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Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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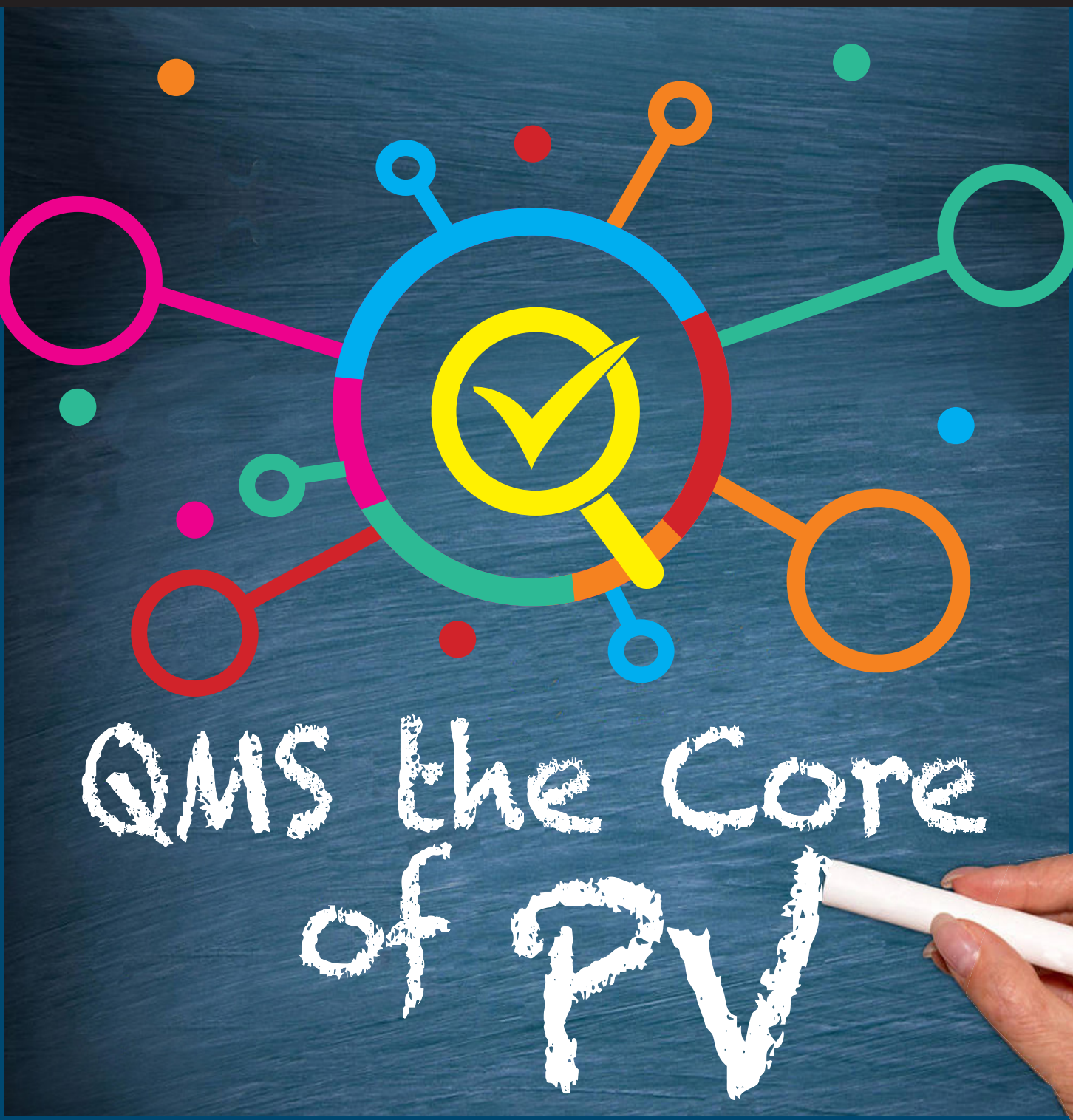

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Newsletter CONTENTS

Secretary-cum-Scientific Director's Message

Dear Readers,

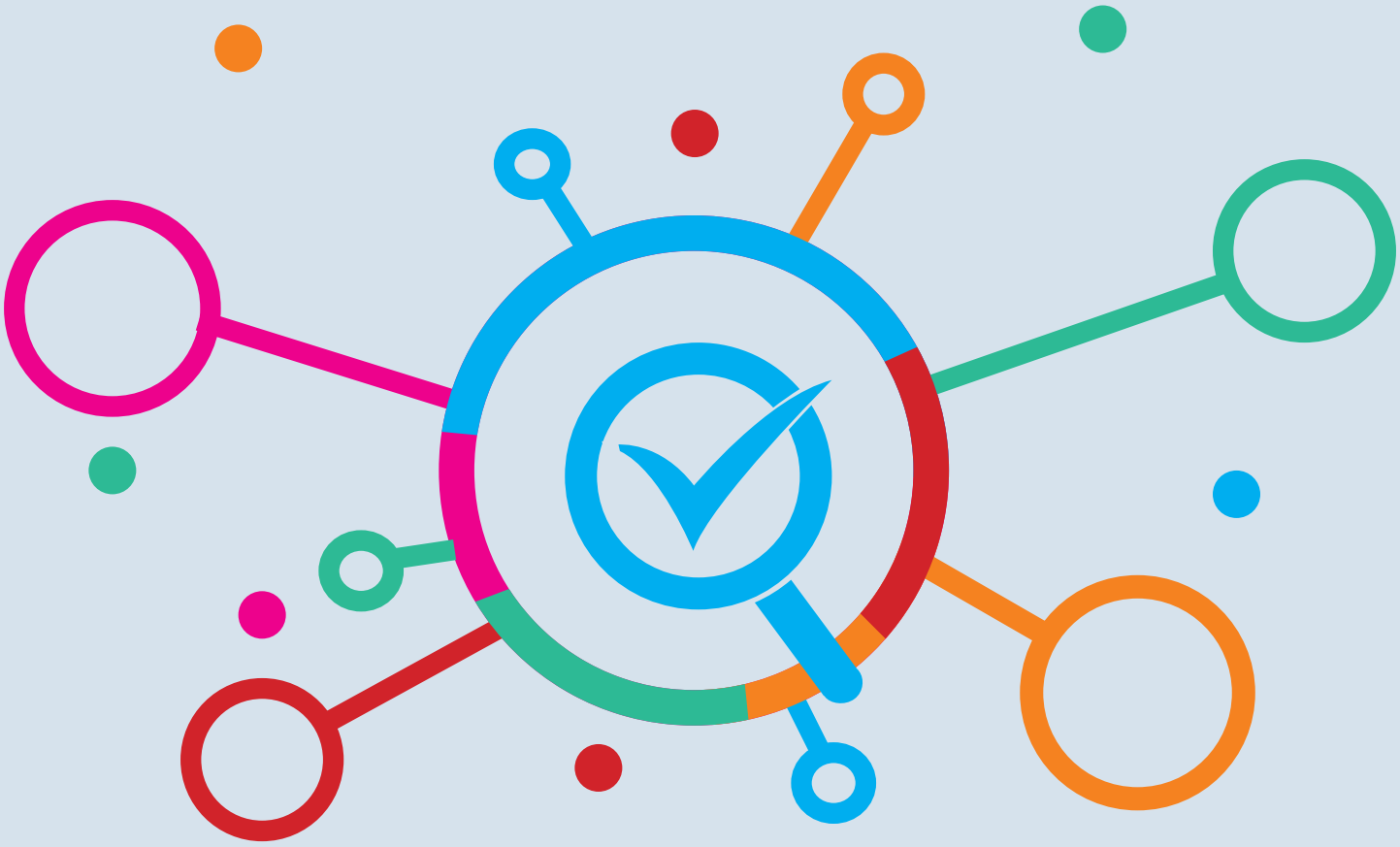
Pharmacovigilance (PV) as a pan-India programme has been consistently gaining momentum in raising awareness among the masses, healthcare professionals, the pharma industry and medical staff at hospitals. However, with the advancement of medical sciences in the arena of both drugs and devices, the journey is long and arduous which warrants constant, scientific tools-based monitoring and eventual optimization of adverse drug reactions in the aftermath of drug consumption or device insertion. The process of collation, assessment, evaluation and eventual regulatory intervention depends as much on the quality of drug safety data as on its efficacious monitoring.

The endeavour of the modern-day Pharmacovigilance in a way shifts the traditional goalposts inasmuch as the emphasis now than ever before has been on an early detection and assessment of a signal to avert the probability of occurrence of an adverse event.

Besides the standardization of processes and procedures for effective Pharmacovigilance on drugs, vaccines and radiopharmaceuticals an equally important component of PV encompasses its application to processed herbal products, cosmetics and ayurvedic medicines. The omnibus nature of Pharmacovigilance, including the traditional Indian forms of medicine and diverse treatment practices which AYUSH caters to, makes PV standardization all the more demanding across the varied social, ethnic and economic fabric of the country. The initiative to set up Pharmacopoeial Education and Patient Safety Cell (PEPSC) at academic institutions is a major step towards realising the aim of inculcating good Pharmacovigilance practices at the institutional level.

The observance of core values and practices of Pharmacovigilance by the Pharma sector and MAHs needs constant oversight by NCC-PvPI, IPC as India emerges the hub of medical tourism and generic drugs. To promote patient-safety by drug-safety across the nook and corner of the country, it is equally important for the IPC to reach out to the regional centres which are nodal to regular conferences on recent advances in Pharmacovigilance vis-a-vis drug discovery and development.

Dr G N SINGH
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare
Government of India



Quality Management System in Pharmacovigilance

Quality of drugs safety data plays an important role as Pharmacovigilance (PV) is one of the components for ensuring patient safety. The drug safety data collected through various stakeholders of PvPI requires mandatory analysis and decision making. Therefore quality data management documentation plays a vital role in PV.

According to the ISO 9000 standard; "Quality is degree to which a set of inherent characteristics fulfils requirements" and as per US FDA 21CFR 820 "Quality management System is organizational structure, responsibilities, procedures, processes and resources for implementing quality management." QMS is essential to indentify, measure, control and enhance core business processes

QMS FRAMEWORK

Strategy & Governance
Strategic direction and principles that demonstrates commitment to operate in a compliant way and is dedicated to continuous improvement

Organisational Effectiveness
Organisation that is structured in a clear way and is well resourced with people that are capable and trained to perform their activities

Processes and Procedures
Policies, SOPs, work instructions, processes and training materials that enables the business to be correctly skilled and compliant

QMS in PvPI

Essential documents of an effective QMS
Quality system is the method used to ensure that the quality level of an organization is maintained. The system documentation can be viewed as as hierarchy containing four tiers, as shown in the following illustrations

CORE PRINCIPLES

The staff working for PvPI should share the principles and values of the NCC, Indian Pharmacopeia Commission, in order to ensure a common understanding of ethics and integrity among all PvPI personnel.

QUALITY POLICY

We are committed to ensure patients safety through a transparent approach and high quality of services, focused on scientific innovation and rationality. We aim to be the centre of excellence in Pharmacovigilance by achieving global standards that fulfil the expectation of every stakeholder.

Records
Objective evidence and associated network of IT systems, documentation and tools to collect, process, manage and store all data associated with GCP/GVP

Continuous Improvement
Process by which an organization continually improves the effectiveness of our procedures and overarching QMS

Scope of the Quality System
The need for independent audits/checks of the quality and accuracy of the data collected in PV system has been considered important to maintain the drug safety. As if the safety of a product is to be assessed and monitored properly, then clearly the company, regularly authorities and consumers must have confidence in the quality and accuracy of the data used to make that assessment.

- Established and followed quality system that is adequate and effective for performing PV activities
- Covers organisational structure, responsibilities, procedures, processes and resources and includes appropriate resource management, compliance management and record management
- Based on quality planning, quality control, quality assurance and quality improvements
- Documented in a systematic and orderly manner in the form of written policies and procedures

AUDITS

Internal Audits
It is the policy of NCC-PvPI to conduct an internal audit for all activities to verify the continued compliance of system and operations as per international standards. The internal audit monitors all the functioning of NCC-PvPI at least once a year; however additional audit may be conducted if required. The Quality Manager is responsible for planning and conducting of audits. Audits are planned and conducted in such a manner that:

- PvPI management system elements and technical activities are verified for compliance
- Trained and qualified personnel are engaged for the internal audit
- Auditors are independent to perform their activities
- Quality Manager/Officer-in-Charge PvPI ensures the schedule and procedure for audits
- Audit is performed as per SOP
- Audit findings (observations and non conformances) are recorded in a designed and approved format.
- Performing the root cause analysis and taking the corrective actions within the stipulated period of time.
- Performing follow up audit activities to verify and record the effectiveness of corrective action implementation.

Audit records comprises of audit program (Plan and schedule), audit notification, filled up check list, audit finding, root cause analysis, proposed corrective actions, details of corrective action taken, corrective action verification, implementation and preventive actions, if any are maintained by Quality Manager.

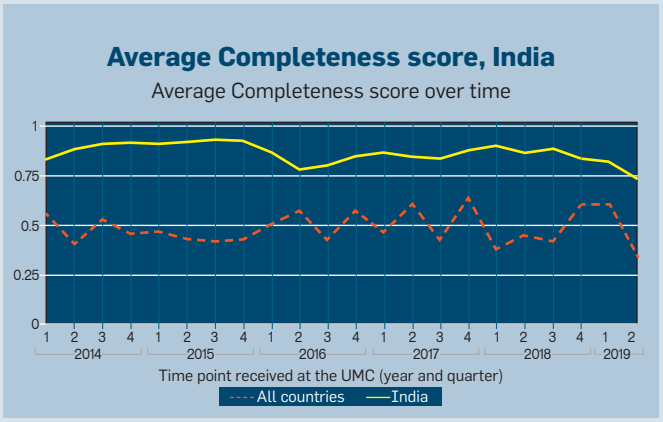
External Audits
It is the policy of NCC-PvPI to conduct an external audit for all activities to verify the continued compliance of system and operations as per international standards. The external audit monitors all the functioning of NCC-PvPI at least once a year. The Quality Manager is responsible for planning and conducting of audits.

Compliance management

- Continuous monitoring of Pharmacovigilance data and consideration of options for risk minimisation and prevention
- Scientific evaluation of all information on the 0risks of medicinal products
- Timely submission of data on adverse reactions
- Effective communication with CDSCO
- Regular recommendation of safety information such as drug alerts, PIL, PIL changes, and signals to CDSCO
- Communication of relevant safety information with HCPs and patients

VIGIGRADE COMPLETENESS SCORE OF ICSRs

Quality of ICSR reporting:
The VigiGrade™ Completeness score is a WHO system to measure the amount of informationprovided on Individual Case Safety Reports (ICSRs). The graph represents average completeness score of ICSRs submitted from India (Purple line) as compared to submitted ICSRs by all the other countries (Green line). The average annual completeness score accounts for >0.8 out of 1.



Artificial Intelligence in Pharmacovigilance

Anoop Kumar

Vipin Bhati

AMC Centre: Adverse drug monitoring centre (AMC), Indo-Soviet Friendship College of Pharmacy (ISFCP), Moga (Punjab)-India

Artificial Intelligence (AI) is a common word which I think every one of us heard from last couple of years. Artificial Intelligence is also known as machine intelligence which means intelligence demonstrated by machines. It is the combination of a computer with human intelligence to solve the problems. The overall objective of AI is to create technology that allows computers and machines to function in an intelligent manner. AI tools these days' affects every area of science and art. The past decade has witnessed the increasing application of AI methodologies in the field of biomedicine.

In Pharmacovigilance, a huge amount of data is handled and analysed during the processes of detection, assessment, understanding, and prevention of ADRs. To cope with this huge data, more healthcare and qualified professionals are required to capture and evaluate the data which ultimately increase the overall budget of Pharmacovigilance. AI could play a significant role in various steps to minimize the human workload, error and achieve 100% compliance with regulatory authorities.

Artificial intelligence will be helpful to reduce the burden and cost of case processing such as auto narrative generation, narrative analysis (case extraction and creation), QC assessment, causality assessment, and 'touch less' case processing, where non-serious cases are received, verified, coded, processed and submitted without any human intervention. In case processing, AI tools can extract the information from adverse drug monitoring form and can do the evaluation of case validity without the use of manpower. Natural language processing (NLP), Image Processing, Optical Character Recognition (OCR) and simple rule-based prioritization techniques will help to process the unstructured individual case safety report (ICSR) into machine-readable format. The AI will be helpful from data intake, translation, triage, and prioritization, to removing duplicates.

The identification of the early signal could save the life of the population from the harmful effects of medicines. The well-known example is thalidomide tragedy which urges the need of the system to detect the signal as early as possible. The artificial intelligence could play a significant role in early signal detection and assessment.

There may be many questions arise in the mind of Pharmacovigilance professionals regarding AI in Pharmacovigilance such as Are the humans will be replaced after the implementation of this technology? It's difficult to answer this question but I think humans will not be replaced but will be displaced. People will be needed in many different ways to make AI operational such as humans are required for creativity, compassion and generalized thinking.

In conclusion, AI will be helpful to accelerate various Pharmacovigilance activities but it's not going to fix everything. We hope that in future various AI techniques will be used in the field of Pharmacovigilance. Although, currently there are IT systems and other safety softwares that automate case processing and reporting activities but the overall process still requires much human intervention and manual effort, particularly in the areas of case intake and data entry. The rules-based, repetitive and deterministic nature of these processes, makes them a suitable candidate for AI. The complete process, from case receipt to reporting, can be automated, thereby limiting the amount of human intervention needed for exception handling, quality checks, and reviews. Employing AI in safety case processing will not only reduce costs but also accelerate the processing of cases and eliminates the chance of human error which ultimately improves quality and accuracy.

Meet on honing HCPs' skills

A meeting on "Updating Knowledge and Skills of Healthcare Professionals, including Academicians" was organized at Indian Pharmacopoeia Commission (IPC), Ghaziabad on April 10, 2019. Dr Jai Prakash, Senior Principal Scientific Officer, IPC, welcomed the participants and requested them for self-introduction. Dr G N Singh, Secretary-cum-Scientific Director, IPC, in his opening remarks emphasized the need for involvement of the participants in Pharmacopoeial standard setting process. He also laid stress on Faculty Exchange programmes and SWOT (strengths, weaknesses, opportunities and threats) analysis. The participants gave their valuable inputs.

SALIENT FEATURES

- Pharmacopoeial Education and Patient Safety Cell (PEPSC) be established in academic institutions
- A team dedicated to this task be identified at the institution level
- Faculty/teachers need to upgrade their knowledge and skills. Training for trainers in a particular discipline be provided
- Proposal to involve at least one expert each from IPC and the academic institution for the proposed activity
- A screening committee for selection of members to PEPSC should have a representative each from IPC and respective institutions
- Old copies of IP, NFI proposed to be provided to academic institutions on a complimentary basis
- Like job-fest, internship modules at undergraduate level be introduced in Pharmacy curriculum
- Like industry connect, community connect be encouraged
- Best publication award in Pharmacopoeial Standards and Pharmacovigilance be initiated by IPC in the near future

National PV conference @Satna

Indian Pharmacopoeia Commission in collaboration with the Amicable Knowledge Solution (AKS) University, Satna organized a National Conference on "Recent Advances in Pharmacovigilance in Drug Discovery & Development" at Satna in Madhya Pradesh on April 12, 2019. The conference was attended by Dr G N Singh, Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, Ghaziabad, Prof Y K Gupta, ex-Prof/Dean, AIIMS, New Delhi, Dr Jai Prakash, Senior Principal Scientific Officer, Indian Pharmacopoeia Commission, Ghaziabad, Dr Ratinder Jhaj, additional professor, Department of Pharmacology, AIIMS, Bhopal, Prof Arun Shrivastava, Dean, Faculty of Medicine, Gandhi Medical College, Bhopal, and Dr Syed Ziaur Rahman, Professor, Department of Pharmacology, Jawaharlal Nehru Medical College, AMU, Aligarh. It was emphasized at the conference that Pharmacovigilance is not confined to chemical drugs only, but equally applies to herbal,

traditional and complementary medicines, biologicals, vaccines, blood products, radiopharmaceuticals and medical devices. Several problems relate to the way in which herbal medicines are named, perceived, sourced and utilized. The field of Pharmacovigilance has been growing rapidly's making inroads into medical sciences and pharmaceuticals.

FOCAL POINTS

- India as a hub for Pharmacovigilance
- Regulatory bodies and Pharmacovigilance
- Challenges for good Pharmacovigilance practices for the generic industry. How to overcome them?
- Pharmacovigilance in ayurvedic /allopathic medicines and herbal products
- Pharmacovigilance programme of India with reference to National Health Programmes
- Pharmacovigilance for traditional medicine
- Importance of Pharmacovigilance for the Pharma industry
- Pharmacogenomics

Signal Detection & Management workshop

A four-day workshop on "Signal Detection and Management for representatives of regulatory authorities in India responsible for vaccine safety" was organised by CDSCO at Hotel Royal Plaza in New Delhi from April 9-12, 2019. Representatives from CDSCO, PvPI with Signal Review panel members and National AEFI members, including Causality Assessment Committee members, attended the workshop. The facilitators of the workshop included representatives from WHO-HQ, WHO-Country office India, CDSCO, MHRA-UK, PvPI, AEFI Secretariat.

FOCAL POINTS

- Introduction to PV activities focussing on organisations/regulatory authorities in Signal Detection and Management
- Overview of Signal Detection and Management
- Global tool for Signal Detection and Assessment
- Qualitative and Quantitative Signal Detection Validation through VigiLyse along with Exercise
- Signal Detection Outcome and Management
- Signal Validation – Hands-on training exercise
- Signal Assessment

9th Regional workshop on PV

9th Regional workshop on "Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward" was organised by PvPI for pharmaceutical industries at Yashoda Hospital, Kaushambi, Ghaziabad, Uttar Pradesh, on May 9, 2019. The workshop was inaugurated by Dr G N Singh, Secretary-cum-Scientific Director, IPC. Dr Jai Prakash, Sr Principal Scientific Officer, IPC, Pharmacovigilance associates of IPC, Dr Vijit Agrawal, Ms Swati Thapliyal, Ms Shavya Singh, Ms Bhanupriya and Mr Maneesh Soni were also present. The workshop was attended by 36 participants.

CDSCO, IPC, academia and pharma industry representatives elaborated on various topics, including a Brief Overview of Pharmacovigilance Practices, Regulatory Aspects of Post-Marketing Safety Assessment of Drugs, MvPI-reporting tools, an introduction to E2B XML format, PvPI-ADR reporting tools and forms. Interaction at the day-long workshop provided the participants an opportunity to clarify their doubts.

OUTCOME:

- Participants gained knowledge on Pharmacovigilance and establishment of Pharmacovigilance System in Pharmaceutical Industries. They were also sensitized to the process of collecting and reporting ADRs.
- Pharmaceutical industry delegates were interested to know more about PvPI's indigenous software for ADR reporting i.e. ADRMS
- Enforcement of Gazette Notification be made both by CDSCO and PvPI for mandatory compliance to ADR reporting by MAHs
- Need for training marketing representatives of Pharmaceutical industries for enhancing ADR reporting and collection directly to the Physicians
- Such workshops may also be conducted in various parts of the country so as to train maximum number of pharmaceutical industries, and streamline all gaps in ADR reporting

Release of IP Addendum 2019

With a view to strengthening the quality of drugs in India, Dr Harsh Vardhan, Hon'ble Union Minister for Health and Family Welfare, Govt of India, released the IP Addendum 2019 to Indian Pharmacopoeia 2018, at Nirman Bhawan, New Delhi on July 5, 2019. The Addendum was released in presence of senior officials of the Ministry of Health & Family Welfare and Scientific Staff of Indian Pharmacopoeia Commission (IPC), Ghaziabad.

IPC is instrumental in ensuring the quality and safety of medicines through science-based tools for wellbeing of patients in the country.

On this occasion, Dr G N Singh, Secretary-cum-Scientific Director, IPC, highlighted the salient features of IP Addendum 2019 to IP-2018, emphasizing the need for harmonization of analytical methods with those accepted internationally. The necessary steps, he added, have been taken by the Commission for monitoring and upgrading drug standards in IP Addendum 2019.

The IP Addendum 2019 to IP-2018 contains 66 new Monographs, including those of Chemicals (61), Herbs and Herbal Products (03), and Radiopharmaceutical Preparations (02). One general Monograph on Lotion has also been included in this Addendum. Special emphasis has been laid on the dosage forms of API whose dosage forms were not in the IP 2018. General chemical tests for identification of an article have been almost eliminated with the inclusion of more specific infrared, ultraviolet spectrophotometric, HPLC and HPTLC tests. Special emphasis has been laid on including/upgrading the dissolution test in existing monographs. Most of the existing assays and tests on related substances have been upgraded to liquid chromatography method.

Workshop on Benefit-Risk Assessment by WHO

A two-day workshop was conducted by WHO in collaboration with the National Regulatory Agency of India (NRA) on "Benefit-Risk Assessment for regulatory authorities in India responsible for vaccine safety", at Hotal Royal Plaza in New Delhi on May 1-2, 2019. IPC delegates -- Dr Jai Prakash, Senior Principal Scientific Officer, IPC, Dr V Kalaiselvan, Principal Scientific Officer, IPC, Dr Shashi Bhushan, Senior Scientific Officer, IPC, Dr R S Ray, Scientific Assistant, IPC, Mr.Pankaj Bhatt, Senior Pharmacovigilance Associate, PvPI, IPC and Ms Swati Thapliyal, Pharmacovigilance Associate, PvPI, IPC -- were present at the workshop.

On the first day of workshop Dr R Chandrashekar, DDC (I), CDSCO, outlined the benefit-risk assessment of medicine and vaccines in India, focusing on regulatory challenges faced in this regard. Dr Viola Macolic Sarinic, Technical Officer, Safety and Vigilance, WHO HQ-Geneva presented an overview of "benefit-risk assessment of medicinal products, CIOMS IV, clinical trials, common technical document, ICH clinical safety guidelines". MHRA/UK representatives (Alie Banner Simpson and Catherine) made presentations on Risk Analysis, Qualitative and Quantitative tools used in benefit-risk assessment, Routine and additional risk-minimization measures, and effective use of educational material and communications for risk minimization.

On the second day of the workshop Dr Viola Macolic made a presentation on patient risk-benefit assessment and management, and routine benefit-risk assessment through periodic safety reports. MHRA/ UK representatives (Alie Banner Simpson and Catherine) discussed the qualitative and quantitative assessment with risk-minimization measures and communication, citing examples such as Valproate, Human Papillomavirus (HPV) vaccine and Pandemic flu vaccine.

OUTCOME/ RECOMMENDATION

- Hands-on training was given to all vaccine safety stakeholders for benefit-risk assessment of both medicines and vaccines
- WHO representatives discussed with participants the need for strengthening benefit-risk assessment for both medicines and vaccines

National AEFI Committee Meeting

National AEFI Committee meeting was held at Conference Hall, NIHFW, New Delhi on June 17, 2019, deliberating on Causality Assessment of reported AEFI cases with an update, systemic review and analysis of AEFI reports. Mr Pankaj Bhatt, Senior Pharmacovigilance Associate, represented IPC. Other participants were Dr S Aneja, Chairperson, National AEFI Committee, Dr M K Aggarwal, Deputy Commissioner, UIP, MoHFW, Dr Deepak Polpakara, AEFI Secretariat, Dr Vikas Madan, Programme Manager, AEFI Secretariat, Dr Vineet Goyal, AEFI focal person, WHO-ICO, and Mr Somnath Basu, ADC (I), CDSCO.

OUTCOME:

- Causality assessment of all serious AEFI cases discussed and evaluated with the team members of National AEFI committee members
- Dr Vikas Madan made a presentation on updated progress of AEFI Surveillance across India
- Discussed updated information on Guillain Barre Syndrome-related adverse events due to vaccines

PV Colloquium at STM-Kolkata

ADR Monitoring Centre of PvPI at School of Tropical Medicine, Kolkata, and NCC-PvPI, IPC jointly organized the Eastern and North Eastern Regional Colloquium on Pharmacovigilance and Patient Safety on April 5, 2019. The event with the Theme of "Pharmacovigilance with Physicians at the Centre Stage" attracted as many as 150 participants including physicians, pharmacists, nurses and PV-associates of AMCs around the Eastern and North Eastern Region of the country. The event has provided a platform for the healthcare professionals in the region to discuss various aspects of Pharmacovigilance activities and related challenges. Director IPC, Dr. G N Singh, in his inaugural speech, addressed the gathering and he insisted that the healthcare professionals must play a key role in enhancing the awareness on PV. Officer in-charge PvPI Dr. Jai Prakash presented about the success stories of PvPI.

OUTCOME:

- Delegation discussed ways to improve awareness on PV among physicians through continuous awareness programmes in the region
- Enhance capacity by providing adequate training for reporting of ADRs and technical aspects of PV such as; Causality Assessment, Signal Detection etc.
- Enroll more number of AMCs in the Eastern and North Eastern Region to expand outreach of PvPI
- Build trust among healthcare professionals in ADR-reporting by continuous motivation and appreciation

Management System Training Programme

A two day training programme on "Documentation, Awareness & Internal Audit on QMS as per IS/ISO 9001:2015" was conducted at National Institute of Training for Standardization (NITS), Noida from 27th & 28th June 2019. This management system training programme was attended by the Technical and Quality manager PvPI-QMS, Dr. Shashi Bhushan, Principle Scientific Officer, IPC, Ghaziabad. Programme was emphasised on the differences between IS/ISO 9001:2008 and IS/ISO 9001:2015 and document to be required for IS/ISO 9001:2015 implementation and basic concept and knowledge of internal audit.

Approved New Drugs in India

New drugs approved by CDSCO during April- June 2019

S. No	DRUG	INDICATION
1	**Remogliflozin Etabonate bulk and Remogliflozin Etabonate film-coated tablets 100 mg**	Indicated in adults aged 18 years and older with Type-2 Diabetes Mellitus to improve glyceamic control as ● Mono-therapy when diet and exercise alone do not provide adequate glycaemic control ● Add-on therapy with metformin, together with diet and exercise, when these do not provide adequate glycaemic control
2	**Concentrate of Proteolytic enzyme enriched in Bromelain topical gel**	Indicated for removal of eschar in adults with deep partial and full-thickness thermal burns
3	**Menotrophin injection 600 IU/ml, 1 ml & 2 ml multidose vial (highly purified)**	Menotropin is indicated for treatment of female and male infertility in the following conditions: ● Anovulation, including Polycystic Ovarian Disease (PCOD), in women who have been unresponsive to treatment with Clomiphene citrate ● Women undergoing controlled ovarian hyper stimulation to induce development of multiple follicles for Assisted Reproductive Technologies ● Hypogonadotropic hypogonadism in men

- Healthcare professionals are urged to closely monitor the safety of these drugs.
- ADRs, if any, to be reported to PvPI.

Source: on https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDk2NA==

Drug Safety Alerts for April-June 2019

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

Suspected Drug: **Amiodarone**

Indication: **Arythimia, Arrtythmia associated with Wolf-White syndrome**

ADR: **Acute Pancreatitis**

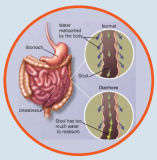
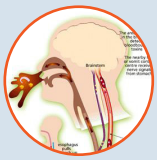
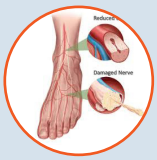
Suspected Drug: **Teicoplanin**

Indication: **Serious gram-positive infection, Staphylococcal infection in patents sensitive or unresponsive to penicillin and ciphalosporins CAPD-related peritonitis.**

ADRs: **Red Man Syndrome, Toxic Epidermal Necrolysis (TEN)**

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

Comparative status of Global Drug Alerts with PvPI Database

NAME OF DRUG	RISK WARNING	INTERNATIONAL STATUS	INDIA STATUS
DACLATASVIR	 Hypoglycaemia	10 ICSRs reported at Global level **Reference: Drug Safety Newsletter, HPRA, April 2019 (www.hpra.ie)**	03 ICSRs reported in PvPI database
DULAGLUTIDE	 Diarrhoea	1,954 ICSRs reported at Global level **Reference: Revision of Precautions, MHLW/PMDA, 19 March 2019 (www.pmda.go.jp/english/)**	14 ICSRs reported in PvPI database
	 Vomiting	2,022 ICSRs reported at Global level **Reference: Revision of Precautions, MHLW/PMDA, 19 March 2019 (www.pmda.go.jp/english/)**	19 ICSRs reported in PvPI database
FLUOROQUINOLONES	 Tendonitis	8,987 ICSRs reported at Global level **Reference: Drug Safety Update, MHRA, 21 March 2019 (www.gov.uk/mhra)**	05 ICSRs reported in PvPI database
	 Peripheral Neuropathy	2,387 ICSRs reported at Global level **Reference: Drug Safety Update, MHRA, 21 March 2019 (www.gov.uk/mhra)**	26 ICSRs reported in PvPI database
	 Joint swelling	1,376 ICSRs reported at Global level **Reference: Drug Safety Update, MHRA, 21 March 2019 (www.gov.uk/mhra)**	07 ICSRs reported in PvPI database

Healthcare professionals are sensitized to carefully monitor the above mentioned alerts, ensuring any event related to these drugs is reported to NCC-PvPI.

PV expansion at SMS-Jaipur

Located in Jaipur district, SMS Medical College is the largest and oldest government medical college in Rajasthan. It conducts graduate and post-graduate courses, including MBBS, BDS, MD/MS/DM, and also MSc in non-clinical and paramedical subjects, GNM, BSc nursing and various other diploma courses. The college is affiliated to Rajasthan University of Health Sciences, Jaipur. The medical college is bridged to various hospitals in Jaipur.

The college was recognized as first ADR Monitoring Centre (AMC) in the state of Rajasthan during the first phase of PvPI in January 2011. Dr Mukul Mathur was appointed as first Coordinator of the AMC.

AMC ACTIVITY:

- Uploading ADR reporting forms, AMC and PvPI posters and contact details ADR Monitoring Centre on the website of SMS Medical College, Jaipur and updating information related to PvPI (posters, ADR forms, Newsletter) at the library of medical college.
- Distribution of PvPI posters to various Clinical Departments of SMS Medical College & attached hospitals in Jaipur.
- Printing of PvPI tollfree Helpline #1800-180-3024 for Adverse Drug Reaction reporting on the OPD registration form in J K. Lon Hospital, Zenana Hospital, Gangauri Hospital, Kanwatia Hospital and S R Goyal Hospital attached to SMS Medical college, Jaipur.
- Coordination with the State Nodal Officer, Deworming Programme Jaipur, Rajasthan regarding Focused Pharmacovigilance on Albendazole administration during the Deworming Programme in the state.
- Publishing a message on "Introduction of ADR Monitoring Centre" as leaflet in the SANJEEWANI (2016-2018)" magazine of SMS Medical College, Jaipur.
- Distribution of hard copies of PVPI Newsletter to Principal and Medical Superintendent and also

circulation of soft copy of the same to other faculty members.

- Approaching NABH-accredited hospitals and other private hospitals in Jaipur for ADR reporting and establishing the practice of Pharmacovigilance at their hospitals.
- Sending information on Pharmacovigilance and ADR reporting forms, contact details of AMC to State Secretary and State President, Indian Medical Association, Rajasthan and Branch President and Branch Secretary, IMA, Jaipur.
- A Pharmacovigilance stall was set up at Mental Health Exhibition in Psychiatric hospital, Jaipur during the World Mental Health Week from 04/10/2018 to 10/10/2018.
- Coordination with the Head of Department, Orthopaedics and Cardiology, SMS Medical College, regarding reporting of adverse drug reactions associated with medical devices.
- Organizing PV training, seminars, lectures for MBBS, Nursing and Pharmacy students as well as doctors, nurses and pharmacists.
- Circulating drug alerts, ADR forms and PV-related matter to the healthcare professionals.

Effective PV system @GMC-Guntur

Guntur Medical College (GMC) is one of the premier medical institutions in south India. The institution has come a long way since its establishment in 1946. The GMC works in conjunction with Government General Hospital (GGH), Guntur. Equipped with 14 surgical theatres and delivery rooms, it comprises 21 departments. Guntur Medical College was designated as an AMC under PvPI on December 10, 2012 and functions effectively under Dr A Meena Kumari, Professor of Pharmacology, as the AMC Coordinator and Dr Pavan K Kumar as the Patient Safety Pharmacovigilance Associate.

AMC ACTIVITY:

- AMC landline number & PvPI tollfree number embossed on OP card.
- Fixation of ADR drop-boxes and display of posters on Pharmacovigilance at in-patient and out-patient departments.
- Monthly reminder emails sent to all DMHOs, Medical colleges and Pharmacy colleges in the periphery.
- Causality Assessment Committee meetings conducted twice a month besides Pharmacovigilance Committee meetings to discuss the status of Pharmacovigilance activities, and meeting on future plans conducted thrice a year.

- Initiation of Intensive Drug Monitoring Programme in association with Chalapathi Institute of Pharmaceutical Sciences (CLPT), Guntur.
- Training & Orientation programmes on ADR reporting for post-graduate (PG) and Pharm-D students.
- Workshop on Pharmacovigilance, Haemovigilance & AEFI at SIMS College of Pharmacy, Guntur
- AMC visit for training, monitoring and reporting of ADRs to Pharm-D students from various colleges (SIMS College of Pharmacy, AM Reddy college of Pharmacy, ASN College of Pharmacy, Hindu college of Pharmacy, Vishwabarathi college of Pharmacy)
- Awareness drive on Pharmacovigilance for upcoming batch of undergraduates, interns and post-graduate students at GMC, Guntur.
- Workshop on Pharmacovigilance at Lalitha Super-specialities hospital, Guntur.
- Introduction of ADR Alert Card System and first ADR-Alert card issued to a patient by GMC Superintendent Dr D S Raju Naidu and HOD of Dermatology Dr S Nageswaramma.
- Workshop on Pharmacovigilance, Haemovigilance & AEFI in association with Chalapathi Institute of Pharmaceutical Sciences, Guntur.

PV @ESIC, Faridabad

ESIC Medical College & Hospital, Faridabad is one of the major medical institutions under Ministry of Labour & Employment, Govt of India. Spread over a 30-acre picturesque area, it is more than a 500-bed multi-speciality hospital established with the mission of bringing medicare of international standards to the doorstep of poor workers i.e. insured persons (IPs) and to roll out medical graduates capable of functioning independently in both urban and rural environment. The session for first MBBS batch commenced in 2015.

ESIC Medical College was recognized as an AMC under PvPI in 2017. The core PV team comprises Dr Monica Aggarwal as Coordinator in-charge, Dr Angelika, Assistant Professor, Department of Pharmacology as the Deputy Coordinator, Dr Deepali Kaushik, Clinician, Department of General Medicine, as Sub-Coordinator, and Ms Shilpa Chaudhary as Patient Safety PV-Associate appointed by NCC-PvPI.

AMC ACTIVITY:

- ESICMC being an AMC has a Pharmacovigilance Committee comprising HODs of different departments and periodic meetings to promote PV are conducted
- Pharmacovigilance awareness posters put up at all OPDs, Medicine wards and Clinical Pharmacology Department
- Distribution of ADR forms and pamphlets, with contact details, to the HCPs on monthly basis.
- Sensitization by regular meetings with HCPs in OPD/Wards by adopting mandatory reporting of ADRs and obtaining feedback from departments to improve ADR-reporting.
- Maintaining ADR database or registries of all ICSR record files for easy access and retrieval in a hassle-free manner
- Sensitization lecture for encouraging MBBS students to report ADR as part of research activities and practical exercise
- Circulation of PVPI newsletter among all HCPs
- Circulation of drug alerts and other information related to drug-safety among HCPs via WhatsApp groups
- Field visit arranged during Induction-cum-Training Programme organised by NCC-PvPI, IPC, Ghaziabad

STAKEHOLDERS' FEEDBACK

Dr LOKENDRA SHARMA
Professor, Pharmacology &Coordinator, AMC,
SMS Medical College,Jaipur

The utilization of drugs is not always beneficial but may cause an ADR, which should be monitored and reported at the earliest to the regulatory authority. We at SMS Medical College, Jaipur are pleased to have an ADR monitoring centre under PvPI since January, 2011. In the interest of patient safety and contribution towards pharmacovigilance programme several activities e.g. CMEs, Workshops, Seminars, Guest Lectures, Pharmacovigilance stall in Science of Life Exhibition and Mental Health Exhibition, PV awareness programme on special Health Days, Placing of PvPI and MvPI posters, sending letters to Director, NHM, Director Medical & Health, Rajasthan and the Chief Medical & Health Officer, Jaipur district to disseminate the information on pharmacovigilance to the CHCs and PHCs, have been conducted to strengthen the practice of Pharmacovigilance in our medical college & attached hospitals in Jaipur district.

Dr SUDHIR BHANDARI
Principal& Controller, SMS Medical College, Jaipur

Pharmacovigilance Programme of India (PvPI) is a great tool for routine monitoring of Adverse Drug Reactions (ADRs) in hospitals. It also gives an opportunity to every Clinician to inform the drug-related problems to the Regulatory body for further necessary action. Monitoring and reporting of ADRs/AEs is inevitable through the life cycle of a pharmaceutical product, so that the high quality of medical care and patient management is maintained.
I appreciate the whole team of ADR Monitoring Centre, SMS Medical College for their active involvement and contribution to patient safety.

Dr D S RAJU NAIDU
Superintendent, Govt General Hospital, Guntur

Pharmacovigilance Programme of India was launched with an objective to safeguard the health of people and to generate awareness among healthcare professionals. Although reporting an ADR has a greater impact, distribution of ADR-Alert Card helps the patient to guard against allergy to a particular drug or combination of drugs. The introduction of ADR-Alert Card system as part of our organisational set-up for better patient care has helped improve outcomes of drug therapy.

Dr A MEENA KUMARI
Professor of Pharmacology & AMC Coordinator,
Guntur Medical College, Guntur

The Pharmacovigilance Programme of India is very useful for the students and clinicians to create awareness about safe and rational use of drugs. Postgraduates at the college are imparted education and knowhow on ADR-reporting and their posting at the AMC helps create a bright career both in academics and industry.

Dr ZAHEDA BANO
Professor & HOD of Pharmacology,
Guntur Medical College , Guntur

The Pharmacovigilance Programme of India empowers all HCPs with the means and procedures for ensuring patient safety. The communication of Drug Safety alerts to healthcare professionals helps improve patient care. By conducting Continuous Medical Education (CME) and Orientation/ Awareness programmes on PvPI boosts heath care at all levels.

Dr MONICA AGGARWAL
AMC Coordinator & Associate Professor, Department of Pharmacology,
ESICMC, Faridabad

We all know that Pharmacovigilance is considered an important pillar of modern pharmacology. As such the establishment of ADR Monitoring Centre (AMC) under Pharmacovigilance programme of India in the Department of Pharmacology is an honour for our ESIC Medical College and Hospital, Faridabad. Being Coordinator of the AMC, I appreciate NCC-PvPI, IPC for their efforts at improving health safety. Our PV team being part of this programme supports all PV activities aimed at raising awareness about drug safety among all HCPs.

Dr SHANTAPASSI
Pharmacovigilance Committee Member & Associate Professor,
Dermatology,ESICMC, Faridabad

ESICMC, Faridabad puts in best efforts for enriching the quality of PV. Our Skin department is proactively engaged in reporting adverse drug reactions and I appreciate the department of pharmacology, ESICMC for its outstanding contribution to promotion of PV activities initiated at all OPDs and wards of our hospital.

Dr A K PANDEY
Pharmacovigilance Committee Member & Registrar,
ESICMC, Faridabad

The Pharmacovigilance Programme of India plays a vital role in the field of reporting Adverse Drug Reactions. The continued PV activity at our AMC, ESICMC, is commendable as it has helped raise awareness for ADR reporting among all HCPs. I congratulate our AMC team for their contribution to health safety and wish them all the best.

Dr ANGELIKA BATTA
Deputy Coordinator & Assistant Professor, Department of Pharmacology,
ESIC Medical College & Hospital, Faridabad

Pharmacovigilance plays a key role in improving health care by ensuring that marketed drugs are safe and effective. As India is a pill-popping country, Pharmacovigilance programme of India (PvPI) has become an essential component for generating drug safety data. Our ADR Monitoring Centre at ESIC, Faridabad has been relentless in its efforts at fostering the culture of ADR reporting among clinicians, nurses and undergraduate students. As such efforts have been paying dividends, I congratulate PvPI for its support and efforts in making this programme a success.

दवाईयों से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की निगरानी एवं मरीजों की सुरक्षा के प्रति जागरुकता

फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार द्वारा जनहित में जारी

जैसा कि हम सभी जानते हैं कि दवाईयों (टैबलेट्स, कैप्सूल्स, सीरप, इंजेक्शन, टीके इत्यादि) के उपयोग से किसी न किसी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की सम्भावना रहती है इसको ध्यान में रखते हुए स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार ने एक विशेष कदम उठाया एवं इस कदम के अंतर्गत फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया को नवीकृत किया, जिसका राष्ट्रीय समन्वय केंद्र भारतीय भेषज संहिता आयोग, राजनगर, गाज़ियाबाद, उत्तर प्रदेश में स्थित है। इस समन्वय केंद्र का मुख्य कार्य दवाओं से होने वाले प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी ए.डी. आर. मॉनीटरिंग सेंटर के द्वारा एकत्रित करके उसका आँकलन एवं विश्लेषण करना है जिससे किसी भी दवा के फायदे एवं नुकसान की जानकारी अग्रिम कार्यवाही हेतु केन्द्रीय औषधि मानक नियंत्रण संगठन, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार को प्रेषित की जा सके।

"फॉर्माकोविजीलैंस का अर्थ है औषधि सतर्कता", यदि किसी मरीज या व्यक्ति को दवाई लेने के बाद कोई प्रतिकूल प्रभाव/दुष्प्रभाव जैसे कि त्वचा संबंधित परेशानी, डायरिया, जी मिचलाना, उल्टी, बुख़ार, रक्तचाप (उच्च/निम्न), सिरदर्द या अन्य कोई दुष्प्रभाव प्रतीत होता है तो ऐसी स्थिति में अपने चिकित्सक से या नजदीकी अस्पताल में जाकर चिकित्सक से परामर्श लें।

राष्ट्रीय समन्वय केंद्र फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया, में दवाईयों के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी एकत्रित करने हेतु विभिन्न सुवधिाजनक माध्यम उपलब्ध हैं, जैसे कि:

- निःशुल्क हेल्पलाइन नम्बर 1800-180-3024
  (सोमवार से शुक्रवार प्रातः 9:00 बजे से सायं 5:30 बजे तक)
- मोबाइल ऐप (ADR PvPI)
- ए.डी.आर. मॉनीटरिंग सेंटर
- ए.डी.आर. रिपोर्टिंग फॉर्म

(ए.डी.आर. मॉनीटरिंग सेंटर एवं फॉर्म की जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट www.ipc.gov.in पर उपलब्ध है)

अगर आपको पहले किसी दवा से किसी भी प्रकार की कोई असुविधा हुई हो तो अपने चिकित्सक को इसकी सूचना अवश्य दें, जिससे चिकित्सक को आपका उपचार बेहतर ढंग से करने में सहायता मिले।

यदि कोई चिकित्सक, फॉर्मासिस्ट, नर्स या अन्य कोई स्वास्थ्यकर्मी प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी देता है तो उनके विरुद्ध किसी प्रकार की कार्यवाही नहीं की जाती है बल्कि इससे दवाईयों के प्रभाव को बेहतर ढंग से समझने में एवं रोगी के उचित उपचार में सहायता मिलती है इसलिए अपने मन से इस प्रकार के समस्त डर व भ्रमों को दूर करके जनहित में स्वास्थ्य संबंधित इस महान कार्य में अपना सहयोग दें।

वर्तमान में भारत के अधिकतर राज्यों में ए.डी.आर. मॉनीटरिंग सेंटर कार्यरत हैं एवं राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजीलैंस विषय पर वर्ष भर कौशल विकास कार्यक्रम का आयोजन किया जाता है। इस कार्यक्रम की पूर्ण जानकारी भारतीय भेषज संहिता आयोग की वेबसाइट पर उपलब्ध है।

राष्ट्रीय समन्वय केंद्र द्वारा फॉर्माकोविजीलैंस प्रोग्राम ऑफ़ इंडिया आप सभी से अनुरोध करता है कि दवाओं के सेवन से हुए सभी प्रकार के प्रतिकूल प्रभाव/दुष्प्रभाव की जानकारी अवश्य दें जिससे कि दवाओं का सुरक्षित उपयोग सभी के लिए सुनिश्चित किया जा सके।

सत्यमेव जयते
IPC

Indian Pharmacopoeia Commission
National Coordination Centre,
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India,
Sector-23, Raj Nagar, Ghaziabad- 201002
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For any other Information/Suggestions/ Query contact:
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Website: www.ipc.gov.in

Let us join hands with PvPI to ensure patient safety

ADR reporting Helpline (Tollfree): 1800-180-3024