputy Commissioner Room, UIP Division in Nirman Bhawan, New Delhi on July 25, 2018. Dr R S Ray, Scientific Assistant, NCC-PvPI and Mr Pankaj Bhatt, Sr Pharmacovigilance Associate, NCC-PvPI represented the IPC. Other partners included Dr M K Aggarwal, DC (UIP) Division, MoH&FW, Dr Deepak Polpakara, AEFI Secretariat, New Delhi, Dr Nidhi Gupta, AEFI Secretariat, New Delhi, Mr Somnath Basu, ADC (I), CDSCO (HQ), New Delhi, Dr Vineet Goyal, WHO-India and Dr Kapil Singh, UNDP, India.

MOOT POINTS

- VAEIMS follow-up and training
- Audio-visual training for all stakeholders with the screening of vaccine-associated anaphylactic shock and adrenaline administration
- Meeting of CDAC and WHO officials for development/update of indigenous PvPI-ADR reporting software
- Follow-up on Institutional Development Plan activities, including plan for Joint Assessment Visit
- Reporting of AEFI cases through notification form by AMCs
- SOP for generation of signals for AEFI data

RECOMMENDATIONS

- Dr Vineet Goyal of WHO-India suggested the upcoming training for AEFI surveillance on VAEIMS software be attended by PvPI officials, too
- AEFI secretariat members proposed a meeting between CDAC and WHO officials for review and comments on development/update of PvPI indigenous software for ADR reporting vis-a-vis AEFI cases
- AEFI partners also suggested a joint internal audit as part of Institutional Development Plan activities at state-level to review the AEFI surveillance system
- Dr Deepak Polpakara of AEFI secretariat stressed that all AMCs be sensitized/directed by PvPI to report AEFI cases through case notification form
- All PV stakeholders, including AEFI secretariat, PvPI and CDSCO, to jointly evaluate vaccines’ signal detection in observance of the SOP as recommended by WHO-NRA team
Technical Committee meet on Kala-azar elimination

The Technical Committee on Kala-azar elimination met at Seminar Hall, NVBDCP, DGHS, Shastri Park in New Delhi on July 6, 2018 to review its status and progress. The participants included Dr Nupur Roy, Additional Director, NVBDCP, Dr Naresh Kumar Gill, Assistant Director, NVBDCP, Dr Shashi Bhushan, Sr Scientific officer, IPC and Mr Pankaj Bhatt, Sr PvA, IPC, NCC-PvPI.

SALIENT FEATURES
- Update on ADR reporting status for Kala-azar from 58 NVBDCP centres discussed
- Data for anti-Kala azar drugs such as Miltefosine and AmBisome shared with Technical Committee members and ADRs related to the drugs discussed in terms of their seriousness, gender, age group and type of reporting
- How to improve ADR reporting for anti-Kala azar drugs: measures such as inclusion of an ADR alert-card, regular follow-up for patients, active watch for possible adverse drug reactions suggested
- Correlation of Indian ADR data with global data in respect of Miltefosine and AmBisome
- Roles and responsibilities to be delineated for all partners

IHPA’s CEP for pharmacists

With a view to imparting training to the clinical pharmacists and other allied healthcare professionals, Indian Hospital Pharmacists’ Association (IHPA) and Sir Ganga Ram hospital, New Delhi, organized a Continuing Education Programme (CEP) for Pharmacists at Sir Ganga Ram hospital in New Delhi on July 21, 2018. The programme was attended by pharmacists, healthcare professionals and clinicians from various hospitals/academic institutions. Representing PvPI at the programme, Sr Scientific Officer, IPC, Dr Shashi Bhushan made a presentation on “Basics of Pharmacovigilance: Mandate and Activities of Pharmacovigilance Programme of India”. The presentation apprised participants of the basics of PV, role of pharmacists in ADR-reporting and tools developed by PvPI for reporting ADRs.
National Deworming Day is observed twice a year – February 10 and August 10. The two days have been designated by the Union government but the state governments customize it as per their own schedule.

This year, too, PV Associates from all AMCs raised awareness at neighbourhood government schools about the possible ADRs following the use of albendazole in the age-group 1-19 years. However, no serious ADRs were reported. Only few incidence of stomach ache and vomiting were reported as ADRs with the Deworming therapy.
PV establishment at Pharma sector

The IPC in collaboration with CDSCO organised 7th regional workshop on “Basics of Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries — A Way Forward” for pharmaceutical industries at Royal Plaza hotel in Gangtok, Sikkim July 13, 2018. The day-long workshop was attended by Mr Vipin Kumar, Sr Pv Associate, NCC-PvPI, IPC, Ms Ritu Jain, Research Associate, NCC-MvPI, IPC, Mr Somnath Basu, ADC (I), CDSCO (HQ), New Delhi, besides representatives from pharmaceutical industries.

ISSUES DEBATED
- Pharmacovigilance: Basics, Methods, Practices and a Brief Overview of PvPI
- Pharmacovigilance: A Legal Obligation under Drugs & Cosmetics Act, 1940 and Rules, 1945, and setting up of a Pharmacovigilance System at Pharmaceutical companies
- Materiovigilance Programme of India (MvPI): An Overview, Role of NHSRC in Medical Device Procurement and MvPI Oversight
- Modules of Pharmacovigilance Guidelines for MAHs in India
- Engagement of MAHs in PvPI: Current Scenario and Way Forward

RECOMMENDATIONS
- Regulatory Pharmacovigilance skills to be enhanced
- Indigenous software be developed by PvPI for ADR reporting & data control
- ADR reporting by MAHs to PvPI be made mandatory as per the CDSCO Gazette Notification
- Participants urged to organize regular trainings on PV system setup procedures
- Training essential for marketing professionals to collect adverse events direct from physicians at hospitals
A day-long CME-cum-Workshop was organized on “Pharmacovigilance: Understanding, Relevance and Challenges” at AMC, Bhagat Phool Singh Government Medical College for Women, Khanpur Kalan at Sonepat in Haryana on August 4, 2018. The CME-cum-Workshop was organized with the objective of strengthening pharmacovigilance system at the AMC. Aimed at enhancing the skills of reporting ADRs in clinical settings, the CME was attended by HCPs, including clinicians, faculty, Pharmacovigilance committee members and postgraduate students. Mr. Amit (PS-PvA) on behalf of PvPI, IPC delved upon the milestones and achievements of Pharmacovigilance Programme of India and the National Health Programmes it collaborated with.

- A participating physician stressed the need for including ADR reporting in Health Management Information System (HMIS).
- Heightened awareness at AMC to report adverse drug reactions via different channels like toll free Helpline, suspected ADR form, mobile application.
- Participants suggested more such training programmes on Pharmacovigilance for other healthcare professionals, including nurses, pharmacists, etc.
10th Skill Development Programme on PV

National Coordinating Centre, Pharmacovigilance Programme of India (PvPI) organised its 10th Skill Development Programme (SDP) at Indian Pharmacopoeia Commission, Ghaziabad from July 2 to July 11, 2018. Aimed at honing the PV skills of healthcare professionals, the 10-day programme was attended by clinicians, students, industry professionals, regulatory officials and academia from Karnataka, Assam, Rajasthan, Tamil Nadu, Uttar Pradesh and Andhra Pradesh. The participants were provided with theoretical and practical knowhow by experts in varied fields. The training also covered a visit to IPC laboratory and a field visit to ADR Monitoring Centre (AMC) at PGIMS, Rohtak.

The training provided an opportunity to the participants to enrol themselves in Pharmacovigilance units of organisations and also to follow Good Pharmacovigilance Practices (GVPs) aimed at ensuring patient safety by risk-optimized drug use. The programme also encourages them to be entrepreneurs in Pharmacovigilance. The certificate of participation was provided to all participants. Adjudged on the basis of performance, top five performers in the training programme may be preferred for recruitment in PvPI.
PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

DETAILS OF THE PARTICIPANTS

<table>
<thead>
<tr>
<th>STATE/UNION TERRITORY</th>
<th>NO. OF PARTICIPANTS</th>
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<tbody>
<tr>
<td>Uttar Pradesh</td>
<td>6</td>
</tr>
<tr>
<td>Tamil Nadu</td>
<td>9</td>
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<tr>
<td>Andhra Pradesh</td>
<td>4</td>
</tr>
<tr>
<td>Rajasthan</td>
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<td>Assam</td>
<td>3</td>
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<td>Karnataka</td>
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PARTICIPANTS’ PROFESSIONAL BACKGROUND

<table>
<thead>
<tr>
<th>Professional Background</th>
<th>No. of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Students</td>
<td>20</td>
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<tr>
<td>Academia</td>
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<tr>
<td>Industry Professionals</td>
<td>2</td>
</tr>
<tr>
<td>Regulators</td>
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Drug Safety Alerts for July-September 2018

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

Suspected Drugs: FLUOXETINE
Indication: Bipolar disorder; Depressive Episode
ADR: Hypoacusis (Hearing Impairment)

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

Approved New Drugs in India

New drugs approved by CDSCO during July-September 2018

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<thead>
<tr>
<th>S. No</th>
<th>DRUG</th>
<th>INDICATION</th>
</tr>
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| 1     | FDC of Ceftolozane (1.0 gm) and Tazobactum (0.5 gm) injection | For the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:  
  • Complicated intra-abdominal infections (cIAI) caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius in combination with metronidazole in ICU setting only.  
  • Complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, and Pseudomonas aeruginosa in ICU setting only. |
| 2     | Vilazodone hydrochloride bulk drug & Vilazodone hydrochloride film coated tablets 20 mg and 40 mg | For the treatment of major depressive disorders in adults |

- Healthcare professionals are urged to closely monitor the safety of these drugs.
- ADRs if any to be reported to PvPI.
### Comparative status of Global Drug Alerts with PvPI Database

<table>
<thead>
<tr>
<th>NAME OF DRUG</th>
<th>REACTIONS</th>
<th>INTERNATIONAL STATUS</th>
<th>INDIA STATUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHLOREHEXIDINE</td>
<td>Allergic reaction like rashes, wheezing or swelling</td>
<td>Product Safety Alerts, HSA, 29 September 2017 (<a href="http://www.hsa.gov.sg/">http://www.hsa.gov.sg/</a>)</td>
<td>Rash-03 ICSRs &amp; Urticaria-01 ICSR reported in PvPI database</td>
</tr>
<tr>
<td>GLIBENCLAMIDE</td>
<td>Palpitation</td>
<td>Comoglio, R. H. SIGNAL Newsletter, Risk Group Signals: Glibenclamide, April 2018</td>
<td>Palpitation-12 ICSRs reported in PvPI database</td>
</tr>
<tr>
<td>TICAGRELOR</td>
<td>Potential risk of pulmonary haemorrhage</td>
<td>Based on the communication from MFDS and KIDS, Republic of Korea, April 2017</td>
<td>Pulmonary haemorrhage-03 ICSRs reported in PvPI database</td>
</tr>
<tr>
<td>DPP-4 INHIBITORS</td>
<td>May cause severe joint pain</td>
<td>Drug Safety Communication, US FDA, August 2015 (<a href="http://www.fda.gov">www.fda.gov</a>)</td>
<td>Joint pain-09 ICSRs reported in PvPI database</td>
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Healthcare professionals are sensitized to carefully monitor the above mentioned alerts, if any event related to these drugs is to be reported to NCC-PvPI.
FIELD ACTIVITY

PV at NRSMC, Kolkata

Nil Ratan Sircar Medical College (NRSMC) and hospital, formerly known as Campbell Medical School, was established at Calcutta in 1864. A 1,890-bed tertiary care teaching hospital, NSMC has an annual intake of 250 undergraduate and 116 postgraduate students. The hospital has been functioning as an Adverse drug reaction Monitoring Centre (AMC) since 2012 with Prof Nina Das, HoD, Pharmacology, as the Coordinator and Mr Anindya Banerjee, Patient Safety-Pharmacovigilace Associate.

ACTIVITIES:
- Sensitizing doctors, nurses and PG students to ADR-monitoring, its importance and how to collect ADR reports
- ADR posters on display at OPDs and IPDs since 2015
- Pharmacovigilance tableau displayed at Dept of Pharmacology, NRSMC, Kolkata on Doctor's Day – July 1, 2017
- Hospital Internship Training on Pharmacovigilance provided from May, 2015 to July, 2018 to B Pharm, M Pharm and BSc Bio-technology students of various colleges
- Annual increase in number of ADRs reported
Established in 1960 as “Medical College Rohtak”, its students were enrolled and taught at Medical College in Patiala until 1963. In 1963, the students were shifted to the parental college at Rohtak. In 1994, the institute was rechristened Pandit Bhagwat Dayal Sharma Medical College, Rohtak, and in 1995 it was upgraded to a Post-Graduate Institute of Medical Sciences (PGIMS). Initially affiliated to Maharishi Dayanand University, Rohtak, PGIMS was put under the aegis of deemed Pandit Bhagwat Dayal Sharma University of Health Sciences, Rohtak in 2008.

Pt B D Sharma PGIMS, Rohtak is a famous institution not only for medical education and research but also for the super-specialized healthcare facilities. In 2011 it was designated as an ADR Monitoring Centre (AMC) in the country under PvPI. Dr M C Gupta, Head of Department, Pharmacology, is the AMC Coordinator, and Dr Savita Verma, Professor, Department of Pharmacology, is the Co-coordinator. Dr Jyoti Sharma and Dr Manjeet Singh Jangra are Sub-Coordinator and Patient Safety PV Associate, respectively.

AMC ACTIVITIES

• Among top 10 AMCs in the country vis-a-vis ADR reporting with an average of 103 ICSRs processed per month
• More than 6,758 quality ICSRs processed since June 2011, with Quality score 0.96
• Conducted 3 CME-cum-Workshops on Pharmacovigilance
• Hosted field visit twice during Skill Development Programme organized by NCC, PvPI, IPC, Ghaziabad
• Regular sensitization programmes conducted with clinicians, PGs, nurses and other HCPs to collect the ADRs from different specialities
• Display of PvPI posters in OPD as well as different wards of hospital
• Embossing PvPI toll free number on OPD cards and in-patient discharge cards
• Distribution of Yellow card (drug reaction alert card) to patients
• Active drug safety monitoring during Deworming programmes at government and private schools and reported significant number of reports from Albendazole
• Coordination with NABH-accredited hospitals of adjoining areas for ADR reporting
• Active screening of patients through research projects in speciality clinics
STAKEHOLDERS’ FEEDBACK

Dr ROHTAS K YADAV
Director
PGIMS, Rohtak

It gives me immense pleasure to place on record the appreciation for the ADR Monitoring Centre at our institution. I am happy that our team is doing a good job in terms of quality reporting of adverse drug reactions. As we all are aware of the fact that drugs are potential poison if not taken as per prescription. Clinical trials tell about the safety profile of the drug molecule but the circumstances are quite different when the drug comes into the market. Hence, the emphasis on monitoring the ongoing drug therapy for any possible side-effect due to its administration. By proper monitoring of drugs we may save our population from a Thalidomide-like disaster. I congratulate Dr M C Gupta and his team for their contribution to patient safety and wish them all the best.

Dr SAURABH CHATTOPADHYAY
Medical Superintendent & Vice-Principal
NRSMCH, Kolkata-700014

Pharmacovigilance is an integral part of evidence-based medicine. The wide range of activities under the guidance of Prof. Nina Das, Head, Dept of Pharmacology, NRSMCH, Kolkata significantly contributes to patient safety by quality observance of pharmacovigilance. ADR reporting, sensitization of doctors, paramedical staff and training of PG, B Pharm and M Pharm students make it a comprehensive centre for Pharmacovigilance activities. My best wishes to the whole team for their endeavour to achieve success in the field of PV.

Dr M C GUPTA
Coordinator, AMC
Senior Professor & Head of Dept, Pharmacology
PGIMS, Rohtak

It has been a wonderful journey contributing to the national health mission, the Pharmacovigilance Programme of India (PvPI). Ensuring the safe outcome of a drug treatment is the most sincere and principal duty of all doctors. ADR monitoring is the most effective step towards ensuring health safety. As coordinator of the AMC at PGIMS, Rohtak I thank all my colleagues in the department and my clinician friends for contributing to this programme and expect their support in the future as well. Our endeavour is to keep the clinicians updated about any concerns regarding the safety of drugs, making it safe for the patient. I exhort all clinicians to follow Good Pharmacovigilance Practices, ensuring the best possible therapeutic outcome for the patients.

Dr ALOK ROY,
Professor & Head of Dept,
Dermatology
NRSMCH, Kolkata

Heartiest congratulations to NCC-PvPI, IPC for their excellent work. Pharmacovigilance at NRSMCH is in full swing under the stewardship of Dr Nina Das, Prof & Head, Dept of Pharmacology, NRSMCH, and Mr. Anindya Banerjee, PS-PvA, NRSMCH, Kolkata as a liaison with our department.

Prof NINA DAS
Head, Dept of Pharmacology,
AMC Coordinator
NRSMCH, Kolkata

PvPI has been performing a commendable task in the field of monitoring Adverse Drug Reactions. It has raised awareness about drug safety among both healthcare professionals and patients/consumers. It helps the day-to-day patient care services in hospitals by providing regularly alert signals about drugs which may have caused an ADR anywhere.

Dr DHRUV CHAUDHARY
Senior Professor & Head, PCCM
PGIMS, Rohtak

Dr M C Gupta has been tirelessly working for making PvPI a success at PGIMS, Rohtak. Many ADRs are reported owing to various factors when the drug is in the market. So their proper monitoring is an essential part of the disease management. If a drug is causing any side-effect it may lead to prolonged hospital stay for the patient and unnecessarily burden them financially. Every healthcare professional must, therefore, report ADRs, ensuring provision of quality healthcare across the spectrum.

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Heartiest congratulations to NCC-PvPI, IPC for being designated as a WHO-Collaborating Centre. PGIMS, Rohtak as an AMC under the leadership of Dr M C Gupta and his team has grown by leaps and bounds and qualifies as one of the top-ranking AMCs in India. Drug monitoring is absolutely important in terms of a patient’s health safety. Moreover, it ensures minimize pharmacoeconomic burden on a populous country like India. A drug may behave differently among different ethnicities of a varied population and have enormous side-effects but proper monitoring of these side-effects will definitely help in the improved outcome of the treatment.

Dr BISWANATH BASU
Associate Professor & In-Charge, Paediatric Nephrology
NRSMCH, Kolkata

The practice of monitoring drug safety is always neglected in countries like India. Pharmacovigilance not only helps us to know the pros and cons of an effective drug but also allow us to use it in a more rational way.

Dr PRANTAR CHAKRABORTI
Prof & Head of Dept, Haematology
NRSMCH, Kolkata

Pharmacovigilance activity at NRSMCH, Kolkata has added a new dimension to monitoring the effect of drugs prescribed to patients with haematological disorders. The continuous training for both teachers and students helps in promoting rational drug use as also understanding the dynamics of new drugs used in oncology.

Dr SWAMI SARN
Consultant MO, Nodal DRTB, PGIMS, Rohtak

I felicitate PvPI for initiating pilot projects in drug monitoring at our institution. For patients of pre-XDR/TDR, a new drug regimen, Tablet Bedaquiline along with optimized background regimen, has been started. A team of experts, including pharmacologists, cardiologists, ENT specialists, ophthalmologists and physicians, has helped make the launch of Bedaquiline an unqualified success. I congratulate the AMC team led by Dr M C Gupta for their contribution to PvPI and National Safety Database. I wish them luck.

Dr NILANJAN SENGUPTA
Prof & Head of Dept, Endocrinology
NRSMCH, Kolkata

The continued Pharmacovigilance activity at NRSMCH, Kolkata is praiseworthy. It acts as an audit regarding drug prescribing norms and also goes a long way in ensuring rational drug use.

Dr O P KALRA
Vice-Chancellor
UHS, Rohtak

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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Let us join hands with PvPI to ensure patient safety

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