INSIDE THE ISSUE

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Mobile App for instant ADR reporting to PvPI

Healthcare professional can access the tool on mobile devices for reporting of ADRs

One touch access to reporting ADRs in India

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

I am excited to reach you all through this newsletter. I am proud of the valued contributions of some of the readers to PvPI. Please accept my heartiest congratulations!

The pharmacovigilance system in India has evolved over the years through your active cooperation. From establishment of ADR monitoring system, reporting system, usage of data communication and supporting Indian regulators for making decision to protect patient’s safety, the Indian Pharmacovigilance system has it all. My belief as many of the reader’s would share, is that the scope for improvement, active surveillance and innovation in this programme is unprecedented. The system has much more to offer than what we are currently able to tap. I appeal to all healthcare providers to adopt the culture of adverse events reporting and make it an integral part of our process. I wish the stakeholders and the employees of IPC, all the best to succeed in their endeavours to achieve the milestones of patient safety.

I hope you will enjoy reading this newsletter.

(K L Sharma)
Joint Secretary (Regulation)
Ministry of Health & Family Welfare
Government of India
Pharmacovigilante’s (PVls) are the professionals engaged in detection, assessment, understanding and prevention of adverse drug reactions (ADRs). The PVls are the specialized, extra committed and dedicated professionals acting as the main link between patients and other healthcare providers for better outcome in promoting safety of drugs.

The budding PVls must have qualities to set the highest professionals standards and to bring the phase of transformation in Pharmacovigilance (PV). They must know the ethics and good PV practices and should also have the basic knowledge of concepts, methodologies of PV, drug regulation etc. so that they can be competent enough to handling the issues like case narrating and processing, causality assessment, identifying new signals, benefit risk assessment. They should also be able to understand and device strategies for risk management and risk minimization plan. At the same time, they must act in the interests of the patients by applying their unique skills and knowledge in drug therapy, prescription etc which are well enough to prevent adverse effects. PV is also technology driven because information technology (IT) is involved in all most all sections ranging from data entry to signal detection. Therefore, the PVls should be able to apply the IT tools in their practice and also need to be updated with the innovative newer technologies to reach out the messages in rapid and effective way.

PV is one of the profession which requires utmost commitment and dedication patient’s care delivery is involved. Therefore there is no time limit for PVls to work in a day. They cannot stick to the official working hours; they have to be vigilant round the clock because ADRs to the patients cannot be expected to occur only during working hours. PV is the only profession in healthcare to coordinate with maximum number of stakeholders such as pharmaceutical manufacturers, doctors, pharmacists, nurses, patients, regulators, media etc. Therefore, PVls should have command over management and organizational skills. They should also have capacity to guide colleagues and lead the team. Since PV is a global network and the activities cannot be limited to one country; hence they also required to be updated with the national and international drug legislations, PV affairs etc.

The purpose of PV is defeated if the PVls fails to communicate the findings to the stakeholders on timely basis. Therefore, they should be fluent in English and Hindi too. It is justified because around 41% population in India speaks Hindi. If the PVls are posted in ADR monitoring centre of non Hindi speaking states such as Tamil Nadu, Karnataka, Kerala etc they must have capacity to understand local languages to communicate with the patients. The PVls should know media ethics while communicating to the Media. Usually the PVls working in the system are not supposed to...
communicate the findings to the media unless otherwise competent authority is authorized to speak.

Another important quality is they should evoke a practice of sufficient and timely feedback to the stakeholders, besides redefining their expectations in order to take them in to confidence in all PV activities and also to seek their continuous support.

In addition to these, the PVLs should have the following qualities to create the excellence in PV:

a. Creating professional bonding with the stakeholders
b. Maintaining the mutual relationship with the colleagues and similarly placed organizations (both national and international)

c. Providing innovative ideas in PV

The PVLs should be proud of entering in to the noble and wonderful profession of PV and for being a partner of patients care. The dynamic PVLs take this opportunity seriously for their career growth and also enhance their respective organization’s quality PV business.

IMPORTANT EVENTS OF PvPI

MOBILE APP FOR ADRs REPORTING AN EFFECTIVE TOOL: SECRETARY HEALTH

The current needs in pharmacovigilance systems in developed countries have almost reached the target because healthcare professionals and marketing authorization holders are well connected with the system. Whereas, in developing countries like India under reporting of ADR remains serious concern. In India it is becoming a great facilitator for promoting public health. India is cementing its place IT sector through mobile connections to reach every individual in a population of 1.27 billion where approximately 77.58% population is already using mobile phones. Hence it is more rationale to introduce the concept of PvPI to stakeholders via mobile phones. NCC-PvPI in technical collaboration with NSCB Medical College, Jabalpur developed a mobile application for the healthcare professionals to promote easy and instant reporting of ADR. This facility was launched by Shri B P Sharma, Secretary Health, Ministry of Health & Family Welfare, Government of India on 22nd May 2015 at Nirman Bhawan, New Delhi. During the launch Shri Sharma mentioned that this mobile application is unique facility which will bring strong network among healthcare providers for promoting patients safety in the country. He also expressed that this application is poised to meet the expectation of stakeholders specially clinicians by saving the valuable time in reporting ADR. He also reviewed the progress of PvPI and appreciated the employees of PvPI for their efforts.

Padmashree Dr. Jagadish Prasad, DG, DGHS, Shri K L Sharma, Joint Secretary, Shri Navreet Singh Kang, Additional Secretary & DG (CGHS), Dr. G N Singh DCG(I) and other higher officials from the ministry were also present on the occasion.

JOINT SECRETARY–INTERACTED WITH PvPI TEAM TO FOCUS ON THE FUTURE ACTION PLAN

Shri K L Sharma, Joint Secretary (Regulation), MoHFW, Government of India, visited IPC on 4th June 2015 to address the induction training for the Assistant Drugs Controller (ADC), CDSCO. He stressed that since regulations are playing vital role in ensuring the quality of medicines, they should understand their responsibilities in delivering quality services. He also interacted with technical staff of PvPI.
and emphasized that PvPI is striving in the right direction to ensure healthcare delivery system in the country. He also reviewed the functioning of ICSR processing, helpline and other activities of PvPI.

He narrated the importance of effective communication among the stakeholders for the strengthening of PvPI. The commitment of PvPI staff and progress made was well appreciated by him.

**MvPI LAUNCHED: DCG(I) URGES STAKEHOLDERS COMMITMENTS**

Materiovigilance Programme of India (MvPI) to monitor the safety of medical devices in the country launched on 6th July, 2015 by Dr. G N Singh, DCG(I) at IPC, Ghaziabad. He emphasized that safety of medical devices cannot be ignored and should be monitored critically; therefore, every stakeholder and health care providers should be committed for the cause. He also urged the pool of scientific fraternity in the country to come forward to protect the health of Indian population by generating science based evidences, which could be set as a gold standard for rest of the world.

He stated that IPC as a National Coordination Centre for MvPI, will provide all support for effective implementation and the technical support will be provided by National Health System Resource Centre (NHSRC), New Delhi. He congratulated Sree Chitra Tirunal Institute of Medical Sciences & Technology (SCTIMST), Thiruvananthapuram for becoming National Collaborating Centre for MvPI. The medical devices in India are regulated by the Central Drug Standards Control Organization (CDSCO) which is part of the Ministry of Health and Family Welfare.

Dr. D S Nagesh, Scientist- G, SCTIMST, Thiruvananthapuram narrated the vast experiences of his institution’s role and commitment in science based approach for promoting the quality of medical devices. He lauded the effort of IPC for implementing MvPI further to monitor the safety of medical devices. He expressed his support in implementing all necessary activities at his institute to function as a National Collaborative Centre for MvPI.

**IGIMS PATNA MODEL TO PROMOTE PATIENT SAFETY**

Indira Gandhi Institute of Medical Sciences (IGIMS), Patna, Bihar as an ADR monitoring centre under PvPI has taken inspirational initiatives to make PvPI helpline number 1800-180-3024 available in all In Patients Department (IPD) & Out Patients Department (OPD) prescription forms to the patients where the main beneficiaries and one of the main stakeholders of PvPI.

**RRCTTS: MORE SCOPE FOR SKILL DEVELOPMENT**

Currently four Regional Resource Centres for Training and Technical Support (RRCTTS) namely JSS Medical College & Hospital, Mysuru (South zone), Seth GS Medical College & KEM Hospital Mumbai (West zone), PGIMER, Chandigarh (North zone), IPGMER, Kolkata (East zone) are functioning under PvPI to provide the training and technical support to the stakeholders of the respective region. There has been a continuous requisite to identify more RRCTTS to provide uniform training to all AMC(s) teams in an effective way as the PvPI is continuously expanding by the enrolment of new AMCs, RNTCP & ART centres under PvPI.
In a significant move, the core training panel of PvPI recommended to add five more RRCRTTS in addition to the existing as follows:

<table>
<thead>
<tr>
<th>Existing RRCRTTS</th>
<th>States under purview</th>
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<tbody>
<tr>
<td>PGIMER, Chandigarh</td>
<td>Jammu and Kashmir</td>
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<tr>
<td></td>
<td>Himachal Pradesh</td>
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<td>Uttarakhand</td>
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<td>Punjab</td>
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<td>Haryana</td>
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<td>Delhi</td>
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<td>Seth GS Medical College &amp; KEM, Mumbai</td>
<td>Maharashtra</td>
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<td>Goa</td>
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<td>JSS Medical College &amp; Hospital, Mysuru</td>
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<td>Karnataka</td>
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<td>Puducherry</td>
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<td>Tamil Nadu</td>
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<td>IPGMER, Kolkata</td>
<td>West Bengal</td>
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<td>Odisha</td>
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<td>Jharkhand</td>
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<table>
<thead>
<tr>
<th>New RRCRTTS</th>
<th>States under purview</th>
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<tbody>
<tr>
<td>All India Institute of Medical Sciences, Bhopal, Madhya Pradesh</td>
<td>Madhya Pradesh</td>
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<td></td>
<td>Chhattisgarh</td>
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<tr>
<td>B J Medical College, Ahmedabad, Gujarat</td>
<td>Gujarat</td>
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<td>Rajasthan</td>
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<tr>
<td>Institute of Medical Sciences, Varanasi, Uttar Pradesh</td>
<td>Uttar Pradesh</td>
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<tr>
<td></td>
<td>Bihar</td>
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<tr>
<td>Nizam’s Institute of Medical Sciences, Hyderabad</td>
<td>Telangana</td>
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<tr>
<td></td>
<td>Andhra Pradesh</td>
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<tr>
<td>Silchar Medical College &amp; Hospital, Silchar, Assam</td>
<td>Assam</td>
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<tr>
<td></td>
<td>Arunachal Pradesh</td>
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<td></td>
<td>Manipur</td>
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<td>Meghalaya</td>
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<td>Mizoram</td>
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<td>Nagaland</td>
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<td>Tripura</td>
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<td>Sikkim</td>
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The initiative to recognize more RRCRTTS not only will enhance skill development for PvPi personnel but also strengthen the AMCs status. This will also reduce the travel cost and time of participants. NCC-PvPi provides technical and financial support to RRCRTTS for the smooth functioning.

**69TH INDEPENDENCE DAY CELEBRATIONS AND AWARD DISTRIBUTION**

The 69th Independence Day was celebrated in IPC, NCC-PvPi with zeal and enthusiasm on 15th August 2015. During the occasion, Dr G. N. Singh, Secretary-cum-Scientific Director, IPC hoisted the tricolour flag and paid homage to the leaders who sacrificed their life for the independence. He also addressed IPC officials with his motivating words and emphasized on working with full dedication and commitment to achieve the goals.

During the occasion based on the significant contribution, development of innovative methods for ADR reporting and expansion of PvPi, the best AMCs were awarded. The coordinators of the selected AMC received award and certificate. In order to motivate the Technical Associates working in various AMCs they were also appreciated for their contributions.

**BEST AMCs COORDINATORS & TECHNICAL ASSOCIATES AWARDS**

**DR. SACHIN KUCHYA**
Associate Professor & Deputy Coordinator
NSCB Medical College, Jabalpur

Notable Contributions
- Developing and promoting mobile Android application for ADR reporting
- This is an unique facility for the healthcare professionals for reporting ADRs
**MR. ADUSUMILLI PRAMOD KUMAR**  
Technical Associate, JSS, Mysuru  
Notable Contributions  
- Encouraged community pharmacist and nursing professionals in Mysuru about ADR reporting and its importance  
- More focus on reporting ADRs of vulnerable population  
- Quality and Quantity reports submitted

**DR. ASHA PATHAK**  
Associate Professor & Coordinator  
UPRIMS, Etawah  
Notable Contributions  
- Engaging ADR monitoring and reporting from all the departments of UPRIMS, Etawah  
- One of the leading AMC in UP for reporting ADRs  
- Promoting PvPI activities in near by tertiary care hospitals as well as other districts

**DR. RAMACHANDRA BHAT**  
HOD & Coordinator  
Govt Kilipauk Medical College, Chennai  
Notable Contributions  
- Commitment to promote the safety of vulnerable population  
- Identification of Erythema Multiforme due to Rabies vaccine – A new safety alert drawn the attention of global community

**DR. HARIHAR DIKSHIT**  
Sub-Dean, Professor & Coordinator  
IGIMS, Patna  
Notable Contributions  
- Creating the concept of PvPI to healthcare professionals in elaborative method  
- Inclusion of PvPI helpline number in all OPD and IPD prescriptions of IGIMS  
- Working for patient safety on top priority basis

**MR. SHAMBHU DOKANIA**  
Technical Associate, IGIMS, Patna  
Notable Contributions  
- Assisted in the process of PvPI helpline number to appear in the prescriptions of IGIMS  
- Promoting PvPI helpline through media  
- Organizing CMEs on Pharmacovigilance
RECOMMENDATION TO AEFI –ROTA VACCINE-INTUSSUSCEPTION

NCC-PvPI received several reports on intussusception due to rota vaccine from the various centres. The ICSRs have been shared with Immunization Technical Support Unit (ITSU) and regular coordination meeting with Adverse Event Following Immunization (AEFI) division of Universal Immunization Programme is going on to arrive conclusion. The AEFI committee meeting which was held on 20th May 2015 at Chennai, National Technical Advisory Group on Immunization (NTAGI) had already limited rollout of rotavirus vaccine adverse events. The National AEFI committee is committed to provide support, as and when the need arises to pilot rotavirus vaccine rollout in the country.

AMCs FIND A PLACE AT STATE LEVEL AEFI COMMITTEE

The proposal by NCC-PvPI to include coordinators of AMCs in the state level AEFI committee was discussed in the national level AEFI committee meeting on 3-4th August 2015 at Patna, Bihar and approved.

RABIES VACCINE ASSOCIATED RISK OF ERYTHEMA MULTIFORME

Rabies vaccine is used to treat active immunization against rabies virus, including pre-exposure immunization, and post-exposure treatment following exposure to rabies virus. In the event of bite with a suspected rabid animal, the same vaccine should be administered according to the schedule.

The mild systemic Adverse Event Following Immunizations (AEFIs) reported are headache, malaise, nausea and fever. Pain and/or swelling may occur at the site of injection, particularly following intradermal administration. Serious AEFIs mainly of allergic or neurological nature rarely occur. To ensure the safety of Rabies vaccine, it is also equally important to protect the vulnerable population’s safety. In India, till August 2015 NCC-PvPI has received two reports where rabies vaccine may have contributed to Erythema Multiforme (EM). This is only preliminary evaluation report based on ICSRs received from different AMCs under PvPI.

These cases were communicated to Immunization Technical Support Unit of Universal Immunization Programme, MoHFW for further follow up with the patients and for causality assessment. Both the reports were not serious. The time of reaction varies from one to four days. Reactions were developed after first dose of vaccination. In both the cases, patient recovered from the reaction.

Rabies vaccine may cause EM related life threatening reaction since this is a new ADR associated with Rabies vaccine, healthcare professionals are advised to monitor and the possibility of EM in patients treated with Rabies vaccine.
ARTEMETHER/ LUMEFANTRINE: STEVENS JOHNSON SYNDROME

The 5th Signal Review Panel (SRP) meeting held on 9th May 2015 at CDSCO, East Zone, Kolkata with an objective to detect signal from Indian database and promote patient safety. In this meeting, the ICSRs of potential signals were evaluated and with following outcomes:

Stevens - Johnson syndrome shall be regarded as the potential signal for Artemether /Lumefantrine. Apart from SRP recommendation, WHO-UMC also suggested for the same.

Package Inserts

In view of the strong causal relationship and published literature, the SRP recommended to insert the adverse reaction to the corresponding package insert of following medicinal products.

- Mannitol – Hypokalaemia
- Piperacillin and Tazobactam – Hypokalaemia
- Piperacillin and Tazobactam – Bronchospasm
- Rota Vaccine – Intussusception

Further SRP recommends CDSCO, to instruct concerned Marketing Authorization Holders (MAHs) to comply the above adverse drug reactions in their package insert.

DEFERASIROX INDUCED ADR IN PAEDIATRICS

Deferasirox is indicated for the treatment of chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older. Gender wise distribution of ICSRs are shown in Figure 2, distribution of ICSRs based on age groups are shown in Figure 3, seriousness criteria and outcome of reaction of ICSRs are shown in Figure 4 & 5 respectively. Graphical representation of Deferasirox induced ADR based on the system organ classification (SOCs) are shown below.

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**Fig-1 Reactions Based on SOCs**

<table>
<thead>
<tr>
<th>Reaction Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastro-intestinal system disorders</td>
<td>6</td>
</tr>
<tr>
<td>Skin and appendages disorders</td>
<td>6</td>
</tr>
<tr>
<td>Liver and biliary system disorders</td>
<td>1</td>
</tr>
<tr>
<td>Body as a whole - general disorders</td>
<td>2</td>
</tr>
<tr>
<td>Red blood cell disorders</td>
<td>1</td>
</tr>
<tr>
<td>Urinary system disorders</td>
<td>1</td>
</tr>
<tr>
<td>White cell disorders</td>
<td>1</td>
</tr>
<tr>
<td>Respiratory system disorders</td>
<td>1</td>
</tr>
<tr>
<td>Central &amp; peripheral nervous system disorders</td>
<td>1</td>
</tr>
<tr>
<td>Musculo-skeletal system disorders</td>
<td>1</td>
</tr>
</tbody>
</table>

**Fig -2 Gender wise Distribution of ICSRs**

- Male: 18
- Female: 15

Among 33 reports 18 were from male patients and 15 were from female patients as shown in Fig- 2.

**Fig -3 Distribution of ICSRs Based on Age Groups**

- Infants: 18
- Child: 10
- Adolescents: 5

**Fig -4 Seriousness Criteria of ICSRs**

- Yes: 4
- No: 29

**Fig -5 Outcome of Reaction of ICSRs**

- Recovering/resolving: 19
- Not recovered/not resolved: 3
- Fatal: 3
- Unknown: 5

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**Package Inserts**

**DEFERASIROX INDUCED ADR IN PAEDIATRICS**

Deferasirox is indicated for the treatment of chronic iron overload due to frequent blood transfusions in patients with beta thalassaemia major aged 6 years and older. Gender wise distribution of ICSRs are shown in Figure 2, distribution of ICSRs based on age groups are shown in Figure 3, seriousness criteria and outcome of reaction of ICSRs are shown in Figure 4 & 5 respectively. Graphical representation of Deferasirox induced ADR based on the system organ classification (SOCs) are shown below.
healthcare professionals are sensitized to carefully monitor SGLT2 inhibitors induced diabetic ketoacidosis, DPP-4 inhibitors induced joint pain and Epoetin beta induced increased risk of retinopathy in preterm infants.

DPP-4 INHIBITORS: RISK OF JOINT PAIN/ARTHRALGIA

The U.S. Food and Drug Administration (FDA) is warning that the type 2 diabetes mellitus medicines sitagliptin, saxagliptin, linagliptin, vildagliptin and alogliptin which belongs to class of dipeptidyl peptidase-4 (DPP-4) inhibitors may cause joint pain that can be severe and disabling. Patients should not stop taking their DPP-4 inhibitor medicine, but should contact their health care professional right away if they experience severe and persistent joint pain. Globally 246 ICSRs were found from VigiBase on sitagliptin induced joint pain. In India three cases were reported to NCC-PvPI in which sitagliptin is suspected to cause joint pain. Patients started having symptoms of joint pain from 12 days to two months after they started taking sitagliptin therapy. Patients recovered from the joint pain after they discontinued the DPP-4 inhibitor. Healthcare professionals are advised to be alert while prescribing this drug and monitor the patients for possible ADRs.

Reference - www.fda.gov

RETINOPATHY ASSOCIATED EPOETIN BETA IN PRETERM INFANTS

Epoetin beta is approved for the prevention of anaemia of prematurity in infants with a birth weight of 0.75 to 1.5 kg and a gestational age of less than 34 weeks. Epoetin beta is identical to erythropoietin, a hormone that stimulates the production of red blood cells. Infants born before 31 weeks of gestation, particularly those weighing less than 1.25 kg have an underlying risk of retinopathy of prematurity. An European review considered the current evidence for retinopathy associated with Epoetin beta treatment of anaemia of prematurity. Two Cochrane systematic reviews assessed the effectiveness of treatment of anaemia with erythropoietin in premature and/or low birth weight infants. Taken together, the two systematic reviews suggest that epoetin beta may increase the underlying risk of retinopathy in premature infants. Healthcare professionals are advised for careful consideration of retinopathy with epoetin beta in premature infants for preventing anaemia of prematurity.

Reference - MHRA Drug Safety Update volume 8 issue 10 May 2015: 3

SGLT2 INHIBITORS: RISK OF DIABETIC KETOACIDOSIS

Sodium-glucose co-transporter 2 (SGLT2) inhibitors are approved for use in adults with type 2 diabetes to improve glycemic control. Pharmacovigilance Risk Assessment Committee (PRAC) started a review of canagliflozin, dapagliflozin and empagliflozin, which belongs to class of SGLT2 inhibitors used to treat type 2 diabetes. The aim of the review is to evaluate the risk of diabetic ketoacidosis with these medicines. Diabetic ketoacidosis is a serious condition that usually develops in people with type 1 diabetes when insulin levels are too low. Healthcare professionals are advised to keep close monitoring of diabetic ketoacidosis, in patients treated with or on treatment with SGLT2 inhibitors, which will help in early recognition and prompt withdrawal of the drug resulting in lesser morbidity.


NEW DRUGS APPROVED STATUS IN INDIA

The following drugs were approved during the period of May- August 2015 by Central Drugs Standards Control Organization (CDSCO).

Table - 1

<table>
<thead>
<tr>
<th>No.</th>
<th>Drug</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Empagliflozin Tablet 10mg</td>
<td>As an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.</td>
</tr>
<tr>
<td>2</td>
<td>Gadobutrol solution for injection</td>
<td>In adult, adolescence and children aged 2 years and older for:</td>
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<td></td>
<td></td>
<td>☐ Contrast enhancement in cranial and spinal Magnetic Resonance Imaging (MRI).</td>
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<tr>
<td></td>
<td></td>
<td>☐ Contrast enhancement MRI of other body regions: liver kidneys.</td>
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<tr>
<td></td>
<td></td>
<td>☐ Contrast Enhancement in Magnetic Resonance Angiography (CE-MRA).</td>
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<tr>
<td></td>
<td></td>
<td>☐ For MRI of the breast to assess the presence and extent of malignant breast.</td>
</tr>
<tr>
<td>3</td>
<td>Teneligliptin Tablet 20mg</td>
<td>For the treatment of type 2 diabetes mellitus as a monotherapy adjunct to diet and exercise.</td>
</tr>
</tbody>
</table>
QUALITY IMPROVEMENT OF TAs IN AMCs

NCC engages periodic refresher courses for existing personnel working in PvPI to enhance their skill developments increase their competency, boost self confidence etc. This ultimately increases the performance of PvPI.

The refresher course for the Technical Associates working in various AMCs such as STM Kolkata, IPGMER Kolkata, VSSMC Burla, SCB Medical College and Hospital Cuttack, JSS Medical College & Hospital Mysuru, Sheri-Kashmir Institute of Medical Sciences Srinagar, CMC Vellore, KMC Manipal, HIMS Dehradun, SAIMS Indore and RGK Medical College Kolkata had been organized on 20th-21st July 2015 at IPC, Ghaziabad. In addition to the refresher course the performance of Technical Associates were also assessed.

INDUCTION CUM TRAINING PROGRAMME FOR NEWLY RECRUITED TECHNICAL ASSOCIATES

NCC- PvPI is always focused on skill development for Technical Associates as top priority. Since Technical Associates are the driving force of PvPI, their skill development is essential to fulfil the objectives. In order to train the newly recruited technical associates in PvPI, NCC organized induction cum training programme in a more systematic way by adopting standardized training module of Pharmacovigilance which consisted of basic concepts of good pharmacovigilance practice, effective Pharmacovigilance system, mode of collecting ADRs, hands on training Vigiflow etc. The participants were also trained on AEFI reporting and management and coordination with regional RNTCP and ART centres.

First batch training of 28 participants, TAs from Uttar Pradesh, Himachal Pradesh, Delhi, Haryana, Chhattisgarh, Rajasthan, Maharashtra, Gujarat and J&K, had been organized from 18th to 22nd August 2015. In the second batch, total 26 TAs from Telangana, Andhra Pradesh, West Bengal, Tamil Nadu, Madhya Pradesh, Kerala and Arunachal Pradesh participated in the training organized on 24th to 28th August 2015.

During the training the participants were given the opportunity to experience the field level activity of ADR monitoring and reporting both at the government and non government set up hospitals. At the end of the training participants expressed their confidence in delivering their services in Pharmacovigilance as per the expectations of NCC. NCC has conveyed strong message to the participants that the concept of PvPI and patient safety movement should be percolated to the rural and urban India.
**FIELD LEVEL ACTIVITIES**

**PvPI SENSITIZATION PROGRAMME AT VSS MEDICAL COLLEGE BURLA**

A sensitization programme was organized by ADR Monitoring Centre, Dept. of Pharmacology, VSS Medical College, Burla, Odisha for the healthcare professionals on 24th June 2015. Prof Dr. Sabita Mahapatra, Head, Dept. of Pharmacology, VSS Medical College, welcomed the participants and addressed the gathering. Prof. Dr. Suparna Chatterjee, IPGMER, Kolkata delivered a talk on highlighting the relevance and importance of drug safety monitoring and reporting by clinicians and students. The recent achievements of the PvPI like toll free number for ADR reporting, direct reporting by consumers and India’s contribution to the global drug safety database i.e. Vigibase were elaborated upon. The meeting ended with a vote of thanks delivered by Dr. Bhabagrahi Rath of the Dept. of Pharmacology, VSS Medical College. All the participants highly appreciated the deliberation.

**CME ON PHARMACOVIGILANCE AT R.D. GARDI MEDICAL COLLEGE, UJJAIN**

Continuing Medical Education (CME) consists of educational activities which help to maintain, develop, or increase the knowledge, skills, professional performance and relationships that a physician uses to provide services for patients, the public, or the profession of Pharmacovigilance. R. D. Gardi Medical College, Ujjain, an AMC under PvPI organized CME on 22nd August, 2015 for healthcare professionals working under integrated counselling and Testing Centre, National AIDS Control Organization (ICTC-NACO) to create awareness related to patient’s safety and to improve ADR reporting culture.

**UPCOMING EVENTS**

**ADVANCED LEVEL TRAINING ON SIGNAL DETECTION AND DATA MINING**

Signal review panel is functioning under PvPI to identify new drug safety alerts from the ICSRs of the Indian Population. The importance of training for the signal review panel members and PvPI team was debated in the previous meetings. NCC approached UMC Sweden for other technical support on the area of signal detection and data mining. The proposal had been agreed in principal by the Swedish delegation headed by Dr. Marie Lindquist, Director, UMC when they visited IPC on 25th Nov 2014. The UMC extends their support to strengthen the signal review process in PvPI, subsequently several rounds of teleconference were organized and exchanged mutual interest. By considering the overwhelming response from India by providing quality ICSRs, signal review team of UMC will be available to IPC as trainers on 5th - 8th Oct 2015 on signal detection and data mining. This gesture will enhance the signal review process and NCC-PvPI expresses sincere gratitude and acknowledges entire UMC team for the continued support.

**DATE BLOCKED FOR ZONE WISE COORDINATOR TRAINING**

Two days training/workshop on pharmacovigilance and interactive session will be organized for the coordinators of east zone on 26th & 27th November, 2015 at IPGMER, Kolkata and north zone on 8th & 9th December, 2015 at PGIMER, Chandigarh.

On first day, training and awareness programme on pharmacovigilance will be organised for the stakeholders/partners of PvPI of respective zone which includes coordinators, technical
PvPI MANDATES PHARMA COMPANIES TO SUBMIT ADRs IN XML FORMAT

In order to strengthen the quality assessment of ICSR to case safety, NCC-PvPI issued an order to submit ADR reports which is mandatory for all the pharmaceutical industries. Now the responses from the industries are encouraging and their participation is increasing. Industries have been asked to submit their ADR reports in XML E2B (Extensible Mark-up Language is an electronic format which is directly imported to our WHO – UMC VigilFlow database) format to PvPI. This format will enable the NCC to hasten the process of uploading the ICSRs to VigilFlow. This message is also expected to enhance the process of enhancement and signal detection.

FOCUSED PHARMACOVIGILANCE ON KALA-AZAR

Kala-azar is a vector borne disease and is being monitored and controlled by National Vector Borne Disease Control Programme (NVBDCP). Kala-azar affected states are Bihar, Jharkhand, West Bengal and Eastern Uttar Pradesh. PvPI began to collaborate with NVBDCP to monitor the safety of kala-azar drugs. In this connection, the meeting was organized by NCC-PvPI on 17th August, 2015 to discuss the work plan and road map with the NVBDCP, MoHFW.

WORKING GROUP EXPRESSED SERIOUS CONCERNS OVER NON PERFORMING AMCs

The 6th Working Group (WG) of PvPI meeting was held on 29th May, 2015 to critically examine the progress of all the AMCs under PvPI. The members expressed their satisfaction with the culture of reporting of ADRs and overall performance of AMCs. The committee members expressed their deep concern over the non performing AMCs. These AMCs shall be communicated to improve their performance in due course.

PHARMACOVIGILANCE PREPAREDNESS FOR BEDAQUILINE

Bedaquilline was approved in India as a combination therapy with the indication of pulmonary tuberculosis due to multidrug resistant Mycobacterium tuberculosis. Central TB Division conducted a meeting for Bedaquilline expanded Conditional Access Programme (BDQ-CAP) for India
which was held on 21st May, 2015 at Nirman Bhavan New Delhi. In this meeting, discussions were made about technical and operational aspects of BDQ-CAP and to be rolled out in six DR-TB centres for active surveillance on Bedaquiline. A national workshop was conducted on Bedaquiline – BDQ-CAP held on 1st to 3rd July, 2015, at New Delhi. On the 2nd day of the workshop NCC-PvPI, IPC officials presented national policies and organization of Pharmacovigilance in India.

JAPANESE PMDA DELEGATION VISITS IPC: SCOPE STRENGTHEN THE BILATERAL RELATIONS ON MEDICAL DEVICES

Japanese delegation from the office of Standards and Guidelines Development, Pharmaceuticals and Medical Devices Agency (PMDA) visited IPC on 28th May 2015 to cooperate with each other in the areas of monograph development and medical devices safety monitoring. Japanese delegations & NCC-PvPI exchanged their initiatives and future plans in Pharmacovigilance and Materiovigilance.

PvPI EXTENDS ITS DESTINATION TO ARUNACHAL PRADESH AND ANDAMAN & NICOBAR

As per the recommendations of 6th WG of PvPI and also recognizing the expectations of stakeholders, NCC acted promptly to enhance the network of PvPI by identifying 29 more AMCs. The new AMCs include Arunachal Pradesh and Andaman & Nicobar. Thus PvPI extended its reach to monitor the drug safety in this population too. As far as NCC is concerned, there are lots of factors that contribute for effective functioning of these AMCs, including logistics, technical, skilled manpower and most importantly pro PV approaches of these centres. The table shows the details of new AMCs in PvPI.

<table>
<thead>
<tr>
<th>SOUTH ZONE</th>
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<tbody>
<tr>
<td><strong>Andhra Pradesh</strong></td>
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<tr>
<td><strong>Karnataka</strong></td>
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<tr>
<td><strong>Sapthagiri Institute of Medical Sciences and Research Centre, Chikkasandra, Bangalore</strong></td>
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<tr>
<td><strong>A.J. Institute of Medical Sciences, Kuntikana, Mangaluru,</strong></td>
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<tr>
<td><strong>S.S. Institute of Medical Sciences &amp; Research Centre, Davangere</strong></td>
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<td><strong>Sri Devaraj Urs Medical College, Tamaka</strong></td>
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<td><strong>Kerala</strong></td>
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<td><strong>Government Medical College, Palakkad</strong></td>
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<td>Tamilnadu</td>
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<td>Telangana</td>
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<tr>
<td>Andaman &amp; Nicobar Islands</td>
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<td>Maharashtra</td>
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<tr>
<td>N.K.P. Salve Institute of Medical Sciences &amp; Lata Mangeshkar Hospital, Nagpur</td>
</tr>
<tr>
<td>Pandit Dindayal Upadhyay Institute of Medical Science, Research and Human Resources, Gadkari Wada, Nagpur</td>
</tr>
</tbody>
</table>

**NORTH ZONE**

**EAST ZONE**

**WEST ZONE**
Ensuring Safe Vaccination
A venture towards a healthy future generation

NCC-PvPI Join hands with
• Central Drugs Standard Control Organization
• Universal Immunisation Programme
• World Health Organization
• Care Providers

To ensure vaccine safety

If you experience any Adverse Event after vaccination

contact to PvPI helpline

1800-180-3024

Toll-free - 9:00 AM-5:30 PM, Monday to Friday

Work together to accomplish the mission of patient's safety

Issued in Public Interest:
Indian Pharmacopoeia Commission
National Coordination Centre (NCC) - Pharmacovigilance Programme of India (PvPI)
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Email: pvpi@ipcindia.net, ipclab@vsnl.net, www.ipc.gov.in
**MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)**

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

### 1. Patient Details

<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Gender</th>
<th>Age (Year or Month)</th>
</tr>
</thead>
</table>

### 2. Health Information

- **a. Reason(s) for taking medicine(s)(Disease/Symptoms):**
  - [ ] Acute
  - [ ] Chronic
  - [ ] Other

- **b. Medicines Advised by:**
  - [ ] Doctor
  - [ ] Pharmacist
  - [ ] Friends/Relatives
  - [ ] Self (Past disease experienced/No past disease experienced)

### 3. Details of Person Reporting the Side Effect

<table>
<thead>
<tr>
<th>Name (Optional)</th>
<th>Address</th>
<th>Telephone No.</th>
</tr>
</thead>
</table>

### 4. Details of Medicine Taking/Taken

<table>
<thead>
<tr>
<th>Name of Medicines/Quantity of Medicines taken (e.g. 250 mg, Two times a day)</th>
<th>Expiry Date of Medicines</th>
<th>Date of Start of Medicines</th>
<th>Date of Stop of Medicines</th>
</tr>
</thead>
</table>

#### Dosage form:
- [ ] Tablet
- [ ] Capsule
- [ ] Injection
- [ ] Oral Liquids

(Please Specify...)

### 5. About the Side Effect

- **When did the side effect start?**
- **When did the side effect stop?**

#### How bad was the Side Effect?

- [ ] Did not affect daily activities
- [ ] Affect daily activities
- [ ] Admitted to hospital
- [ ] Others

### 6. Describe the Side Effect

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

Please turn the page to read the instructions.
Send your report by mail or Fax to:

Pharmacovigilance Programme of India
National Coordination Centre,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Govt. of India
Sector-23,Rajnagar,Ghaziabad-201002.Uttar Pradesh
Tel.:0120-2783400, 2783401, 2783392
FAX: 0120-2783311

Email: pvpi.compat@gmail.com
For more information visit us at www.ipc.gov.in

Instructions to Complete the Reporting Form

**Section 1 - Patient Details**
- In patient Initial, write first letter of the name and first letter of the surname (e.g. Pradeep Sharma-PS).
- Provide personal information (Gender, Age).

**Section 2 - Health Information**
- Provide reason(s) for taking medicines and medicines advised by (Doctor, Pharmacists, Friends/ Relatives and Self).

**Section 3 - Details of Person Reporting the Side Effect**
- Provide the name (optional), address; telephone no. and email are necessary to assess the report.

**Section 4 - Details of the Medicines Taking/Taken**
- Give all details about the Medicines (Name of Medicines, Quantity of Medicines taken, Expiry Date, start and stop date of Medicines) that have caused side effect.
- Please provide Dosage form (Tablets, Capsule, injections, Oral liquid) and if others please specify.

**Section 5 - About the Side Effect**
- Provide side effect start and stop dates and also specify whether the side effect is still continuing.

**Section 6 - How was the Side Effect**
- Please tick marks the appropriate boxes that apply.

**Section 7 - Describe the Side Effect**
- Please describe the details of side effect and what treatment was taken to manage the side effect.

---

**Call us on Helpline/**

**1800-180-3024 (Toll Free/**

**(9:00 AM to 5:30 PM, weekdays/**

**s. 9:00 ते सध्या, 5:30, आठत्तियाच्या दिवशी)****

Confidentiality: The patient’s identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter’s identity in response to a request from the public.

Send your report by mail or Fax to:

Pharmacovigilance Programme of India
National Coordination Centre,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Govt. of India
Sector-23,Rajnagar,Ghaziabad-201002.Uttar Pradesh
Tel.:0120-2783400, 2783401, 2783392
FAX: 0120-2783311

Email: pvpi.compat@gmail.com
For more information visit us at www.ipc.gov.in

Instructions to Complete the Reporting Form

**रिपोर्ट करण्याचे प्रमाण भरण्यासाठी सूचना**

**भाग 1 - रुग्णाची माहिती**
- रुग्णाचा आवश्यकतांमध्ये नवकाळे पहले अस्थायी आणि आहाराच्या पहली अस्थायी लिहाव (उदा. प्रत्येक साल-प्रत्येक).
- व्यक्तिकी माहिती दा (लिंग, वय).

**भाग 2 - आरोग्यविषयक माहिती**
- ओषधिपाठ्याचे प्रत्येकांना अभ्यासी प्राप्त वेळी फेस्ट लेले ते लिहा (होस्टल, अभ्यास, निव-निवारणांक आणि आदि).

**भाग 3 - कर्त्याधिकाऱ्यांनी व्यक्तीकी माहिती**
- रिपोर्ट दिल्यासाठी तुम्हाले नाव (तृतीय स्तर), पता दा, पूर्वजी क्र. व मिळेल काही काय आपल्याचा अवसर आहे आहे.

**भाग 4 - लेट असलेल्या/पॅसेंजर अभ्यासाची माहिती**
- असलेल्या उपर्युक्तांमध्ये दा या अभ्यासाच्या सारख्या माहिती दा (अभ्यास्यांना नव्यांना ओषधिपाठ्याचे प्रेक्षाप्रमाणे, मुद्दासमाप्तिक मिळावा, ओषधी रुग्णाचा व बंड केलेल्या मिळावा).
- कृपया डोळे म्हणजेच रुग्णांना (कोंड, कळ्यां, केंद्र, मॉडल) आणि हूँ या अवसरासाठी कृपया स्वयं करा.

**भाग 5 - कर्त्याधिकाऱ्यांची माहिती**
- तुर्यापूर्वक एवढे सहयोग व व्यक्तिकी मिळावा तर तुर्यापूर्वक एवढी लागू आहेच त्याचे हेच तयार करा.

**भाग 6 - कर्त्याधिकाऱ्याकडून वाईट होता**
- कृपया या अवसरांना आत्त्विक भांडूने खण्ड करा.

**भाग 7 - कर्त्याधिकाऱ्याकडून वांछन करा**
- कृपया तुर्यापूर्वक एवढी माहिती अनेक त्यातुर्यापूर्वकांमध्ये व्यवस्थापन करण्यासाठी कोणते उपचार पेहेल्यात खण्ड करा.

**Thank you for taking the time to complete this form**

हे प्रमाण भरण्यासाठी वेळ दिल्यावेळ तुमचे आधार
भारतीय भेषज संहिता आयोग — एक मनोयोग

ह्रदय में रस धारा बही, इच्छा शक्ति भी प्रबल रही।
प्रबुद्धता हुई विन्दुस्नील, लक्ष्य शिखर पर मननशील।
कर्मधी मानव रहता जहाँ, प्रशन विन्दु भी आ ठहरता बही।
क्यों न आई.पी. आयोग भी साजे, जो विश्व में अयोग्य विराजे।
उमग के इस भेषज चमन में, उमड़ती सांसारिक स्फर्धों के गगन में,
एन.ए.बी.एल. और डब्लूअ०.सी० से प्रमाणित, भारत सरकार से उत्साहित,
सर्व सुखाय:चमकाता कर्मयोग है, आई.पी. आयोग एक मनोयोग है।
औषधि सत्कर्ता के प्रसंग में, जी.वी.जी.आई. के संग में,
पी.वी.पी.आई. आयोग की शान है, औषधि सत्कर्ताओं का कार्य महान है।
आई.पी., एन.एफ.आई. प्रकाशन व संसाधन, आई.पी.आर.एस मानकता व अनुमोदन,
नई औषधि जॉंच व शोध, प्रशिक्षण व आई.पी. मोनोग्राफ संपर्क संबंध, नई
औषधि गुणवत्ता व सुरक्षा सन्दर्भ में, जन पुष्टि स्वास्थ्य रक्षा प्रसंग में,
बहुआयामी बीच गम्भीर संयोग है, आई.पी.सी. प्रगतिशील मनोयोग है।
इस मनोयोग की वेला में, जनकल्याण व सेवा में,
हम तपस्वी हरदम रहेंगे, खुदा कसम किसी से कम नहीं रहेंगे।
कष्ट मिटे, सुख समृद्धि, बढ़ें देश भक्ति व ज्ञान।
सब लोकों में भारत की, बढ़ें निरंतर शान।
हम कर्म करें महान, रक्षा करें भगवान।

जयहिन्द

रचयिता
सत्य प्रकाश त्यागी
वैज्ञानिक अधिकारी
भारतीय भेषज संहिता आयोग, गाजियाबाद
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार

अनुमोदकर्ता
डा. जी. एन. सिंह
सचिव—सह—वैज्ञानिक निदेशक
भारतीय भेषज संहिता आयोग, गाजियाबाद
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
भारत सरकार
At NCC we take pride in the caliber of young professionals who partner with us in delivering highest quality service in PvPI. All our team members are highly qualified & trained in GVP in India & abroad. The care provided to promote patients safety is at par with international standards.

ACKNOWLEDGEMENT

NCC-PvPI acknowledges Dr. Pawan K. Saini (Scientific Officer, IPC), Technical Associates namely Mr. Akhilesh Sachan, Ms. Archana Saurabh, Ms. Asmi Kumari, Ms. Ismeet Kaur, Dr. Itikshya Mohapatra, Mrs. Kinnari J. Dabhi, Mrs. Madhvi Rathore, Mr. Prabhakar Mishra, Mr. Pranay Kumar, Mr. Rakesh Kumar Gupta, Mr. Ranvir Kumar, Mr. Rishi Kumar, Mr. Tanzeel Ahmad Khan, Ms. Vaishali Bhardwaj, Mr. Vipin Kumar, Mr. Vivek Dabas, Mrs. Anusha R. (HR) and Mr. Deepak Malik (IT Consultant) at NCC for their contribution in bringing out this issue.