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IPC

News Letter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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INSIDE THE ISSUE

- Important Events of PvPI
- Drug Safety Information
- Training and Education
- Upcoming Events

- 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



DOWNLOAD ADR APP FROM
GOOGLE PLAY STORE & REPORT ADRs
ANYWHERE, ANYTIME

PUBLISHED BY:

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

MESSAGE

FROM

JOINT SECRETARY (REGULATION), MoHFW



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

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PHARMACOVIGILANTE'S QUALITIES AND SKILLS

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, JS(R) reviewing PvPI activities with Dr. G.N. Singh, DCG(I), Dr. Surinder Singh, Director, NIB and IPC officials



Shri. B P Sharma, Secretary Health and higher officials of MoHFW, Govt. of India during the meeting to review the progress of PvPI and launching the Mobile Apps for ADR reporting held on 22nd May 2015 at Nirman Bhawan, New Delhi

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 others 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



Experts during launch of Materiovigilance Programme of India (MvPI) at IPC, Ghaziabad on 6th July 2015

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), IPGIMER, 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.

इन्दिरा गाँधी आयुर्विज्ञान संस्थान, शेखपुरा, पटना - 14
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Super Speciality Tertiary Care Institute
Phone No. : 0612-2297631, 2297099, Website : www.igims.org

बाह्य रोगी विभाग Consultant Doc. : _____

दिनांक : _____ पंजीकरण : _____ Department : _____
मरीज का नाम : _____ Room No : _____
लिंग : _____ उम्र : _____ Followup No. : _____

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दवाओं से किसी भी प्रकार के रोगविले दुष्प्रभाव होने की स्थिति में दवाविराग रूप से फार्माकोलॉजी विभाग अथवा टॉल फ्री नम्बर 1800-180-3024 मोबाइल नम्बर 08271405455, लैण्डलाइन नम्बर 0612-2296057 पर अवश्य सूचित करें। यह आपके एवं जनहित में है।

सोम मंगल बुध बृह शुक्र शनि

IT Solutions : Mehta Datamatics, email : rpm@mehta@yahoo.com

PvPI-Helpline number in the Prescription form used by IGIMS Patna

In a significant move, the core training panel of PvPI recommended to add five more RRCTTS in addition to the existing as follows:

Existing RRCTTS	States under purview
PGIMER, Chandigarh	Jammu and Kashmir
	Himachal Pradesh
	Uttarakhand
	Punjab
	Haryana
	Delhi
Seth GS Medical College & KEM, Mumbai	Maharashtra
	Goa
JSS Medical College & Hospital, Mysuru	Kerala
	Karnataka
	Puducherry
	Tamil Nadu
IPGIMER, Kolkata	West Bengal
	Odisha
	Jharkhand
New RRCTTS	States under purview
All India Institute of Medical Sciences, Bhopal, Madhya Pradesh	Madhya Pradesh
	Chhattisgarh
B J Medical College, Ahmedabad, Gujarat	Gujarat
	Rajasthan
Institute of Medical Sciences, Varanasi, Uttar Pradesh	Uttar Pradesh
	Bihar
Nizam's Institute of Medical Sciences, Hyderabad	Telangana
	Andhra Pradesh
Silchar Medical College & Hospital, Silchar, Assam	Assam
	Arunachal Pradesh
	Manipur
	Meghalaya
	Mizoram
	Nagaland
	Tripura
	Sikkim

The initiative to recognize more RRCTTS 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 RRCTTS 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

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 Kilpauk 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

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



**MR. MOHAMMAD RAFI**

Technical Associate, SAIMS, Indore

Notable Contributions

- Published two case reports and one research article in reputed journals
- Installation of drop box in IPD and OPD
- Effective communication of PvPI resource material to the stakeholders

MRS. UPASANA SHARMA

Technical Associate, HIMS, Dehradun

Notable Contributions

- Contribution in Identifying new drug safety alert
- Publication on Pharmacovigilance in reputed journals
- Sustaining good quality ICSRs (completeness score: 0.98)



VACCINES SAFETY INITIATIVES

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.

DRUG SAFETY INFORMATION

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.

Fig-1 Reactions Based on SOCs

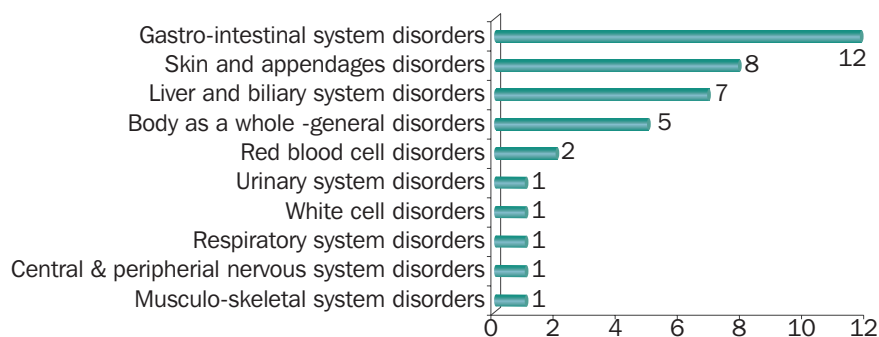
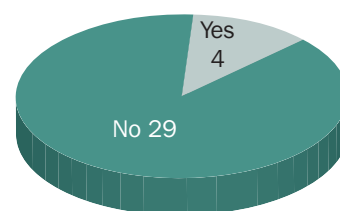


Fig -4 Seriousness Criteria of ICSRs



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

Fig -2 Gender wise Distribution of ICSRs

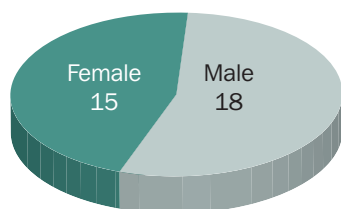


Fig -3 Distribution of ICSRs Based on Age Groups

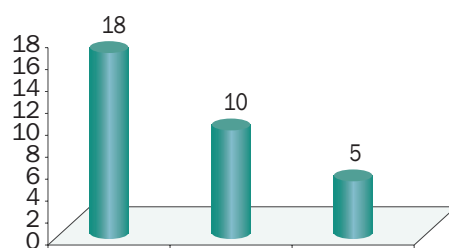
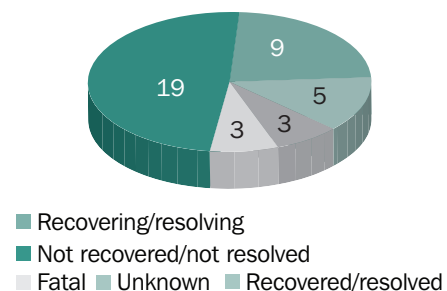


Fig -5 Outcome of Reaction of ICSRs



Out of total 33 cases, outcome of 3 reports were fatal, 19 reports were not recovered, 5 reports were recovered, 9 reports were recovering, and 3 reports were unknown (Fig. 5). In conclusion while prescribing and monitoring this drug we should be alert and forward such reports to the concerned.

- ⊙ WHO notifies Deferasirox induced pancreatitis as a signal
- ⊙ PvPI database shows 33 ICSRs related symptoms of pancreatitis
- ⊙ Healthcare professionals to be alert while prescribing and monitoring this drug and forward such reports to the concerned

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*

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.

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.

Reference: <http://www.ema.europa.eu/>

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

1	Empagliflozin Tablet 10mg	As an adjunct to diet and exercise to improve glycemic control in adults with Type 2 diabetes mellitus.
2	Gadobutrol solution for injection	In adult, adolescence and children aged 2 years and older for: <ul style="list-style-type: none"> ⊙ Contrast enhancement in cranial and spinal Magnetic Resonance Imaging (MRI). ⊙ Contrast enhancement MRI of other body regions: liver kidneys. ⊙ Contrast Enhancement in Magnetic Resonance Angiography (CE-MRA). ⊙ For MRI of the breast to assess the presence and extent of malignant breast.
3	Teneligliptin Tablet 20mg	For the treatment of type 2 diabetes mellitus as a monotherapy adjunct to diet and exercise.

TRAINING AND EDUCATION



Existing TAs of quality improvement training programme on 20th - 21st July 2015

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, Sher-i-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.



Newly recruited TAs during training programme with PvPI officials

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 organised 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

associates, clinicians, pharmacists, nurses, regulators/ policy makers & consumer forums etc. On second day interactive session for coordinators and technical associates will be organised.

WHO-IPC GETS READY TO WELCOME INTERNATIONAL DELEGATES

In association with World Health Organisation (WHO) Country Office (India), NCC-PvPI will be organizing 38th Annual Meeting of WHO Programme for International Drug Monitoring (PIDM) in India. Dr. Nilima Kshirsagar, National

Chair in Clinical Pharmacology, Indian Council of Medical Research (ICMR), Government of India will be presiding over two days workshop on WHO ATC/DDD methodology and drug utilization research which will be on 2nd November 2015 and second workshop Let's talk PV! will be conducted by UMC professionals on 3rd November 2015. Main meeting will be held on 4 -6th November 2015. In this regard IPC in association with WHO Country Office are arranging regular meetings to make the event a grand success. Approximately 129 countries will participate in this programme. Following link can be accessed for registration of this meeting. <http://www.whopvindia2015.com/umc.aspx>.

DR. G N SINGH IS THE PRESIDENT FOR 67TH INDIAN PHARMACEUTICAL CONGRESS

The 67th Indian Pharmaceutical Congress (IPC) will be held from 19th to 21st December, 2015 at JSS University, Mysuru, Karnataka. Dr. G N Singh, DCG(I) is being elected as president. This event is focused to discuss the various issues and current status on pharmaceutical manufacturing, standard setting process, regulatory, medicine safety and pharmacy education in India as compared to global scenario. The 67th IPC is also planned to organise round table meeting on Pharmacovigilance where global players will be invited in the discussion.

NEWS DIGEST

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 VigFlow database) format to PvPI. This format will enable the NCC to hasten the process of uploading the ICSRs to VigFlow. This message is also expected to enhance the process of enhancement and signal detection.

FOCUSSED 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

Bedaquiline 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 Bedaquiline 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.



Japanese Delegations visited IPC-PvPI on 28th May 2015

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.

SOUTH ZONE				
1	Andhra Pradesh	Sri Venkateswara Institute of Medical Sciences, Sri Padmavathi Medical College for Women, Tirupati	Dr. Umamaheswara Rao	svimspharmacovigilance@gmail.com
2	Karnataka	ESIC-MC & PGIMSR Rajajinagar, Bangaluru	Dr. Suchitra A.D	suchisham@hotmail.com
3		Sapthagiri Institute of Medical Sciences and Research Centre, Chikkasandra, Bangaluru	Dr. Shubha R.	shubhapreksha@gmail.com
4		A.J. Institute of Medical Sciences, Kuntikana, Mangaluru,	Dr. Sharath Kumar K.	docsharath@gmail.com
5		S.S. Institute of Medical Sciences & Research Centre, Davangere	Dr. Umakant N. Patil	drunpatil@gmail.com
6		Sri Devaraj Urs Medical College, Tamaka	Dr. Bhuvana K.	drbhuvana_k@yahoo.com
7	Kerala	Cochin Medical College, Kalamassery, Cochin	Dr. S. N. Veenasree	veenabiju73@yahoo.com
8		Government Medical College, Palakkad	Dr. N. Sunil	docsunil2005@yahoo.com

9	Tamilnadu	Velammal Medical College Hospital and Research Institute, Anuppanadi, Madurai	Dr. S. Thamilaras	tamilsoundar@gmail.com
10		Government Hospital of Thoracic Medicine, Tambaram	Dr. Nalini Jayanthi	nalinijayanthi59@gmail.com dpstncni@mtcp.org
11	Telangana	Chalmeda Anand Rao Institute of Medical Sciences, Bommakal, Karimnagar	Dr. Santosh Kumar. B	drsantoshkumar999@gmail.com
12	Andaman & Nicobar	Andaman & Nicobar Islands Institute of Medical Sciences, Portblair	Dr. Mangesh Bankar	drmangesh_bankar@yahoo.co.in
NORTH ZONE				
13	Uttar Pradesh	Sarojini Naidu (S. N.) Medical College, Moti Katra, Agra	Dr. Mona Verma	dpsupagr@tbcindia.nic.in dpsupagr@mtcp.org
14	Chhattisgarh	All India Institute of Medical Sciences, Tatibandh, Raipur	Dr. Suryaprakash Dhaneria	dean@aiimsraipur.edu.in
15	Haryana	Faculty of Medicine & Allied Health Sciences, Shree Guru Gobind Singh Tricentary University, Budhera, Gurgaon	Dr. Naveen Kumar	nk999999@rediffmail.com
16	Punjab	Government Medical College, New Lal Bagh, Patiala	Dr. Anita Gupta	dr Guptaanita@hotmail.com gmcpharmacologypatiala@gmail.com
17	Delhi	Rajan Babu Institute of Pulmonary Medicine and Tuberculosis, GTB Nagar, New Delhi	Dr. Anuj Bhatnagar	anuj1968@gmail.com
18		National Institute of Tuberculosis and Respiratory disease (Lala Ram Sarup Institute of Tuberculosis And Respiratory Diseases), New Delhi	Dr. Rohit Sarin	drsarin@yahoo.com r.sarin@nitrd.nic.in
EAST ZONE				
19	Assam	Assam Medical College and Hospital, Barbari, Dibrugarh	Dr. Urmi Choudhary	urmichoudhury6@gmail.com
20	Arunachal Pradesh	Arunachal State Hospital, Naharlagun	Dr. Dohkum Raina	medicalsupt@yahoo.com
21		Health Training & Research Centre, Pasighat	Dr. T Tali	drjgibi@yahoo.com
22	Bihar	Katihar Medical College, Karimbagh, Katihar	Dr. C. B Choudhary	drcb_choudhary@yahoo.co.uk
23	Odisha	Kalinga Institute of Medical Sciences and P.B.M Hospital, KIIT University, Bhubaneswar	Dr. Manjushree Mohanty	drmm992014@gmail.com
24	West Bengal	Midnapore Medical College & Hospital, Vidyasagar Road, Paschim Medinipur	Dr. Balaram Ghosh	drbrghosh@gmail.com amc.mmch@gmail.com
WEST ZONE				
25	Rajasthan	Institute of Respiratory Diseases, SMS Medical College, Subhash Nagar, Jaipur	Dr. Rajendra Singhvi	dpsrjjpr@mtcp.org
26	Gujarat	Gujarat Medical Education and Research Society (GMERS) Medical College, Gandhinagar	Dr. J. G. Buch	drjgbuch@hotmail.com deangmersmcg@gmail.com
27	Maharashtra	Aundh Chest Hospital, Aundh Camp New Sangavi, Pune	Dr. Smita Sanjeev Shiras Dr. Mrs. Dhavle	dpsmhpna@mtcp.org
28		N.K.P. Salve Institute of Medical Sciences & Lata Mangeshkar Hospital, Nagpur	Dr. Archana S. Borkar	drarchana50@gmail.com
29		Pandit Dindayal Upadhyay Institute of Medical Science, Research and Human Resources, Gadkari Wada, Nagpur	Dr. Viral Kamdar	drvirkamdar@gmail.com

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)

औषधांचे दुष्परिणाम कळविण्यासाठीचे प्रपत्र (उपभोक्त्यांसाठी)

Version 1.0
आवृत्ती 1.0

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.
भारतीय औषधिकोश आयोग, राष्ट्रीय समन्वय केंद्र – भारतीय औषध देखरेख कार्यक्रम, आरोग्य व कुटुंबकल्याण मंत्रालय, भारत सरकार.

1. Patient Details/ रुग्णाची माहिती				
Patient Initials/ रुग्णाची आद्याक्षरे:	<input type="text"/>	Gender/ लिंग (V): Male/ पुरुष <input type="checkbox"/> Female/ स्त्री <input type="checkbox"/>	Age (Year or Month)/ वय (वर्ष किंवा महिना)	
2. Health Information/ आरोग्यविषयक माहिती				
a. Reason(s) for taking medicine(s)(Disease/Symptoms)/ औषध(धे) घेण्याचे कारण(णे) (रोग/लक्षण):				
b. Medicines Advised by/ औषधे सुचविणारी व्यक्ती (V): Doctor/ डॉक्टर <input type="checkbox"/> Pharmacist/ औषधतज्ञ <input type="checkbox"/> Friends/Relatives/ मित्र/नातेवाईक <input type="checkbox"/> Self (Past disease experienced/No past disease experienced)/ स्वतः (पूर्वी रोग अनुभवला/अनुभवला नाही) <input type="checkbox"/>				
3. Details of Person Reporting the Side Effect/ दुष्परिणाम कळविणार्या व्यक्तीची माहिती				
Name (Optional)/ नाव (ऐच्छिक):				
Address/ पत्ता:				
Telephone No/ दूरध्वनी क्र:			Email/ ईमेल:	
4. Details of Medicine Taking/Taken/ घेत असलेल्या/घेतलेल्या औषधाची माहिती				
Name of Medicines/ औषधांची नावे	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ औषधांचे घेतलेले प्रमाण (उदा. 250 मिग्रॅ, दररोज दोन वेळा)	Expiry Date of Medicines/ औषधांचा मुदतसमाप्ती दिनांक	Date of Start of Medicines/ औषधे सुरु केल्याचा दिनांक	Date of Stop of Medicines/ औषधे बंद केल्याचा दिनांक
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
Dosage form/ डोसचे स्वरूप (V) : Tablet/ गोळी <input type="checkbox"/> Capsule/ कॅप्सूल <input type="checkbox"/> Injection/ इंजेक्शन <input type="checkbox"/> Oral Liquids/ तोंडावाटे द्रव <input type="checkbox"/> If Others (Please Specify.....)/ अन्य असल्यास (कृपया स्पष्ट करा.....)				
5. About the Side Effect/ दुष्परिणामाची माहिती				
When did the side effect start?/ दुष्परिणाम कधी सुरु झाला?		dd/mm/yy	Side Effect is still Continuing (Yes/No)/ <input type="checkbox"/>	
When did the side effect stop?/ दुष्परिणाम कधी थांबला?		dd/mm/yy	दुष्परिणाम अजून सुरु आहे (होय/नाही): <input type="checkbox"/>	
6. How bad was the Side Effect? (Please ✓ the boxes that Apply)/ दुष्परिणाम किती वाईट होता? (कृपया लागू चौकट्यांमध्ये ✓ करा)				
<input type="checkbox"/> Did not affect daily activities/ दैनंदिन कार्यांवर परिणाम केला नाही		<input type="checkbox"/> Affect daily activities/ दैनंदिन कार्यांवर परिणाम केला		
<input type="checkbox"/> Admitted to hospital/ रुग्णालयात दाखल केले		<input type="checkbox"/> Death/ मृत्यू		
<input type="checkbox"/> Others/ इतर				
7. Describe the Side Effect (What did you do to manage the side effect?)/ दुष्परिणामाचे वर्णन करा (दुष्परिणामाचे व्यवस्थापन करण्यासाठी तुम्ही काय केले?)				

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.

हा रिपोर्ट ऐच्छिक आहे, त्याचे कोणतीही कायदेशीर परिणाम नाहीत आणि रुग्णाची सुरक्षितता सुधारणे हा त्याचा हेतू आहे. तुमचा सक्रिय सहभाग मोलाचा आहे. या प्रपत्रात दिलेली माहिती पाठपुराव्यासाठी एडीआर मॉनिटरिंग सेंटरकडे पाठविली जाईल. जेव्हा कार्यक्रम अधिकारी अधिक माहितीसाठी तुमच्याशी संपर्क साधतील तेव्हा त्यांच्याशी सहकार्य करण्याची तुम्हाला विनंती करण्यात येत आहे. कृपया जरी तुमच्याकडे सर्व माहिती नसली तरी अवश्य कळवा.

Please turn the page to read the instructions
कृपया सूचना वाचण्यासाठी पान उलटा

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



Call us on Helpline/ हेल्पलाईनवर आम्हाला कॉल करा

1800-180-3024 (Toll Free/
(टोल फ्री))

(9:00 AM to 5:30 PM, weekdays/ स. 9:00 ते
संध्या. 5:30, आठवड्याच्या 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.

गोपनीयता: रुग्णाची ओळख गोपनीय ठेवली जाते व तिचे अधिकतम रक्षण केले जाते. कार्यक्रमाच्या कर्मचाऱ्यांनी लोकांच्या विनंतीवरून खबर देणार्या व्यक्तीची ओळख उघड करणे अपेक्षित नाही व ते तसे करणार नाहीत.

Instructions to Complete the Reporting Form रिपोर्ट करण्याचे प्रपत्र भरण्यासाठी सूचना

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 bad 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.

भाग 1 - रुग्णाची माहिती

- ✓ रुग्णाच्या आद्याक्षरांमध्ये नावाचे पहिले अक्षर व आडनावाचे पहिले अक्षर लिहा (उदा. प्रदीप शर्मा- प्रश).
- ✓ व्यक्तीगत माहिती द्या (लिंग, वय).

भाग -2 आरोग्यविषयक माहिती

- ✓ औषधे घेण्याचे कारण(णे) आणि ते कोणी सुचविले ते लिहा (डॉक्टर, औषधतज्ञ, मित्र/नातेवाईक आणि स्वतः).

भाग 3 - दुष्परिणाम कळविणार्या व्यक्तीची माहिती

- ✓ रिपोर्ट पडताळण्यासाठी तुमचे नाव (ऐच्छिक), पत्ता द्या; दूरध्वनी क्र. व ईमेल कळविणे आवश्यक आहे..

भाग 4 - घेत असलेल्या/घेतलेल्या औषधाची माहिती

- ✓ ज्यामुळे दुष्परिणाम झाला त्या औषधांची सर्व माहिती द्या (औषधांचे नाव औषधांचे घेतलेले प्रमाण, मुदतसमाप्ती दिनांक, औषधे सुरु केल्याचा व बंद केल्याचा दिनांक).
- ✓ कृपया डोसचे स्वरूप द्या (गोळ्या, कॅप्सूल, इंजेक्शन, मौखिक द्रव) आणि इतर काही असल्यास कृपया स्पष्ट करा.

भाग 5 - दुष्परिणामाची माहिती

- ✓ दुष्परिणाम सुरु होण्याचा व थांबण्याचा दिनांक तसेच अजून तो दुष्परिणाम सुरु आहे का, हे स्पष्ट करा.

भाग 6 - दुष्परिणाम किती वाईट होता

- ✓ कृपया लागू असलेल्या चौकट्यांमध्ये खूण करा.

भाग 7- दुष्परिणामाचे वर्णन करा

- ✓ कृपया दुष्परिणामाची माहिती आणि त्या दुष्परिणामाचे व्यवस्थापन करण्यासाठी कोणते उपचार घेतले त्याचे वर्णन करा.

Thank you for taking the time to complete this form

हे प्रपत्र भरण्यासाठी वेळ दिल्याबद्दल तुमचे आभार

भारतीय भेषज संहिता आयोग – एक मनोयोग

हृदय में रस धारा बही, इच्छा शक्ति भी प्रबल रही।
प्रबुद्धता हुई चिन्तनशील, लक्ष्य शिखर पर मननशील।
कर्मठी मानव रहता जहाँ, प्रश्न चिन्ह भी आ ठहरता वहाँ।
क्यों न आई.पी. आयोग भी साजे, जो विश्व में अग्रणीय विराजे।
उमंग के इस भेषज चमन में, उमड़ती सांसारिक स्पर्धा के गगन में,
एन.ए.बी.एल. और डब्लूएचओ से प्रमाणित, भारत सरकार से उत्साहित,
सर्व सुखायःचमकाता कर्मयोग है, आई.पी. आयोग एक मनोयोग है।
औषधि सतर्कता के प्रसंग में, पी.वी.पी.आई. के संग में,
पी.वी.पी.आई. आयोग की शान है, औषधि सतर्कता का कार्य महान है।
आई.पी., एन.एफ.आई. प्रकाशन व संशोधन, आई.पी.आर.एस मानकता व अनुमोदन,
नई औषधि जाँच व शोधन, प्रशिक्षण व आइ.पी. मोनोग्राफ संवर्धन,
औषधि गुणवत्ता व सुरक्षा सन्दर्भ में, जन पशु स्वास्थ्य रक्षाप्रसंग में,
बहुआयामी बोध गम्य संयोग है, आई.पी.सी. प्रगतिशील मनोयोग है।
इस मनोयोग की वेला मे, जनकल्याण व सेवा में,
हम तत्पर हरदम रहेंगे, खुदा कसम किसी से कम नहीं रहेंगे।
कष्ट मिटे, सुख समृद्धि, बड़े देश भक्ति व ज्ञान।
सब लोकों में भारत की, बड़े निरन्तर शान।
हम कर्म करें महान, रक्षा करें भगवान।

जयहिन्द

रचयिता

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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.



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