PVPI Achievements 2020

- HCQ Focussed Pharmacovigilance
- Drug Safety Alerts
- Regulatory Actions Recommended
- Skill Development Programme
- New ADR Monitoring Centres Enrolled

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National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI)
Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare, Government of India
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Dear Readers,

I am glad to take this opportunity to release the Newsletter Volume 10, Issue 33 of the Pharmacovigilance Programme of India (PvPI) for the index period from October 2020 to December 2020.

It is noteworthy to mention that during this index period, Shri Rajesh Bhushan, IAS, Secretary (HFW), Government of India has requested the Chief Secretaries/Administrators of all States/Union Territories to strengthen the implementation of Pharmacovigilance system in the country.

Amongst the highlights of the events, PvPI conducted 17th Signal Review Panel meeting to identify the Signal/Prescribing Information Leaflet changes/Drug Safety Alerts to be recommended to CDSCO, 15th Skill Development Programme aimed to develop the skilled human resource in the area of Pharmacovigilance. This issue of the Newsletter also highlights the achievements of PvPI in the calendar year 2020.

The stakeholders’ feedback received from time to time across the Country, which reminds us to assess our strengths & weaknesses, motivates for taking the new initiatives in the interest of patient safety.

I acknowledge the efforts of all the PvPI experts, who have contributed to the strengthening of PvPI. Their in-depth subject knowledge and insights into the Pharmacovigilance system in smoothly achieving the objectives of PvPI. Their timely support encouraged the PvPI staff towards achieving the mission of PvPI. The overall administrative and financial support of the Ministry of Health and Family Welfare, Government of India is also duly acknowledged.

I am sure that with the continuous dedicated efforts of the PvPI team, Subject Experts and the support of the Ministry of Health and Family Welfare, Government of India, PvPI will keep growing and become the Centre of Excellence in future.

I congratulate the entire PvPI team at the National Coordination Centre-Pharmacovigilance Programme of India and ADR Monitoring Centres across the country for their ceaseless efforts and cooperation in establishing and developing a robust Pharmacovigilance system in India.

**Dr. Jai Prakash**
Sr. Principal Scientific Officer & Officer-in-Charge, PvPI, Secretary-cum-Scientific Director (In-Charge) (Till November 2020)
Indian Pharmacopoeia Commission
(Ministry of Health & Family Welfare, Govt. of India)
Ghaziabad-201002
Cover Story

PvPI Achievements 2020

5th #MedSafetyWeek
PvPI had participated in “5th #MedSafetyWeek” organised by WHO-UMC, Sweden from 2nd to 8th November 2020.

Request sent by MoHFW, Govt of India
Shri Rajesh Bhushan, IAS, Secretary (HFW) requested the Chief Secretaries/Administrators of all States/UTs to further improve the implementation of PV system in the country.

Completeness Score of ICSRs
The average annual completeness score reflecting the quality of ICSRs generated under PvPI accounted for about 0.73 out of 1

New AMCs
Enrolled 41 new AMCs. Total number of AMCs increased from 270 to 311 across the country.

Focussed Pharmacovigilance
PvPI devised new Suspected ADR Reporting Form for COVID-19 drugs and shared the safety data with the use of HCQ to MoHFW, ICMR & DCG(I).

ICSRs
57731 ICSRs received from AMCs, MAHs/Pharmaceutical Industries, Patients/Consumers etc.

Drug Safety Alerts
PvPI had issued 15 Drug Safety Alerts.

6th Asia Pacific Pharmacovigilance Training Course
Organized from 24th Feb 2020 to 6th Mar, 2020 at Ghaziabad. Total 14 participants from six countries- Bangladesh, India, Nigeria, Philippines, Yemen and Zimbabwe attended.

Focussed Pharmacovigilance
PvPI devised new Suspected ADR Reporting Form for COVID-19 drugs and shared the safety data with the use of HCQ to MoHFW, ICMR & DCG(I).

Regulatory Actions
Based on the PvPI recommendations, CDSCO issued 2 orders to State/UT Drugs Regulators.

Skill Development Programmes
NCC-PvPI organized one Skill Development Programme in which 183 participants were trained.

Interactive Meeting with MAHs
To improve the quality of ICSRs, PvPI conducted 12 online-interactive sessions with representatives of MAHs/Pharmaceutical Industries.

Awareness-cum-Training Programmes
PvPI had regularly conducted 198 training/awareness programmes in which 10926 participants were trained.
Overview of reported ICSRs

PvPI database revealed that 52.1% ADRs occurred in male patients and 44.3% in the female patients. No information about the gender of the patients was provided in 3.6% ICSRs. During the index period, 28.10% ICSRs were fulfilling the seriousness criteria as defined by WHO-UMC.

The maximum number of ICSRs were received from the 18 to 44 year age group (36.6 %) whereas minimum number of ICSRs were received from 0-27 days age group (0.2 %). No information about the age of the patients was provided in 9.1% ICSRs. NCC-PvPI received ICSRs from various stakeholders and spontaneous reports from physicians (45.8%) accounted for major source of reports received, followed by Consumers/Non-Healthcare Professionals (31.2%). The highest reported System Organ Class (SOC) was blood and lymphatic system disorders (21.8%) followed by cardiac disorder. The highest reported Anatomical Therapeutic Chemical (ATC) class was the “anti-infective for systemic use” class (26.9%, ATC: J) followed by anti-neoplastic and immunomodulating agents (26.4 %, ATC: L).
Cover Story

Patient age

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 27 days</td>
<td>0.2%</td>
</tr>
<tr>
<td>28 days to 23 months</td>
<td>1.5%</td>
</tr>
<tr>
<td>2 - 11 years</td>
<td>3.2%</td>
</tr>
<tr>
<td>12 - 17 years</td>
<td>2.6%</td>
</tr>
<tr>
<td>18 - 44 years</td>
<td>21.8%</td>
</tr>
<tr>
<td>45 - 64 years</td>
<td>21.1%</td>
</tr>
<tr>
<td>65 - 74 years</td>
<td>18.3%</td>
</tr>
<tr>
<td>≥ 75 years</td>
<td>10.8%</td>
</tr>
<tr>
<td>Unknown</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

Reaction (MedDRA)

<table>
<thead>
<tr>
<th>SOC Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system</td>
<td>26.9%</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>26.4%</td>
</tr>
<tr>
<td>Congenital, familial and congenital</td>
<td>17.2%</td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td>13.5%</td>
</tr>
<tr>
<td>Endocrine disorders</td>
<td>13.5%</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>10.3%</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>12.8%</td>
</tr>
<tr>
<td>General disorders and congenital</td>
<td>9.4%</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>5.7%</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

Drug (WHODrug)

<table>
<thead>
<tr>
<th>ATC Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>J Antimicrobials</td>
<td>26.9%</td>
</tr>
<tr>
<td>L Antineoplastics</td>
<td>26.4%</td>
</tr>
<tr>
<td>A Alimentary tract miscellaneous</td>
<td>17.2%</td>
</tr>
<tr>
<td>D Dermatologicals</td>
<td>13.5%</td>
</tr>
<tr>
<td>S Senses organs</td>
<td>12.8%</td>
</tr>
<tr>
<td>C Cardiovascular</td>
<td>12.0%</td>
</tr>
<tr>
<td>N Nervous system</td>
<td>10.2%</td>
</tr>
<tr>
<td>B Blood and lymphatic</td>
<td>9.4%</td>
</tr>
<tr>
<td>R Respiratory system</td>
<td>5.7%</td>
</tr>
<tr>
<td>G Genito urinary</td>
<td>5.4%</td>
</tr>
</tbody>
</table>

Reporter qualification

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>45.8%</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>12.0%</td>
</tr>
<tr>
<td>Other Health Professional</td>
<td>18.8%</td>
</tr>
<tr>
<td>Lawyer</td>
<td>0.0%</td>
</tr>
<tr>
<td>Consumer/Non Health Professional</td>
<td>31.2%</td>
</tr>
</tbody>
</table>
Quality Score of reported ICSRs

The VigiGrade™ Completeness score is a WHO grading system based on the information provided on ICSRs. The following graph represents average completeness score of ICSRs submitted from India (Blue line) as compared to submitted ICSRs by all the other countries (Green line). The average annual completeness score accounted for about 0.73 out of 1, which is much higher than the rest of the countries.

All stakeholders are requested to maintain as well as further improve the quality of ICSRs to be submitted by them in future to PvPI. In order to improve the quality of ICSRs reported by the MAHs/Pharmaceutical Industries, PvPI conducted online-interactive sessions with their representatives regularly across the country.

Focussed Pharmacovigilance of Drugs used in the Management of COVID-19

NCC-PvPI took lead in the pharmacovigilance of COVID-19 drugs and initiated a concerted effort by sensitizing all AMCs Coordinators and PvAs to report ICSRs related to drugs used in COVID-19 pandemic. In this regard, a special Suspected Adverse Drug Reaction Reporting form for drugs used in the Prophylaxis/Treatment of COVID-19 was designed.

Based on the analysis of adverse events from HCQ, the National Taskforce for COVID-19 constituted by Indian Council of Medical Research (ICMR), while revising their Advisory on the use of HCQ for the prophylaxis/treatment of COVID-19 considered the PvPI data.
Brief overview of reported ICSRs of HCQ used as prophylaxis/treatment of COVID-19 disease is as follows:

**HCQ-Month-wise ICSRs received in 2020**

<table>
<thead>
<tr>
<th>Month</th>
<th>ICSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>57</td>
</tr>
<tr>
<td>May</td>
<td>341</td>
</tr>
<tr>
<td>June</td>
<td>139</td>
</tr>
<tr>
<td>July</td>
<td>216</td>
</tr>
<tr>
<td>August</td>
<td>157</td>
</tr>
<tr>
<td>September</td>
<td>108</td>
</tr>
<tr>
<td>October</td>
<td>90</td>
</tr>
<tr>
<td>November</td>
<td>45</td>
</tr>
<tr>
<td>December</td>
<td>46</td>
</tr>
</tbody>
</table>

**Serious vs Non Serious ICSRs**

- Serious: 95.50%
- Non-Serious: 4.50%

**Gender-wise distribution of HCQ related ICSRs**

<table>
<thead>
<tr>
<th>Gender</th>
<th>ICSRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>583</td>
</tr>
<tr>
<td>Female</td>
<td>614</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
</tbody>
</table>
Letter issued by the Secretary (HFW) to all States/UTs for effective implementation of PV system in India

Shri Rajesh Bhushan, IAS, Secretary (HFW), Government of India has requested the Chief Secretaries/Administrators of all States/UTs to further improve the implementation of PV system in the Country. He requested Chief Secretaries/Administrators to direct all the hospitals/medical colleges under their jurisdiction to regularly and promptly report Adverse Drug Reactions (ADRs) to NCC-PvPI or nearest AMC in the larger interest of patient safety.

Celebration of 5th #MedSafetyWeek 2020 in India

The Uppsala Monitoring Centre (UMC), Sweden had organized the 5th #MedSafetyWeek from 2nd to 8th November 2020.

India was one of the 74 Countries, who participated in this campaign. During this campaign, PvPI represented India and used its social media platforms – Twitter, Facebook and LinkedIn to make Healthcare Professionals (HCPs) and common public aware about ADR reporting and its importance in public health. The animations and media developed by UMC in English & Hindi languages were used during the #MedSafetyWeek to spread awareness. During this event, PvPI successfully managed to engage around 50,000 people (including HCPs) across social media platforms through 66 social media posts which included animations and other PvPI communication tools.

On successful completion of the campaign, UMC has appreciated and congratulated PvPI for all the activities carried out in “#MedSafetyWeek”.

6th Quality Review Panel Meeting

PvPI has organized a virtual meeting of “6th Quality Review Panel (QRP)” under the Chairmanship of Dr. Y.K. Gupta, National Scientific Advisor, PvPI on 6th October, 2020. The QRP reviewed the action taken on the minutes of the previous meeting. During the meeting following points were discussed:

- Finalization of Suspected Adverse Drug Reactions Reporting Form (Version- 1.4)
- Quality Manual of PvPI- Review and Approval
- SOPs – Review and Approval
- Discussion on strengthening of QMS in PvPI

17th Signal Review Panel (SRP) Meeting

PvPI has virtually organised 17th SRP meeting under the Chairmanship of Dr. Y.K. Gupta and Co-Chairmanship of Dr. Urmila Thatte on 3rd November, 2020 and recommended as under:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Suspected Drugs</th>
<th>Adverse Drug Reactions</th>
<th>SRP Recommendations to PvPI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Clarithromycin</td>
<td>Burning Sensation</td>
<td>Drug Safety Alert</td>
</tr>
<tr>
<td>2.</td>
<td>Cefpodoxime</td>
<td>DRESS Syndrome</td>
<td>Drug Safety Alert</td>
</tr>
</tbody>
</table>

Training on “Data Entry in VigiFlow” for National AIDS Control Organization

PvPI has organized a virtual training on “Data Entry in VigiFlow” for the National AIDS Control Organization (NACO) Centres enrolled under PvPI on 24th November, 2020. The performance of 20 NACO centres was discussed and the need to enhance the quality and quantity of reporting ADRs from these centres was expressed. Dr. Vijit Agrawal, Sr. PV Associate made a presentation on “How to login & Data entry in the New VigiFlow”. A hands-on session was arranged for the participants to enter the ADR data of Anti-HIV drugs in to VigiFlow.

PvPI recommendations in International Media

PvPI had sent the recommendations of 16th Signal Review Panel meeting to CDSCO for further appropriate regulatory actions, which were published in WHO-Pharmaceuticals Newsletter No. 5, 2020. For more information, please refer link: https://apps.who.int/iris/bitstream/handle/10665/336439/9789240014534-eng.pdf?sequence=1&isAllowed=y
PvPI in Print Media

In order to spread the awareness and strengthening of reporting Individual Case Safety Reports (ICSRs) to PvPI, two press communiqué in public interest were published in newspapers on October 11, 2020, one each in Hindi & English language in Hindustan and Hindustan Times respectively.

6th CTP-cum-5th RTC Coordinators meet

PvPI has organized a virtual “6th Core Training Panel-cum-5th Regional Training Center (RTC) Coordinators meeting” under the Chairmanship of Dr. Neelima Kshirsagar on 11th December 2020 at IPC. The CTP members appreciated the progress made by PvPI. Dr. Jai Prakash, Member Secretary, CTP made a presentation on training activities conducted by RTC during this year (up to 11th December 2020).

The recommendations of CTP members were as follows:

i. New RTCs will be identified to reduce the workload on existing RTCs across the country.

ii. PvPI, IPC will write a letter to DCG(I) for seeking the involvement of PvPI for the effective monitoring of Adverse Events Following Immunization of COVID-19 Vaccines at Regional Training Centres and Adverse Drug Reaction Monitoring Centres across the country.
National webinar organized by AMCs of PvPI

Siddhartha Institute of Pharmacy, Dehradun in collaboration with Dr. Yashwant Singh Parmar, Government Medical College, Sirmaur, Himachal Pradesh have organized a webinar on “Sensitization Programme for Pharmacovigilance and reporting of ADRs” on 15th December 2020. Dr. Shashi Bhushan, Sr. Scientific Officer, IPC delivered a presentation on “Pharmacovigilance & Current Updates on PvPI” in this webinar.
14th Regional Workshop for MAHs

NCC-PvPI, IPC has organized a virtual 14th regional workshop on “Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward” for the Marketing Authorization Holders (MAHs)/Pharmaceutical industries on 9th October 2020. A total of 48 participants had participated in this workshop.

The objective of this workshop was to address the basic concepts of PV & how the PV system can be effectively implemented at MAHs/Pharmaceutical Industries and also focussed on the submission of ICSRs in E2B XML format by MAHs/Pharmaceutical Industries to PvPI.

The Technical session of this workshop covered the following topics:

i. An Overview of Pharmacovigilance Programme of India
ii. Establishment of PV system & Good Pharmacovigilance Practices (GVP)
iii. Pharmacovigilance regulations in Drugs & Cosmetics Rules 1945: New Drugs & Clinical Trials Rules, 2019 & Schedule M

15th Skill Development Programme

NCC-PvPI has organized a virtual 15th Skill Development Programme on Pharmacovigilance of Medical Products from 9th–13th November 2020 at IPC, Ghaziabad. The aim of this Skill Development Programme was to develop the skilled human resource in the area of Pharmacovigilance across the country.

A total of 183 participants having diverse background including Pharma Industries Professionals, Physicians, Academicians, Coordinators & Pharmacovigilance Associates of ADR Monitoring Centres, Research Scholars, students (Pharmacy and Medical) across the country, participated in this 5 days training programme.

International webinar organized by MKCG MCH, Odisha

Dr. Y. Roja Ramani, MKCG MCH Berhampur, Odisha organized an International webinar on “PV Regulations across the world: Similarities and Differences” on 6th Nov 2020. A total of 738 participants (528 from India and 210 from other countries) have participated in this webinar. The technical session covered the following topics:

i. Role of Healthcare Professionals in Pharmacovigilance
ii. Signal management in US, EU and Japan
iii. Causality assessment methods
iv. Impact of Pharmacovigilance in pharmaceutical labeling,
v. Regulations in Germany, Brazil, Argentina, Paraguay, Uruguay, Mexico and all over the Latin America
Training and Education

Interactive meet with MAHs on ICSRs quality

To improve the quality of ICSRs, PvPI conducted regular interactive webinars with representatives of MAHs/Pharmaceutical Industries. During the index period from October to December 2020, PvPI has conducted following three meetings:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Date</th>
<th>MAHs/ Pharmaceutical Industries</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>8th December 2020</td>
<td>Bharat Serum &amp; Vaccines Limited</td>
</tr>
<tr>
<td>2.</td>
<td>5th November 2020</td>
<td>BMS India Pvt. Ltd</td>
</tr>
<tr>
<td>3.</td>
<td>28th October 2020</td>
<td>Boehringer Ingelheim</td>
</tr>
</tbody>
</table>

During these interactive meet, PvPI officials presented the summary of report on quality of ICSRs received from the above MAHs/Pharmaceutical Industries. The presentation has covered the following:

- Completeness scores of ICSRs
- Lacking information in reported ICSRs
- Weightage for each field of ICSR and its impact on the overall quality score
- Under-reporting of ICSRs to PvPI

After interactive meet, recommendations to the above MAHs/Pharmaceutical Industries were:

- Mandatory fields must be provided to validate the ICSR
- AE/ADR should be coded appropriately
- Information regarding Start & Stop date of suspected drug along with its indication, time to onset and outcome of AE/ADR etc.
- Case narrative must cover all the required information
- Communication regarding generated queries after review of ICSR must be responded by above MAHs/Pharmaceutical Industries within time frames to expedite the case processing.
- Causality Assessment should be made available in reported ICSRs, preferably as per WHO-UMC scale.
- ICSRs in E2B, XML format should be highlighted separately for serious and non-serious AEs/ADRs.
- To increase the reporting of ICSRs by the above MAHs/Pharmaceutical Industries to PvPI, it was recommended to sensitize/train their Marketing Representatives across the country.
Materiovigilance Programme of India

Medical Device Adverse Events Reports

During index period, National Coordination Centre-Materiovigilance Programme of India (NCC-MvPI) received 366 Medical Device Adverse Events (MDAEs) from MAHs, Medical Device Adverse Events Monitoring Centres (MDMCs) and Adverse Drug Reactions Monitoring Centres (AMCs) as shown below:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Month</th>
<th>No. of MDAEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>October, 2020</td>
<td>146</td>
</tr>
<tr>
<td>2.</td>
<td>November, 2020</td>
<td>86</td>
</tr>
<tr>
<td>3.</td>
<td>December, 2020</td>
<td>134</td>
</tr>
</tbody>
</table>

Brain storming session on Causality Assessment of Medical Devices

MvPI in collaboration with Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh organized a virtual Brain Storming Session on “Causality Assessment of Medical devices” on 16th December, 2020. Coordinators, Deputy Coordinators and Research Associates of 52 MDMCs participated in this webinar across the country. Technical session of this webinar covered the following topics:

i. Causality assessment of medical devices: Gray areas and challenges.
ii. Hands-on session on case studies associated with Medical Devices.
**Participation of Medical Device Manufacturers in MvPI**

MvPI in collaboration of Indian Medical Device Industry (AIMED) organized a virtual webinar on “Participation of Medical Device Manufacturers in MvPI” on 4th December 2020. The objective of this webinar was the sensitization of Medical Device Manufacturers for the compliance of Medical Device Adverse Event Reporting as per Medical Device Rules (MDR), 2017.

**Training Programme on “Role of Biomedical Engineers in Assessment of MDAEs”**

MvPI in collaboration with Andhra Pradesh MedTech Zone (AMTZ), Vishakhapatnam organized a virtual training programme on “Role of Biomedical Engineers in Assessment of Medical Devices Adverse Events” on 4, 5, 11, 12, 18, 19, 23 & 24 December 2020. Biomedical, Clinical and Service Engineers of different hospitals participated and were sensitized about the basics of Materiovigilance, Medical Device Adverse Event Reporting, Post-Market Surveillance, Risk Minimization and Risk Management and Causality Assessment of Medical Devices.

**Regulatory Updates on Medical Device**

MvPI has sensitized the HCPs & stakeholders by circulating the Order issued by Drugs Controller General (India) regarding regulation of Blood Glucose Monitors, Blood Pressure Monitors, Nebulizers and Thermometers as Drugs on 28th December 2020. For more information, please refer link: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=Njc5Mg==
New Drugs approved in India

The following New drugs were approved by CDSCO from October - December 2020

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Drugs</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Netarsudil mesylate bulk and Netarsudil ophthalmic solution 0.02% w/v</td>
<td>For the reduction of elevated intracocular pressure in patients with open angle glaucoma or ocular hypertension.</td>
</tr>
<tr>
<td>2.</td>
<td>Risdiplam powder for oral solution 60mg</td>
<td>For the treatment of Spinal Muscular Atrophy (SMA) in patients 2 months of age and older</td>
</tr>
<tr>
<td>3.</td>
<td>FDC of Azelnidipine 8mg and Telmisartan 40mg tablet</td>
<td>For the treatment of Stage-II hypertension</td>
</tr>
</tbody>
</table>

Healthcare Professionals are urged to closely monitor the safety of the above drugs

ADR(s) (if any) should be reported to PvPI


Drug Safety Alerts - October to December 2020

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Issued Date</th>
<th>Suspected Drugs</th>
<th>Indication</th>
<th>ADRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>30th December, 2020</td>
<td>Beta-Blockers (Atenolol, Bisoprolol, Metoprolol)</td>
<td>Indicated in the treatment of hypertension, angina pectoris, cardiac arrhythmias, Congestive Heart Failure (CHF)</td>
<td>Lichen Planus</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td>Omeprazole</td>
<td>Anti-ulcer, short term treatment of duodenal ulcer, gastric ulcer, reflux oesophagitis, management of Zollinger Ellison Syndrome</td>
<td>Dysuria</td>
</tr>
<tr>
<td>3.</td>
<td>4th November, 2020</td>
<td>Clarithromycin</td>
<td>For the treatment of mild to moderately severe infections like acute exacerbation of chronic bronchitis, community acquired pneumonia including infections due to Chlamydia, Mycoplasma spiegocelia acute streptococcal pharyngitis, skin and soft tissue infections.</td>
<td>Acute Generalised Exanthematous Pustulosis (AGEP)</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td>Tamsulosin + Deflazacort</td>
<td>For the treatment of sign &amp; symptoms of benign prostate hyperplasia. For Asthma, Rheumatoid Arthritis when Glucocorticosteroid therapy is warranted.</td>
<td>Ear pain</td>
</tr>
<tr>
<td>5.</td>
<td>5th October, 2020</td>
<td>Clindamycin</td>
<td>Antibiotic indicated in the treatment of gram +ve organism pathogens, staphylococcus &amp; streptococci, pneumococci.</td>
<td>Symmetrical Drug Related Intertiginous and Flexural Exanthema (SDRIFE)</td>
</tr>
</tbody>
</table>

Healthcare Professionals (HCPs), Patients/Consumers are advised to closely monitor the above mentioned suspected ADRs associated with the use of above drugs. If such reactions are encountered, please report to the NCC-PvPI, IPC by filling up Suspected Adverse Drug Reactions Reporting Form for HCPs/ Medicine Side Effect Reporting Form for the consumers (download from http://ipc.gov.in), through Android Mobile App and PvPI Helpline No. 1800-180-3024 (Toll free)

Drug Safety Alerts: PvPI vs other Countries

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>ADRs</th>
<th>No. of ICSRs in Global database</th>
<th>No. of ICSRs in PvPI database</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluorouracil</td>
<td>Bradycardia</td>
<td>144</td>
<td>20</td>
<td><a href="https://apps.who.int/iris/bitstream/handle/10665/336439/9789240014534">https://apps.who.int/iris/bitstream/handle/10665/336439/9789240014534</a> eng.pdf?sequence=1&amp;isAllowed=y</td>
</tr>
<tr>
<td>Hydroxychloroquine</td>
<td>Prolonged QT</td>
<td>1017</td>
<td>27</td>
<td>Revision of Precautions,MHLW/PMDA, 8 September2020 (<a href="http://www.pmda.go.jp/english/">www.pmda.go.jp/english/</a>)</td>
</tr>
<tr>
<td>Asparaginase</td>
<td>Sepsis</td>
<td>191</td>
<td>02</td>
<td>Based on the communication from MFDS and KIDS, Republic of Korea, November 2020</td>
</tr>
</tbody>
</table>
Government Medical College (GMC), Srinagar, Jammu & Kashmir

GMC, Srinagar was enrolled as an ADR Monitoring Centre under Pharmacovigilance Programme of India in year 2014. The various Pharmacovigilance activities were carried out by Dr. Zubair Ashai, Coordinator, Dr. Muzaffer Ahmad Pukhta, Deputy Coordinator and Mr. Urfan Nabi, Pharmacovigilance Associate as given below:

- Incorporated ADR reporting form in IPD case file of all associated hospitals, PvPI Toll free No. and Pharmacovigilance Associates number on OPD tickets of all associated hospitals.
- Displayed PvPI posters in vernacular language in all IPD and OPD set-ups.
- Incorporated Pharmacovigilance topics in curriculum of D. Pharm and Medical Assistants framed by J&K Medical faculty.
- Incorporated a chapter “Pharmacovigilance and ICSRs reporting” in clinical case study projects for 2nd year MBBS students.
- Coordinated with newly established medical colleges like GMC, Baramulla and GMC, Anantnag for setting up Pharmacovigilance centres.

Achievements:

GMC, Srinagar was recognized as top performing AMC across India in 2019 and received appreciation letter for same from Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India.
Government Medical College & Hospital (GMCH), Kanyakumari, Tamil Nadu

GMCH, Kanyakumari is a tertiary level health care institute and was enrolled as an AMC in 2016 under PvPI. The various Pharmacovigilance activities were carried out under the supervision of Prof. Dr. T. Ashok Kumar, MD (Coordinator), Dr. Sam Anbu Sahayam, MD (Deputy Coordinator) and Dr. Magleen Kingsly, MDS (PV Associate) at GMCH, Kanyakumari.

Dr. B. Thiruvasagamani
MS, Mch (Uro)
Dean, GMC-Kanyakumari

Kanyakumari Government Medical College and Hospital is an esteemed institution in South Tamil Nadu providing health care services to the nearby population. In addition to our other services it is happy to work with the Pharmacovigilance Programme of India through our AMC as it enhances patient safety. On behalf of our management, I wish the entire PvPI a great success.

Dr. T. Ashok Kumar
MD, Professor & Head (Pharmacology)
Coordinator, GMC- Kanyakumari

Knowledge about Pharmacovigilance is to be made mandatory in the current situation. Adverse Drug Reactions are highly noted not only because of individual drugs but also due to genetic variations among the population which can be identified by the causality assessment and the risk can be minimized. PvPI plays an important role in gathering the ADR and by assessing the cause promotes drug safety throughout the nation. Best wishes to the PvPI team to reach their heights.

Dr. Sam Anbu Sahayam
MD, Asst, Professor of Pharmacology
Deputy Co-ordinator, GMC-Kanyakumari

Medicines are chemical or biological products and are more powerful. As the quote says “All things are poison and nothing is without poison” while expecting a cure there may be some untoward reactions too, which should be identified and if reported it brings awareness among individuals. The above role is well played by PvPI by providing knowledge to HCP’s and also minimizing ADR’s. On behalf of all staff’s of the Department of Pharmacology, GMC Kanyakumari, I appreciate the diligent effort of PvPI.
Prof. (Dr.) Samia Rashid  
Principal/Dean  
GMC, Srinagar, J&K  

I feel privileged and honoured to head one of the prestigious medical institute of Srinagar, Jammu and Kashmir. Establishment of ADR Monitoring centre under Pharmacovigilance Programme of India in the Department of Pharmacology is an honour to Government Medical College, Srinagar and its associated hospitals.

It makes a new beginning in improving patient care in general and drug safety in particular and I appreciate the team of ADR Monitoring Centre, Department of Pharmacology for their active participation and contribution to patient safety.

Prof. (Dr.) Samina Farhat  
Head, Department of Pharmacology  
GMC, Srinagar, J&K  

Pharmacovigilance being an important pillar of modern Pharmacology. Department of Pharmacology, Government Medical College, Srinagar working as ADR Monitoring Centre under Pharmacovigilance Programme of India has contributed more than 2500 Individual case safety reports with good completeness score. AMC at GMC, Srinagar is persistently promoting PvPI activities in all possible directions to strengthen the safety monitoring of medicines.

Dr. Zubair Ashai  
Assistant Professor (Pharmacology) & Coordinator AMC  
GMC, Srinagar, J&K  

I am happy and privileged for being a part of Pharmacovigilance Programme of India (PvPI) with its robust surveillance system to monitor Adverse Drug Reactions and generation of safety signals from time to time. AMC at Government Medical College, Srinagar, J&K is actively contributing for the safety of patients. In recent times after the rollout of COVID-19 vaccine our AMC has carried out active Pharmacovigilance for monitoring Adverse Events Following Immunization in which more than 6000 vaccine recipients were followed actively post vaccination. I am thankful to the healthcare professionals like doctors, nurses and pharmacists for making this Programme a success.

Dr. Muzaffer Ahmad Pukhta  
Associate Professor (Pharmacology) & AMC-Deputy Coordinator  
GMC, Srinagar, J&K  

Since the inception of Pharmacovigilance Programme of India and establishment of Adverse Drug Reaction Monitoring Centre at Government Medical College, Srinagar, we have been following the programme guidelines in letter and spirit for which we received letter of appreciation from Indian Pharmacopoeia Commission. After starting the sensitization programme of healthcare workers at our centre an improvement in reporting of Adverse Drug Reactions has occurred but a lot more needs to be done. Moreover, in our department we are training and sensitizing MBBS students to Pharmacovigilance Programme at undergraduate level. Needless to mention this programme is going to improve the healthcare delivery.
PvPI invites Letter of Intent from Medical Colleges/Hospitals/Corporate Hospitals/Premier Pharmacy Institutions to enrol under PvPI

The Advantages of being an AMC are

1. Health partner for the Nation-wide ADR Reporting System.
3. Scientific Publications/ Case Studies/Project related to PV.
4. Eligible for Financial / Manpower assistance for training/conferences/ Telephone/internet expense.
5. Reduce India’s dependence on western world data for taking regulatory decision on drug safety.

NCC-PvPI, IPC invites letter of intent (LOI) to enroll under PvPI in the interest of Patient safety. The Letter of Intent is freely downloadable from www.ipc.gov.in. Interested stakeholders are requested to send the filled-in LOI and communicate it to NCC-PvPI via email (pvpi.ipc@gov.in) and the hardcopy LOI by post to Secretary-cum-Scientific Director, National Coordination Centre, Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission, Ministry of Health and Family welfare, Govt. of India, Raj Nagar, Sector-23, Ghaziabad-201 002.

For any further details please write to pvpi.ipc@gov.in
दुवाईयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरूकता

फॉर्मॉकोविजीलैस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनता से जागरूक करते हैं कि दुवाईयों (डेल्टा, कैभिड, सीपीए, इंजेक्शन, टॉकी इन्डिया) पर संक्रमण होने पर यह देश में नहीं हो सकता।

“फौर्मॉकोविजीलैस प्रोग्राम का अर्थ है औपचारिक सरकारी सेवा, यदि कोई मरीज या व्यक्ति को दुवाई करने के बाद कोई प्रतिकूल प्रभाव/दुष्प्रभाव जैसे कि लहर संबंधित विपरीत, डायलॉजिक, डी निमिल, इंडलिक, वूकल, स्वास्थ्य (UPP/UPN), सिद्दित या अक्सर दुष्प्रभाव प्रतिकूल होता है तो ऐसे मामले में अपने चिकित्सक से या नजदीकी अस्पताल से जाकर चिकित्सक से पता लिये।

राष्ट्रीय समन्वय केंद्र फॉर्मॉकोविजीलैस प्रोग्राम ऑफ़ इंडिया, में दुवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी प्राप्त करने हेतु विभिन्न सुचारू विभागों के माध्यम से निम्नलिखित नंबर करें:
• प्रोफेसर हेमलाल नंबर 1800-180-3024
  (सांस्कृतिक व विद्युत निर्माण विभाग में संबंधित)
• गोवर्द्धन एप (ADR,PvPI)

कोविड-19 महामारी के दौरान उपयोग होने वाले औषधियों से होने वाले दुष्प्रभाव की जानकारी कहाँ और कैसे दें?

इसकी जानकारी आप फॉर्मॉकोविजीलैस प्रोग्राम ऑफ़ इंडिया के अंतर्गत किसी भी निकटवर्ती एडीआरवी मोन्टरिंग सेंटर पर दे सकते हैं। इस सब्जैक में एक विशेष फॉर्म—suspected adverse drug reaction reporting form (for drugs used in prophylaxis/treatment of COVID-19) भी डिजाइन किया गया है, जो www.ipc.gov.in पर उपलब्ध है।

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacopoeia Programming of India
Ministry of Health & Family Welfare, Govt. of India,
Sector-23, Raj Nagar, Ghaziabad- 201002
Tel.: 0120-2783400, 2783401, 2783392

For any other Information/Suggestions/Query contact:
Officer Incharge
Pharmacovigilance Programme of India
Email: lab.ipc.gov.in, pvpi.ipc.gov.in
Website: www.ipc.gov.in

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