



## Journal of Pharmacovigilance & Drug Safety

### Conference Proceedings

## International Conference on Safety of Medicines & 21st Annual Conference of Society of Pharmacovigilance India

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### INTRODUCTION

In the ever-evolving landscape of healthcare, where the tapestry of medications expands with each passing year, ensuring the **safety** of these interventions remains paramount. This fundamental principle forms the bedrock of **pharmacovigilance**, a multifaceted discipline dedicated to the detection, assessment, understanding, and prevention of adverse effects associated with pharmaceutical products. With the growing prominence of **modern medicines** alongside the resurgence of **alternative therapies**, the field of pharmacovigilance faces an ever-increasing challenge: safeguarding patient well-being in the face of diverse pharmacological landscapes.

This crucial mission was the driving force behind the **International Conference and 21st Annual Conference of the Society of Pharmacovigilance, India (SoPICON 2024)**, held on February 10th–11th, 2024, at the Jawaharlal Nehru Medical College & Hospital. Hosted by the institution's pharmacology department, the conference served as a vital platform for fostering dialogue and collaboration among leading experts in the field. The theme, **"Safety of Medicines"**, resonated deeply, highlighting the collective responsibility to ensure the judicious use of both established and emerging therapies.

Pharmacovigilance (PV) stands as the cornerstone in the realm of healthcare, dedicated to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. It is a scientific discipline that focuses on monitoring and evaluating the safety profile of pharmaceuticals, striving to identify and manage risks associated with drug use. It extends beyond the clinical trial

phase, encompassing post-marketing surveillance to detect adverse drug reactions (ADRs) and ensure the ongoing safety of medications. The need for pharmacovigilance arises from the inherent complexity of drug interactions within diverse patient populations. Monitoring ADRs and understanding the benefit-risk balance becomes crucial in maintaining public health, ensuring patient safety, and fostering trust in healthcare interventions.<sup>1</sup> As the field continuously evolves, it becomes imperative to understand the essence of PV and its pivotal role in ensuring the safety of medicines.

Internationally, bodies such as the World Health Organization (WHO) and the Uppsala Monitoring Centre play key roles in coordinating global pharmacovigilance efforts. On the national front, regulatory agencies like the Central Drugs Standard Control Organization (CDSCO) in India oversee drug safety and regulate pharmacovigilance activities.

Pharmacovigilance in India began in 1986 with an official adverse drug reaction (ADR) monitoring system overseen by the drug controller of India. India became a member of the World Health Organisation (WHO) Programme for International Drug Monitoring in 1998, but did not achieve success. The National Programme of Pharmacovigilance was initiated in 2005 and rebranded as the Pharmacovigilance Programme of India (PvPI) in 2010. Steps were done to establish a strong pharmacovigilance system in India. The National Coordination Centre was relocated from AIIMS New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad. The PvPI aims to protect the health of the Indian population by ensuring that the advantages of medications surpass the hazards linked to their usage. ADRs reporting culture in India has made significant progress, with 250 PvPI-established adverse drug monitoring centres nationwide and training provided to healthcare workers. The initiative aims to establish trust between physicians and patients, enhancing patient safety and public confidence in

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the national healthcare system. It also focuses on identifying inferior medications and errors in prescribing, distributing, and administering medications. The IPC-PvPI is officially designated as a WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services. Despite its accomplishments, the PvPI encounters problems such as monitoring generic pharmaceuticals, biosimilars, and disease-specific adverse drug reactions of antidiabetic, cardiovascular, and antipsychotic medications. Additionally, raising awareness is an ongoing task. The PvPI is also working to tackle issues such as counterfeit medications, antimicrobial resistance, and surveillance during mass vaccinations and other government projects<sup>2</sup>.

The Society of Pharmacovigilance India (SoPI), the driving force behind this conference, stands as a national non-profit scientific organization committed to fostering both scientific and educational advancements in the field of pharmacovigilance. SoPI's mission transcends geographical boundaries, aiming to enhance all facets of safety concerns related to medicines. By facilitating a friendly environment for networking, providing collegial support among pharmacovigilance professionals, and offering an open forum for sharing experiences and knowledge, SoPI endeavours to promote science and learning in pharmacovigilance throughout India<sup>3</sup>.

Society of Pharmacovigilance India became the collaborator of the International Drug Monitoring Program in 1997. To train the young pharmacologists and allied health scientists, the first international workshop on Adverse Drug Reaction Monitoring was held at JNU Auditorium, New Delhi from November 9-12, 1998. It was hosted by Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh. Prof. K. C. Singhal was the organizing secretary for this event. During the international workshop mentioned above, it was deliberated to have an exclusive platform where scientists can share their own experiences related to ADR related issues, hence a separate society namely 'Society of Pharmacovigilance, India' (SoPI) was constituted and registered in 1999 with multiple aims and objectives. The main aim was to promote the study of the use and effects of drugs in population in a rational way; to determine the risk/benefit ratio of drugs in an individual and in general population and to establish a dialogue on Pharmacovigilance as a distinct and influential clinical specialization.

SoPI was the first national professional society in the world after European Society of Pharmacovigilance (ESoP). Prof. K. C. Singhal (Aligarh) was elected as the first president of the SoPI. Coincidentally, International Society of Pharmacovigilance (ISoP) was also formed in 1999. ISoP is originated from ESoP. For decades, ISoP and SoPI remained the only specialized societies in the world where like-minded consultants met and deliberated<sup>4</sup>.

The Department of Pharmacology at Jawaharlal Nehru Medical College (JNMC), Aligarh Muslim University, established in 1964 under the able guidance of Late Prof. P. N. Saxena, has been actively involved in Pharmacovigilance<sup>5</sup>. The Department is a pioneer in initiating Pharmacovigilance activities in India. Under the leadership of Prof. K.C. Singhal, the ADR multi-centric reporting system in India was established in 1989 as ICMR Project which later on was converted to ICMR Task Force Project in 1992.

The Department had also been designated as 'WHO Special Centre for ADR Monitoring' in 1997 until the Govt. of India started its own ADR Monitoring Program under the aegis of CDSCO with the help of the World Bank. The department showed keen interest in the new 'ADR Monitoring Program' and sent a 'letter of intent to CDSCO in 2003 to recognise the Department at least as one of the 'Peripheral Centers for ADR Monitoring'. When the status was not granted, a reminder was again sent to CDSCO in 2006 to participate in the National Pharmacovigilance Program (NPV). At present, under the new scheme of 'National Pharmacovigilance Program of India (PvPi)' being governed by the Pharmacopeia Commission of India, the J. N. Medical College and Hospital under the direct charge of the Principal and Chief Medical Superintendent is approved as one of the 'ADR Monitoring Centre (AMC)'.

The department strives hard by observing Pharmacovigilance Week every year and organizing several awareness drives for HCPs and the general public on PV and ADR reporting as well as sensitizing everyone on the need for rational use of medicines. The institute has a robust and efficient AMC (Adverse Drug Event Monitoring Centre) and a DPIC (Drug and Poison Information Centre) which is being helped to be run by the Pharmacology department.

In the past also, the Department of Pharmacology, J N Medical College, Aligarh Muslim University had hosted the 'International Symposium on Safe Medicine and Safe Patient' in collaboration with the Organizing Committee of XIV Annual Conference of Society of Pharmacovigilance, India (SOPICON'14)<sup>6</sup>.

Pharmacovigilance careers are in high demand worldwide, notably in the US and Europe. India has benefits for pharmacovigilance expansion, including widespread awareness of drug side effects, several formulations in the home market, numerous licenced drug makers, and a prospective global ADR database. India is one of the top pharmaceutical producers and exporters worldwide. It is the fourth largest pharmaceutical producer worldwide. India holds approximately 6,000 licenced medicine manufacturers and produces over 60,000 branded formulations. This will generate substantial career possibilities for pharmacovigilance professionals.<sup>7</sup>

In this report, we delve into the key highlights and insights gained from SoPICON 2024, exploring the multifaceted landscape of pharmacovigilance. From the role of artificial intelligence in revolutionizing pharmacovigilance practices to the importance of good pharmacovigilance practices and benefit-risk assessment and many more, this conference report aims to encapsulate the essence of the discussions that unfolded during the symposium speeches.

### Inauguration of SoPICON 2024

At the inauguration, the official souvenir of the conference was released amidst grand applause followed by the addresses of the chief guest, the guests of honour and the members of the organizing committee. The **Chief Guest, Dr. Peter Hjelmström, Director / CEO of Uppsala Monitoring Centre, Uppsala, Sweden**, provided insightful information, and important facts and figures on Pharmacovigilance. He reiterated the importance of pharmacovigilance. He emphasized that the UMC, the global





apex centre of pharmacovigilance, was diligently monitoring the safety of pharmaceuticals and adverse drug reaction reporting. He mentioned that India is a significant player in the pharmaceutical and healthcare sectors, but there is still a long way to go in adverse drug reaction reporting and monitoring. He expressed gratitude to SoPI and the Department of Pharmacology, JNMC, AMU, for organizing the event and their productive efforts in this regard. He said that he was grateful to have been invited here to present his insights and hear from other experts. **Dr. Joan D'souza, an International PV consultant from Switzerland**, expressed gratitude to the organisers, particularly **Prof. (Dr.) Syed Ziaur Rahman**, for inviting her to speak at the conference. She mentioned her enthusiasm to gain knowledge about the Indian situation and exchange her perspectives from the US and European nations.



**Dr. Yvonne Yirenyiwa Esseku, the Rector of the Ghana College of Pharmacists**, expressed gratitude to the organizers for inviting her to speak at the occasion. She emphasized the importance of international events in promoting awareness about Pharmacovigilance and the safety of pharmaceuticals. She stated that the conference aims to inspire aspiring pharmacologists and other professionals to enhance their understanding of pharmacovigilance and promote productive debates and partnerships. She expressed gratitude for learning about photovoltaics on a global and Indian scale and for being able to share her perspective and experiences in Ghana.

**Prof. Veena Maheshwari, the Dean of the Faculty of Medicine at JNMC, AMU**, highlighted the importance of prioritising patient safety and pharmacovigilance in her opening speech. She emphasized the historical origins of pharmacovigilance, linking it to the Thalidomide tragedy, which resulted in over ten thousand children being born with phocomelia after their mothers were given thalidomide during pregnancy. She recalled her undergraduate days when she learned about Pharmacovigilance from Prof. K.C. Singhal, who popularised the subject in India. **Prof. Haris M Khan, Principal and Chief Medical Superintendent of J.N. Medical College**, expressed gratitude and extended a warm welcome to all attendees at the conference. He anticipated that this event will provide an opportunity for sharing vital knowledge, exchanging creative research, and cultivating productive partnerships. He extended his best wishes to the organising committee for arranging the great event and expressed pride in JNMCH being selected as the location. **Professor Gulrez, the Vice-Chancellor of AMU**, expressed gratitude and delight for the institute being selected as the host for this worldwide event.

The conference offers a chance to engage in discussions with renowned experts and enhance knowledge in the areas of Pharmacovigilance and appropriate medication use. **Prof. Syed Ziaur Rahman**, in his roles as the Secretary of SoPI, the Organising Secretary of the Conference, and Chairman of the Department of Pharmacology at JNMC, AMU, warmly welcomed all attendees. He stated that the conference would act as a guiding light for sharing knowledge and ideas in the field of pharmacovigilance. SOPICON 2024 aims to expand academic perspectives and facilitate networking, collaborations, and conversations focused on guaranteeing the safety of pharmaceuticals for worldwide populations. **Dr. Sandeep Agarwal, the president of the Society of Pharmacovigilance in India**,

## J Pharmacovig Drug Safety

greeted all the esteemed guests and participants at the Conference. He extended a welcome to all delegates at the event on behalf of the Society of Pharmacovigilance (SoPI) India. He expressed gratitude emphasized the importance of prioritising medication safety and patient well-being. He further commended the Department of Pharmacology at Jawaharlal Nehru Medical College, Aligarh for its longstanding reputation for excellence in research and instruction. He stated that AMU is privileged to hold the 21st annual conference of the Society of Pharmacovigilance, India (SoPICON 2024). He expressed gratitude to Prof. (Dr.) Syed Ziaur Rahman, for undertaking the significant responsibility of organising a large event on short notice. We influence the future of pharmacovigilance by combining our collective experience and shared knowledge. **Dr. Jameel Ahmad, the Joint Organising Secretary**, urged all participants to actively participate in talks, provide unique thoughts, and expressed confidence that by working together, they could strengthen their dedication to ensuring the effectiveness and safety of pharmaceuticals. He anticipated that this conference would spark innovative techniques that would improve worldwide public health.

## John Autian and K. C. Singhal Orations



Every year in the honour of the two great figures in Pharmacovigilance- Dr. John Autian and Prof (Dr.) K. C. Singhal; two eminent speakers and pharmacovigilant experts, for making efforts and significant contributions in the field of Pharmacovigilance, are conferred with the prestigious John Autian and K.C. Singhal oration awards where for each oration, an expert delivers a speech.<sup>8</sup>

This year, the **K.C. Singhal oration** was given by **Dr. Peter Hjelmström, Director & CEO, UMC, Sweden** and was chaired by Prof K. C. Singhal (Aligarh) and Dr. Joan D'souza (Switzerland). The John Autian oration was given by **Dr. Joan D'souza, Intl. Consultant PV, Switzerland** and was chaired by Dr. Peter Hjelmström (Director UMC, Sweden) & Dr. Sandeep Agarwal (President, SoPI).

**Dr. Peter Hjelmström** is the Director/CEO of Uppsala Monitoring Centre (UMC) since March 1, 2023. UMC is designated as WHO Collaborating Centre for International Drug Monitoring, where Dr. Peter has the overall responsibility for its operation. He is by profession a physician and scientist, with MD and PhD degrees. He did his postdoctoral fellowship at Yale University, Connecticut (USA), and was an associate professor at Karolinska

**Rahman SZ, et al:** Internation Conference on Safety of Medicines

Institutet, Stockholm (Sweden). Earlier, he served the pharmaceutical industry for 17 years. His most recent role before joining UMC was as Chief Medical Officer at a Swedish pharmaceutical company. He has published several manuscripts in peer-reviewed scientific journals mainly within immunology and the pharmacoepidemiology of opioid dependence.

**Dr. Joan D'souza** is a Pharmacovigilance Physician and a Consultant. She has expertise in pre- and post-safety surveillance in pharma and medical devices. She is a lawyer (JD licensed to practice law in the state of Minnesota (US) and a physician with a Bachelor's in Homeopathic Medicine and Surgery. She earned a Dean's List recognition for academic performance after completing a post-baccalaureate clinical research program at the University of Cincinnati in the US.

She also obtained an advanced diploma in pharmacovigilance with software training. She is associated with many academic organisations including the DIA, World Drug Safety Congress, International Society of Pharmacovigilance (ISoP) and Global Pharmacovigilance Society. She is active in several ISoP special interest groups, including risk communication (secretary), medical devices, geriatric pharmacovigilance, vaccinations, medication error, and eco-pharmacovigilance and frequently contributes in the ISoP Drug Safety Journal. She also participates in other pharmacovigilance and medical devices special interest groups of the European Medical Writers Association and writes in its Journal.

## Conference Lectures

The conference featured presentations by pharmacovigilance specialists on several facets of pharmacovigilance.

The first session was chaired by Prof. Seema Rani (Sonapat) & Prof. Sunita Singh (Delhi). In this session, three guest speakers covered following topics. Dr. Ratinder Jhaj of AIIMS Bhopal discussed AI in pharmacovigilance. Pharmacovigilance uses AI technologies like ML, Deep Learning, and NLP to find unreported adverse events, Individual Case Safety Reports (ICSR), assess causation, and detect signals. PV data is difficult to use yet contains essential information. Traditional programming cannot solve data processing problems; hence AI is used.

Dr. Yvonne Yirenyiwa Esseku, Rector of Ghana College of Pharmacists, Ghana, spoke about pharmacovigilance and the critical nexus between community pharmacy practice and medication safety. Her talk showed that encouraging community chemists to use their skills reduces needless damage.

Dr. Manoj Sharma, Assistant General Manager and Head of the Global Pharmacovigilance Department of Win-Medicare Pvt. Ltd. in New Delhi, highlighted Good Pharmacovigilance Practices and Benefit-Risk Assessment. Post-authorization pharmacovigilance is needed due to insufficient benefit-risk balance in pharmaceutical development. The Good Pharmacovigilance Practices address clinical drug safety issues.

The special session on Materiovigilance was chaired by Dr. V. Kalaiselvan (Senior Principal Scientific Officer and Incharge, MvPI, IPC, Ghaziabad), **Dr. Vandana Roy**





In this special symposium on Materiovigilance, Dr. Sana Rehman, HIMSR, Delhi's Materiovigilance Coordinator and Asst. Professor lectured on how Healthcare increasingly relies on medical devices. Adverse incidents related to medical gadgets have increased as their use has increased. Medical device adverse events must be monitored to protect patients. The other speakers were from IPC, Ghaziabad including Dr. Shatrúnajay Shukla (Scientific Asst.), Ms. Krishna (Jr MvPI Associate) and Mr. Surya (Jr MvPI Associate).

Another interesting session was dedicated to Herbal Pharmacovigilance chaired by Dr. Abdur Rauf (Aligarh). In the special symposium of TM Pharmacovigilance, Vd. (Dr.) Sudipt Rath, an Associate Professor of Dravyaguna and IPVc Coordinator at NIA Deemed University in Jaipur, emphasized on Ayurveda pharmacovigilance. He used examples from Ayurvedic texts to show that PV was widely used in ancient India. In current pharmacovigilance, one should not only report adverse drug reactions (ADRs) but also minimise risks to ensure medication safety.

Dr. Sudha Revathy, Assistant Professor in the Department of Gunapadam at the National Institute of Siddha in Chennai, discussed Siddha pharmacovigilance. Despite many medical systems' advent, Siddha stands as effective. As an Intermediary Pharmacovigilance Centre, the National Institute of Siddha records adverse medication reactions at Ayothidas Pandithar Hospital, NIS, Chennai. It also records peripheral centre adverse medication responses and misleading ads. They reported 300 ADRs to the National Pharmacovigilance Centre, according to Dr. Revathy.

Unani Pharmacovigilance was explained by Dr. Noman Anwar of the Regional Research Institute of Unani Medicine in Chennai. The revival of holistic healthcare systems like Ayurveda, Unani, and Siddha has increased the usage of old medicines. AYUSH products are promising but unregulated. He highlighted that Traditional medicine (TM) is a valuable source of health remedies worldwide, and its popularity is growing. Traditional medicine is becoming more popular in many countries, raising concerns about safety and harmful drug reactions. A Pharmacology expert at CCRUM Headquarters in New Delhi, Dr. Ritu Karwasra discussed Pharmacovigilance in the Unani System of Medicine. Based on Hippocrates' ancient teachings, the Unani school of

medicine provides preventative, promotive, curative, and rehabilitative therapy. Her lecture stressed the significance of Pharmacovigilance in the Unani System of Medicine to monitor, report, and prevent illness.

Symposium 5 was chaired by Dr. Ahmad Najmi (Bhopal). In this session, it was deliberated that pharmacovigilance is a key patient safety indicator, according to HIMSR's (New Delhi) Dr. Nusrat Nabi. She described how The Pharmacovigilance Programme of India (PvPI) uses its extensive network to check pharmaceutical safety and patient safety, showing patient care quality. Likewise, Dr. Anisha Prasad of MCDMC, New Delhi, explained pharmaceutical mistakes. The lecture concluded that understanding drug errors may help healthcare workers deliver safe treatment. Dr. Nitin Kothari, Professor and Head of Pharmacology at GMC Dungarpur in Rajasthan, stressed paediatric pharmacovigilance.

Symposium 8 was chaired by Dr. Yvonne Yirenyiwa Esseku (Ghana) and Dr Sanjeev Kumar (Khanpur kalan, Sonapat). In this session, Dr. Vandana Roy, Director Professor & HOD (Pharmacology), MAMC, New Delhi, highlighted spontaneous and newer ways of ADR reporting. Computerised adverse medication reaction detection methods are improving drug safety monitoring alongside spontaneous reporting. Drug safety monitoring requires determining their potential and condition. Dr. Kirti Vishwakarma, Associate Professor and Head of the Department of Pharmacology at ASMC Firozabad, lectured on Pharmacovigilance and Antimicrobial Resistance. AMR is a global public health issue that makes infections harder to treat, straining healthcare systems. Drug ineffectiveness and treatment failure reports should include antimicrobial resistance, a neglected side event.

The previously reported PVPI tablets, signals, and drug alerts were studied by Dr. Seema Rani, Professor and Head of the Department of Pharmacology at BPS GMC for Women in Khanpur Kalan, Sonipat. For Indian drugs, PvPI has amended 56 prescribing information leaflets (PIL), verified 12 signals, and issued 156 drug safety alerts. She reported that 12 signals have been confirmed and CDSCO has ordered the updating of 53 medicines and 3 vaccine Patient Information Leaflets (PIL). Prof. Prithpal Singh Matreja, Head of the Department of Pharmacology at TMMCRC in Moradabad, explained pharmacoepidemiology. Pharmacoepidemiology studies pharmacological efficacy, side effects, and use in large populations. This epidemiology section focuses on pharmaceuticals.

Symposium 9 was chaired by Dr. Prithpal S Matreja (TMU, Moradabad) and Dr. Pramendra Maheshwari (Bareilly). Dr. Ahmad Najmi, an Associate Professor of Pharmacology at AIIMS Bhopal, presented a Narrative Review of Orthopaedic Implant Associated Adverse Events on Materiovigilance. The study found that orthopaedic implant MDAEs were mostly caused by infections. Causality and root cause assessments are greatly delayed by underreporting. He suggested healthcare practitioners have continuing awareness and training to combat underreporting.

Dr. Anil K. Chaudhary from BRD Medical College in Gorakhpur studied cardiovascular disease risk variables

among HIMS Sitapur medical and nursing students. He found that health education and primary therapies including weight loss, blood pressure control, and glucose management improve biological risk factors for cardiovascular disease. Lucknow's Integral Institute of Medical Science and Research Department of Pharmacology's Dr. Jahangir Ahmad Shaikh addressed Adverse Events Following Immunisation. India manufactures global vaccinations as a developing nation. The nation's immunisations are safe and effective. Like other pharmaceuticals, vaccines contain risks and may cause side effects.

### Valedictory Function and Cultural Night

Dr. Syed Z. Rahman, Organizing Secretary, thanked all contributors, participants, administration and funding agencies for supporting and making this international conference successful. The conference saw a record registration of more than 212 participants and delegates from other countries as well. The guest of honours presented the Uppsala award to Dr. Ayan Roy, Assistant Professor at the Department of Pulmonology, VIMSAR, Sambalpur, Odisha, for his poster on Trigger Tools for Comprehensive ADR Reporting in A Tertiary Care Pulmonology Indoor: A Record Based Study. All the participants of the free oral and poster presentations were congratulated for their brilliant efforts and were handed their certificates.

A cultural night was also organized in the evening of the first day. It proved to be a great opportunity for all the participants to socialize with their peers and counterparts from other institutes all over the country as well as exchange their ideas and seek guidance from experts from India and other nations.



All the delegates were enthralled by the mesmerizing cultural performances by the AMU students which included singing performances and a live sand art performance. The renowned Ghazal singer- Mr Johnny Foster won the audience's hearts with his soul-stirring ghazals. The cultural night ended with a sumptuous dinner.

### Conclusion

The conference was successful in creating awareness and stressing the importance of pharmacovigilance. Everyone, including the guests of honour, praised the efforts of the organizing committee and the residents of the pharmacology department, JNMCH, for putting up such a grand scale international event at such short notice. Prof. Ratinder Jhaj, from AIIMS, Bhopal, released the official invitation to the next SoPICON at AIIMS, Bhopal before the conference came to a close.

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