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About SEARN

The South-East Asia Regulatory Network (SEARN), launched by the World Health Organization (WHO), is a groundbreaking initiative aimed at enhancing health security and improving regulatory practices across the South-East Asia Region. By fostering collaboration among the 11 member countries—Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, and Timor-Leste—SEARN seeks to address the challenges of regulating medical products, particularly in smaller countries. The network's focus on harmonizing regulatory standards and promoting information sharing aims to ensure better access to high-quality, safe, and effective medical products, ultimately contributing to stronger health systems and progress toward universal health coverage.

To achieve its objectives, SEARN is supported by five specialized Working Groups (WGs), each providing specific technical support to drive the initiative forward. These groups include: WG1: Quality, which ensures the safety and efficacy of medical products; WG2: Regulatory Strengthening, focused on enhancing national regulatory agencies; WG3: Vigilance, responsible for ongoing monitoring of medical product safety; WG4: Information Sharing, which promotes data exchange and best practices among members; and WG5: Medical Devices, dedicated to the regulatory aspects of medical devices. By working together, these groups help strengthen regulatory frameworks and promote continuous improvement in health security across the region.

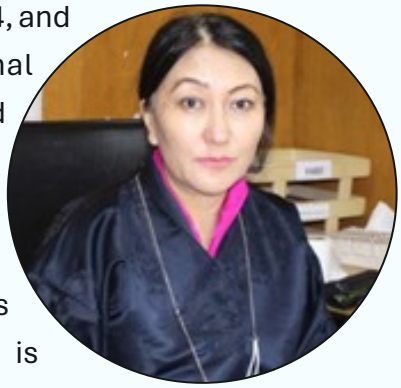
South-East Asian Region

Introduction to SEARN countries

Bangladesh

The Drug Regulatory Authority (DRA) of Bangladesh is the Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare (MoHFW), currently led by Major General Md. Shameem Haider, Director General. Located in Dhaka, the Directorate of Drug Administration, established in 1976 under the MoHFW was upgraded to the DGDA in 2010. The DGDA is responsible for ensuring the safety, efficacy and quality of pharmaceutical products & Vaccines in use in the country, and also regulates all manufacturing processes involved for medicinal products, (including Ayurveda, Unani, Herbal and Homeopathic products), including procuring raw materials and import and export of pharmaceutical products. In 2013, the ADR Monitoring Cell was established by the DGDA as the national pharmacovigilance center under the MoHFW. There are currently 54 districts offices under the DGDA, with each office having districts officials to uphold Drug & cosmetics Laws and to assist as the Licensing Authority.

Bhutan



The Medical Product Division was established in Thimphu, Bhutan in 2004, and is responsible for monitoring, authorizing and registering medicinal products manufactured, exported and imported in the country and disseminating updated information regarding medical products and pharmacovigilance to the general public. Mrs. Gyem Bidha is the current director of the Bhutan DRA. The Post Marketing Control Division (PMCD) is responsible to ensure safety, efficacy and quality of medicinal products marketed in Bhutan. The Pharmacovigilance Unit, under the PMCD, is responsible for collecting and monitoring of ADRs, performing causality assessment and reporting the same to the UMC.

India

The Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health & Family Welfare, Government of India, is the national regulatory authority responsible for ensuring the safety, efficacy, and quality of drugs, cosmetics, and medical devices in India. Headquartered in New Delhi, CDSCO plays a crucial role in approving new drugs, overseeing clinical trials, setting standards for medicines, and regulating medical devices. With the introduction of the Pharmacovigilance Programme for India (PvPI) in 2010 and its mandatory implementation in 2016, CDSCO has strengthened its focus on drug safety, ensuring that manufacturers and importers adhere to stringent monitoring practices.Under the leadership of Dr. Rajeev Singh Raghuvanshi, the Drugs Controller General of India (DCGI), CDSCO continues to evolve and adapt to emerging challenges in the pharmaceutical and healthcare sectors. The organization is at the forefront of aligning India's regulatory practices with global standards, ensuring the country's pharmaceutical products are of the highest quality and safety.

Indonesia

The Food and Drug Authority in Indonesia: Badan POM, located in Jakarta, was founded in the year 2001, with the purpose of assessing safety and quality of food and medical products marketed in the country, and to ensure and adhere to regulatory laws governing the same. The current head of Badan POM is Dr. Taruna Ikrar. The organization is responsible for preparing and implementing national policies for supervision, manufacturing and distribution of drug and food products, and for providing technical guidance where required.

Maldives

The Maldives Food and Drug Authority (MFDA) was established under the Ministry of Health in the year 2006, and is currently led by Dr. Faleen Mahadh. The MFDA regulates the manufacturing and distribution, and ensures the safety, efficacy and quality of drug and food products in Maldives. The Medicines and Therapeutic Goods Division (MTG) under the MFDA is particularly responsible for regulation of medicines and medical products, and also for reviewing existing policies and procedures to optimize drug quality.

Myanmar

The Food and Drug Administration (FDA) of Myanmar was first established in 1995 as a division under the Ministry of Health. It was later upgraded to a separate department in April 2013. The FDA's primary mission is to ensure the safety and quality of food, drugs, medical devices, and cosmetics across the country. Its headquarters is located in Nay Pyi Taw, Myanmar's capital. In 2018, Myanmar joined as an associate member of the World Health Organization- Programme for International Drug Monitoring (WHO PIDM). While Myanmar's pharmacovigilance program is still in its early stages, the country has made significant progress. The Myanmar FDA established an adverse drug reaction (ADR) reporting system in 2002 and has distributed ADR reporting forms to hospitals, health offices, and drug advisory committee members nationwide.

Nepal

The Department of Drug Administration (DDA) was established by the Government of Nepal in 1979 in accordance with the Drug Act of 1978, under the Ministry of Forests and Soil Conservation, before transitioning to the Ministry of Health and Population. The DDA serves as the focal point for Nepal's National Pharmacovigilance Center in 2004, tasked with monitoring and ensuring the safety of pharmaceuticals in the country. The DDA focuses on improving the coordination and collaboration among government, non-governmental, and private organizations involved in the entire pharmaceutical supply chain—from production and import to distribution, sales, and regulatory control. Under the leadership of director general Narayan Prasad Dhakal, who assumed office in June 2023, the DDA continues to enhance its operations with three regional offices located in Biratnagar, Birgunj, and Nepalgunj. These offices are pivotal in conducting routine inspections, handling drug registrations, and overseeing the renewal of pharmacies, all while ensuring the effective enforcement of the Drugs Act of 2035 and other DDA guidelines.

Sri Lanka

The National Medicines Regulatory Authority (NMRA) was established in Colombo in 2015, under the Ministry of Health, as the DRA of Sri Lanka, with the aim of improving patient access to quality medical products. The current chairman of NMRA is Dr. Ananda Wijewickrama. NMRA is responsible for approval and monitoring the manufacturing, pricing and adverse reactions associated with marketed drugs in Sri Lanka.

Thailand

In 1967, the Drug Act was introduced in Thailand, leading to the establishment of the first drug policy committee in 1980. The Adverse Drug Reaction Monitoring Centre was founded in 1983, and in 1994, the FDA moved to the Ministry of Public Health in Nonthaburi. Dr. Surachoke Tangwiwat currently serves as the Secretary-General of the Food and Drug Administration. The organization's vision is to be the leading entity for consumer protection and the promotion of health product entrepreneurs, ultimately benefiting public health. Its mission focuses on elevating consumer protection standards in line with international guidelines, regulating health products to ensure compliance with laws, and guaranteeing their quality and safety through digital technology and innovation.

The Democratic People's Republic of Korea

The Food and Drug Safety Administration in the People's Democratic Republic of Korea was established in February 1998. In 2004, the Medical Device Management Division and the Bio Product Technical Support Division were formed. By 2010, the Adverse Effect Inspection Team from the National Institute of Food and Drug Safety Evaluation was dissolved and transitioned into the Pharmaceutical Safety Information Team under the Pharmaceutical Safety Bureau of the KFDA. In November of that year, the KFDA relocated to the Osong Health Technology Administration Complex in Chungbuk. OH Yu-Kyoung, the former minister of the Ministry of Food and Drug Safety, focuses on ensuring the safety of food and medical products essential for daily life. The Ministry of Food & Drug Safety is committed to achieving international harmonization in regulations governing food and medical products while enhancing its role in the global community.

Timor-Leste

The Ministry of Health in Timor-Leste is responsible for managing and executing the nation's healthcare policies and initiatives. Its mission is to guarantee access to quality healthcare services for the population and to promote overall public health. In May 2019, Timor-Leste became an associate member of the World Health Organization's Programme for International Drug Monitoring, joining 29 other associate members alongside 136 full members. Since gaining independence and becoming a United Nations member state in 2002, the country has continued to strengthen its healthcare system and international collaborations

Pharmacovigilance in Bangladesh

GVP guideline implementation Programs for MAH

In September 2023, the Directorate General of Drug Administration (DGDA) organized three training programs in Dhaka on the newly formulated Good Pharmacovigilance Practices (GVP) Guidelines for Marketing Authorization Holders (MAHs). The sessions, which included orientations, group work, and Q&A, aimed to help MAH representatives understand their responsibilities under the guidelines. These programs were supported by WHO and the USAID MTaPS Program, and a copy of the guideline was distributed to all participants. The GVP Guidelines were developed by DGDA with the Ministry of Health and Family Welfare's endorsement, involving industry representatives and public consultations.

GVP Inspection

The Pharmacovigilance Department of the Directorate General of Drug Administration (DGDA) plays a critical role in ensuring the safety and efficacy of pharmaceuticals in Bangladesh. As part of its regulatory efforts, the DGDA conducts regular inspections of Marketing Authorization Holders (MAHs) to ensure compliance with the Good Pharmacovigilance Practices (GVP) Guidelines and the Drugs and Cosmetics Act 2023.

PV inspection going on at Incepta Pharmaceuticals Ltd.(left) and Healthcare Pharmaceuticals Ltd

These inspections, which follow a structured annual plan, assess key aspects such as adverse drug reaction monitoring, safety reporting systems, and risk management plans. The DGDA has already conducted inspections at leading MAHs like Incepta Pharmaceuticals Ltd., Popular Pharmaceuticals Ltd., Healthcare Pharmaceuticals Ltd., Radiant Import & Export Ltd., and Janata Traders. These inspections help identify compliance gaps, promote alignment with international best practices, and strengthen the safety of medicines in the country. The DGDA also provides recommendations for improving pharmacovigilance practices and offers assistance in enhancing safety reporting and monitoring systems.

GVP Inspection at different MAHs: (1) Radiant Export & Import (2) Janata Traders (3) Popular Pharmaceuticals

World Patients Safety Day-2024 celebration

On September 17, 2024, the Directorate General of Drug Administration (DGDA) hosted a roundtable discussion in observance of World Patient Safety Day, led by the DGDA Director General. The event brought together key stakeholders, including the Bangladesh Association of Pharmaceutical Industries (BAPI), healthcare providers, the World Health Organization (WHO), USAID's MTaPS Program, and others, to discuss ways to enhance patient safety in Bangladesh. Topics included quality control in medicines, safe prescribing, and minimizing healthcare errors. The event also emphasized the importance of accurate diagnosis in patient safety, aligning with this year's theme, “Improving Diagnosis for Patient Safety” and the slogan, “Get it Right, Make it Safe!” A rally with banners and festoon balloons further promoted awareness around diagnostic practices and safe medication use.

Roundtable discussion session at the DGDA Conference Hall

The event also emphasized the importance of accurate diagnosis in patient safety, aligning with this year's theme, “Improving Diagnosis for Patient Safety” and the slogan, “Get it Right, Make it Safe!” A rally with banners and festoon balloons further promoted awareness around diagnostic practices and safe medication use.

Rally on World Patient Safety Day, 2024

Strategy development for increasing Non EPI Vaccines' AEFI Reporting

The Directorate General of Drug Administration (DGDA) in Bangladesh is working toward achieving WHO maturity level III in vaccine safety surveillance. In response to WHO recommendations, DGDA has developed two key strategies: the National Non-EPI Vaccine Safety Surveillance Strategy-2024, focused on non-routine vaccines, and the National Strategy for Integrating Post-Vaccination Vigilance, aimed at integrating vaccination vigilance into broader health surveillance systems. Both strategies were developed with WHO technical support and guidance from consultants based in Bangladesh. To refine these strategies, DGDA held three consultative workshops with stakeholders, including health professionals and public health experts. These efforts align with WHO's SEARN Action Points 10 and 11, aiming to improve vaccine safety reporting and integrate vigilance systems, ultimately enhancing Bangladesh's ability to monitor and manage vaccine safety. These initiatives are key to achieving WHO maturity level III and safeguarding public health.

Workshop on National non EPI Vaccine Safety Surveillance Strategy-2024 & National Strategy for integrating post-vaccination vigilance

Pharmacovigilance in Bhutan

The Medical Product Division (previously known as Drug Regulatory Authority) under the Bhutan and Food and Drug Authority became a member of the WHO Program for International Drug Monitoring in the year of 2014. The agency was identified as National Phamacovigilance center by the Bhutan Medicines board with three regional vigilance centers, represented by eastern, central and National referral hospitals. Since then, pharmacovigilance has been slowly growing and suspected Adverse Drug Reaction reports were shared to UMC through VigiFlow.

The national pharmacovigilance center with support from regional centers, have been conducting sensitization workshops, distributing guidelines and reporting forms to the health centers in the country.

As of today we have sensitized over a thousand healthcare professionals specially physicians, Nurses and pharmacists. VigiFlow access was provided to every health center in the country. ICSRs are verified and shared to the global database.

Pharmacovigilance Workshop conducted in Bhutan

Pharmacovigilance Workshop conducted in Punakha

In the year of 2024, the BFDA has conducted two rounds of vigilance workshops with the financial support from the WHO, targeting all the relevant healthcare professionals. Doctors, Nurses and Pharmacists/Pharmacy Technicians from all the hospitals from 10 bedded to referral hospitals in the country including military hospitals of the Royal Bhutan Army were trained on pharmacovigilance, Materiovigilance system; and related tools for reporting incidents to the BFDA. The first batch of the sensitization workshop took place from April 22nd to 26th, 2024, at Kaila Guest House, Bumthang with 35 participants from the eastern districts. The second batch was held from May 27th to 31st, 2024, at Hotel River Valley in Punakha with 48 participants from the western districts.

Pharmacovigilance Workshop conducted in Bhutan

A 5 day Pharmacovigilance Workshop held in Bhutan

Participants were educated on the importance of vigilance and skills for identifying adverse events associated with medical products. They were also trained on using reporting forms and online reporting systems. Additionally, participants were provided credentials for VigiFlow and the Substandard & Falsified Product Reporting System for reporting incidents related to use of medical products. Hands-on training on using the system was also carried out during the workshop.

The workshop included participant introductions, a brief mindfulness meditation session, presentations, Q&A sessions, group work, and hands-on activities. The 5-day program concluded with participants committing to actively engage in the vigilance system. They agreed to share the knowledge gained with their colleagues and promote a culture of reporting any suspected adverse events associated with medical products and substandard or falsified products.

Training on Materiovigilance for regulators and Health professionals

In 2022, the Medical Product Division (MPD) of the Bhutan Food and Drug Authority (BFDA) expanded its regulatory scope to include medical devices, recognizing the increasing reliance on these products and technologies in healthcare. Given the nascent stage of medical device regulation in Bhutan and the complexities involved, building capacity in key areas particularly post-marketing surveillance became a strategic priority for the BFDA.

To address this critical need, the BFDA, in collaboration with the Indian Pharmacopoeia Commission (IPC) and the Central Drug Standard Control Organization (CDSCO), organized a five-day training on materiovigilance in February 2024. The program aimed to empower regulators and health officials with the knowledge and tools necessary to ensure the continued safety, quality, and effectiveness of medical devices in Bhutan.

The IPC, serving as the National Coordination Centre (NCC) for the Materiovigilance Programme of India (MvPI), brought extensive expertise to the training, leveraging its proven track record of delivering high-quality materiovigilance training sessions. The trainers provided participants with hands-on technical insights into monitoring and reporting adverse events related to medical devices—a critical component of post-marketing surveillance.

The training also emphasized a multi-stakeholder approach, recognizing the integral roles played by health professionals such as nurses, biomedical engineers, and other technical personnel. These participants were sensitized to the broader framework of medical device regulation and the importance of vigilant practices to identify and mitigate risks associated with medical devices in clinical settings. The training introduced the participants to Materiovigilance Systems, Adverse Event Reporting, significance of stakeholder engagement especially the vital role of Health professionals in ensuring device safety and creating a collaborative approach to post-marketing surveillance.

IPC and CDSCO officials, in collaboration with the BFDA, organized a 5 day training on Materiovigilance at Bhutan

This initiative marks a significant step forward in strengthening Bhutan's regulatory framework for medical devices, ensuring that the evolving healthcare landscape is supported by robust safety measures.

Pharmacovigilance in India

Pharmacovigilance in India began in 1986 with the establishment of a formal ADR monitoring system under the Drug Controller of India. Although India joined the WHO Programme for International Drug Monitoring in 1998, it initially faced challenges. In 2005, the National Programme of Pharmacovigilance was launched and renamed the Pharmacovigilance Programme of India (PvPI) in 2010. The National Coordination Centre moved from All India Institute of Medical Sciences, New Delhi to the Indian Pharmacopoeia Commission (IPC) in Ghaziabad to strengthen the system. PvPI now oversees 976 ADR monitoring centres and trains healthcare professionals to ensure medicine safety for the Indian population.

The IPC has conducted a total of 2,104 training sessions, engaging approximately 164, 963 participants in the year 2024. In India, Pharmacovigilance Week is celebrated annually during the 3rd week of September. As in previous years, Pharmacovigilance Week was celebrated from the 17th to the 23rd to raise awareness.

National Pharmacovigilance Week at IPC, 2024

The National Pharmacovigilance Week 2024 was celebrated from 17th-23rd September , with the theme "Building ADR Reporting Culture for Patient Safety," organized by the National Coordination Centre for the Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC). The event aimed to raise awareness about the significance of reporting Adverse Drug Reactions (ADRs) and its role in enhancing patient safety across India. Coinciding with World Patient Safety Day on September 17, it was observed both physically and virtually, engaging a wide range of participants from healthcare professionals, pharmaceutical industries, academic institutions, and the general public.

Lamp Lightning by Dr Rajeev Singh Raghuvanshi Secretary-cum-Scientific Director, IPC during the Inaugural ceremony of 4th National Pharmacovigilance Week celebration on 17th September, 2024

The event began with an inaugural ceremony attended by Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director of IPC, who highlighted the progress of the Pharmacovigilance Programme of India (PvPI). Distinguished speakers, including Prof. Y.K. Gupta, Dr. Sunil Singhal, Dr. Rajendra P. Joshi, and Shri Bikash R. Mahato, emphasized the importance of ADR reporting in safeguarding patient health. During the ceremony, various promotional materials were launched, including the PvPI poster, Quality Manual, Guidance Document, and a comic to educate the public about pharmacovigilance.

The week also featured an international webinar on optimizing Individual Case Safety Reports (ICSRs) for signal detection, with experts from the World Health Organization (WHO) and participants from the South-East Asian region. Additional activities included a Pharmacovigilance Quiz, an E-Poster competition (which received 197 submissions), and a Stakeholders' Meeting.

International Webinar during the National Pharmacovigilance Week Celebration 2024 on 18th September 2024

The celebration concluded with a valedictory ceremony on 23rd September recognizing top ADR monitoring centres (AMCs) and Marketing Authorization Holders (MAHs). Experts like Prof. M. Ramesh and Prof. Vandana Roy were acknowledged for their contributions to the success of PvPI. The event ended with the distribution of certificates and a video recap of the week's activities.

Dr. Shanthi Pal addressing at International Webinar during The National Pharmacovigilance Week Celebration 2024 on 18th September, 2024

Pharmacovigilance in Indonesia

Establishment of East Java Province Task Force for drug safety review on 21st May 2024, Surabaya, East Java.

Realizing one of the key successes of pharmacovigilance system to be effectively functioning, for such a big country like Indonesia, a good collaboration, coordination, and communication amongst relevant stakeholder both in national and sub national level is a quite challenging. BPOM continues to strive to increase the implementation of pharmacovigilance in Indonesia. Since 2018, one of the efforts to strengthen pharmacovigilance that has been carried out includes strengthening the national pharmacovigilance center by establishing a pharmacovigilance center at the Technical Implementation Unit (UPT) which located in each Provinces throughout Indonesia. Furthermore, to improve the collaboration, coordination, and communication with relevant key stake holder, BPOM have also conducted advocacy programs to raising awareness on the important of pharmacovigilance and seeking stakeholder supports by also appoint dedicated focal point from each institution for pharmacovigilance at the Provincial Health Office, District Health Office, and Hospitals. BPOM have also conducted continuous programs for strengthening pharmacovigilance capacity by carrying out training and technical guidance for the pharmaceutical industry and health workers, strengthening cross-sector networks in implementing pharmacovigilance.

To enhance the collaboration, coordination, and communication at the provincial level, BPOM develop an implementation framework of Coordination Team, that consists of focal points from UPT BPOM and relevant stakeholders, including develop a task force (comprises of panel experts from academia, health care professional associations, and clinicians) for supporting the team to review serious the AE/ADR reports from the Hospitals in the region.

Opening of a National Communication Forum for Pharmacovigilance by the Acting Head of Indonesian FDA (Dr. Rizka L. Andalucia), on 1st- 4th May 2024, Bandung, West Java

Pharmacovigilance training for pharmaceutical companies (batch 2) on 29th- 31st May 2024, Bekasi, West Java.

BPOM also has regular national meeting for pharmacovigilance, one of the events that had been held was a national communication forum for pharmacovigilance, by inviting all relevant key players. In 2024, this forum was conducted in Bandung, West Java, on 2 – 3 of May inviting various key players, from Ministry of Health, National Committee of AEFI, Academia, and WHO. The forum was a hybrid meeting, attended by participants and speakers both offline and online. One of the speakers that attended online was Dr. Adrien Inoubli (Regional Advisor-World Health Organization-Southeast Asia Region) to share with us and our colleagues in Indonesia, regarding regulatory system strengthening that covers WHO Global Benchmarking Tools, as well as WHO Listed Authority topics.

For improving the capacity of pharmaceutical industries to be able to implement good pharmacovigilance practice, BPOM has conducted a series of training divided into 3 (three) batches, with the total participants were 153 participants. The Training materials provided with some working group and exercises activities that allow interactive processes throughout the training sessions. The trainers are not only from regulator and academia, but also representative from pharmaceutical company that already develop a good pharmacovigilance system. The topic of this training covers i.e.: Regulation, Pharmacovigilance Principles, Causality Assessment, Individual Case Safety Report Management, Develop Pharmacovigilance System in a pharmaceutical company based on updated regulation, Risk Management, Signal Management, and Risk Communication. By increasing pharmacovigilance competency for the pharmaceutical industry, it is hoped that it can increase the understanding of the pharmaceutical industry in implementing pharmacovigilance, so that drug safety monitoring is carried out optimally to ensure patient safety and protect the health of the Indonesian public.

A good vigilance system will support the BPOM as a competent drug regulatory authority, becoming a reference at both national and international levels. This includes fulfilling a strengthened structured pharmacovigilance system in all levels, starting from the national, sub-national and health facilities levels.

Pharmacovigilance in Nepal

Department of Drug Administration (DDA), with the vision to ensure safe, quality and effective medicines to safeguard the health of the people of Nepal, working towards strengthening national pharmacovigilance program. At present, there are 19 regional PV centers recognized by the department and they report the ADRs to the national PV center via vigiflow. With the objective to improve ADR reporting and strengthen coordination and information sharing among national centre and regional PV centre hospitals, a one-day interaction program on pharmacovigilance and adverse drug reaction reporting was conducted on 20 December 2024 with the support of WHO Nepal. 45 participants representing from regional PV Centre hospitals, DDA, Nepal Medical Council, Nepal Pharmacy Council, Nepal Nursing Council, WHO Nepal attended the program.

Key discussions were mainly on updates on national pharmacovigilance program, progress on PV interventions along with challenges and possible ways forward by regional PV center's hospitals. The challenges mainly includes lack of awareness of PV importance to Hospital Administration/ Management level, inadequate knowledge and awareness to all health professionals, HR issues, multiple tasks, unwillingness of health care professionals to report and high turn-over rate of staffs. Despite the challenges, remarkable progress has been made by some of the regional PV centre hospitals which include establishing PV unit with appointed PV officers, periodic awareness program for health professionals in the hospitals, development of Yellow card form, ADR alert stickers, Drug Allergy card, Medical errors monitoring, efforts to implement integrated software within the hospital for early and timely reporting.

Interaction program on pharmacovigilance and adverse drug reaction reporting held on 20th December 2024

Interaction program on pharmacovigilance and adverse drug reaction reporting held on 20th December 2024

The key recommendations highlighted included increasing the frequency of interaction among the National and Regional PV centers, advocacy meeting with hospital management and health care professionals in the regional centre hospitals, nationwide awareness campaign on pharmacovigilance to health professionals, inclusion of PV and ADR reporting in medical, pharmacy and nursing curriculum, research and publications related to patient safety and PV, collaboration with universities, patient organizations and other stakeholders in order to coordinate resources and streamline efforts in medicines safety in the country. The program has helped to improve the information sharing between national and regional centre to improve the pharmacovigilance program.

SEARN Assembly 2024 at Dhaka

A meeting was conducted for members of the South-East Asian Regulatory Network (SEARN) in Dhaka, Bangladesh to discuss the theme 'Safe Medicines during Pregnancy' from 1-4 July, 2024, chaired by Major General Muhammad Yousuf from Bangladesh.

SEARN assembly meeting held at Dhaka, Bangladesh from 1st- 4th July, 2024

The Assembly was informed about the latest global developments in the regulation of medical products and covered the importance of reliance, activities strengthening the regulatory system, and WHO Listed Authorities (WLAs). The process of introducing new vaccines and challenges faced in the region, as well as the importance of streamlining regulatory processes to ensure timely access to quality, safe and effective vaccines were also discussed. The main theme of the meet, regarding drug safety in pregnancy, was discussed in two sessions. Topics presented include safety surveillance of maternal and perinatal health challenges and importance of counseling patients with complete, accurate and current information on the risks and benefits of medicinal products, and drug safety in pregnancy and strategies for risk management and minimization. The Assembly's recommendations to SEARN were recorded in Action Points in the work plan.

Also discussed was the challenge of antimicrobial resistance in the region, and the measures taken to combat the challenge. The support provided by the SEARN Coalition of Interested Parties (CIP) during the 2023-2024 work plan was reviewed by the Assembly. The 2024-2025 work plan was discussed, amended and adopted, along with the proposed rapporteurs and drafting group members. For the assembly of SEARN members in the upcoming years, Bhutan was announced to be the hosting nation for 2025, followed by Nepal in the year 2026.

SEARN meeting on increased reporting

A meeting was held on October 13, 2024, with the aim of enhancing the safety of medical products by supporting member states in improving the reporting of adverse events related to medicines and vaccines. Chaired by Dr. Adrien Inoubli, the Regional Advisor for Medical Products & Quality at the World Health Organization (WHO), the meeting brought together key participants, including Pharmacovigilance (PV) focal points from National Regulatory Authorities (NRAs) and National PV Centers, vaccine safety focal points from National Immunization Programs, members of the Indian Pharmacopoeia Commission (IPC), and representatives from the Uppsala Monitoring Centre (UMC). The event, which was held both in-person and virtually at Vivanta by Taj, Dwarka, focused on fostering collaboration to strengthen reporting systems across the region.

SEARN meeting on increased reporting held at New Delhi, India on 13th October , 2024

The meeting's objectives included developing national strategies to boost reporting through a template created by the Southeast Asian Regional Pharmacovigilance Network (SEARN), sharing insights from IPC's experience in addressing low reporting rates, and agreeing on target reporting rates and timelines at the regional level. Participants also discussed key barriers to reporting and identified priority actions, tools, and stakeholders to overcome these challenges in subsequent workshops.

To support the discussions, SEARN members presented their draft national strategies for increasing reporting, while Dr. V. Kalaiselvan, Senior Principal Scientific Officer at IPC, shared insights on tackling low reporting rates, challenges encountered, and the tools utilized to improve the system.

The second part of the meeting focused on developing a regional strategy for increasing reporting. Barriers were identified, and target stakeholders were selected for engagement. A reporting target was also set, aiming for improved vigilance and safety in the reporting of both medicines and vaccines through 2030.

WHO Pharmacovigilance Partners' Meeting on The Global Smart Pharmacovigilance Strategy

On 13 October 2024, the WHO Pharmacovigilance Team at HQ, together with the regional and country offices, convened a meeting of pharmacovigilance partners and stakeholders in New Delhi, India, on the margins of the 19th International Conference of Drug Regulatory Authorities (ICDRA). The purpose of the meeting was to review and refine the concepts of the WHO Global Smart Pharmacovigilance Strategy, with a focus on making pharmacovigilance systems more sustainable, science-based, and efficient.

The meeting brought together 147 participants from 68 countries, including representatives from National Regulatory Authorities (NRAs), National Immunization Programs (NIPs), National Pharmacovigilance Centres (NPVCs), and various international organizations. Key discussions centred

WHO PV Partners' meeting on the Global Smart Pharmacovigilance Strategy held at New Delhi, India on 13th October , 2024

on improving pharmacovigilance systems, sharing lessons learned from global and regional initiatives, and advancing safety surveillance methods.

The plenary session featured presentations on successful pharmacovigilance initiatives in Armenia, Ghana, and India. These presentations highlighted the importance of collaboration, the role of mobile applications and electronic platforms in reporting adverse events, and the integration of pharmacovigilance into national immunization programs. Participants emphasized the need for harmonized databases and efficient signal detection systems to enhance safety monitoring, particularly in the context of global health emergencies.

Officials at the dias discussing the analysis of PV data: Past, Present and Future approaches

Challenges in pharmacovigilance were also addressed, including insufficient recognition of its importance by governments, low reporting rates, and the need for better integration across stakeholders. WHO presented its outline for a Global Smart Pharmacovigilance Strategy, stressing a risk-based approach, prioritization of resources, and the integration of pharmacovigilance into broader regulatory strengthening efforts.

The breakout sessions provided in-depth discussions on optimizing pharmacovigilance data collection, analysis, decision-making and coordination. Recommendations focused on the need for sustainable resources, capacity building, and the use of artificial intelligence for signal detection and risk management. The importance of collaboration among stakeholders at all levels—local, regional, and global—was highlighted as essential for effective pharmacovigilance.

As the meeting concluded, WHO outlined the next steps for the strategy's development, including revising the draft strategy document and engaging WHO member states for further comments. Additionally, it was announced that the VigiFlow tool, provided by the Uppsala Monitoring Centre (UMC), will be made available without licensing fees for members of the WHO programme for International Drug Monitoring starting in 2025, marking a significant step toward enhancing global pharmacovigilance efforts.

This meeting underscored the growing need for coordinated, science-driven pharmacovigilance strategies to ensure public health safety and foster international collaboration in the face of emerging health challenges.

ICDRA

WHO official delivering the inaugural speech virtually during the 19th ICDRA

The 19th International Conference of Drug Regulatory Authorities (ICDRA), organized by the World Health Organization (WHO) in collaboration with the Central Drugs Standard Control Organization (CDSCO), India, brought together global regulatory authorities for in-depth discussions on the evolving landscape of drug regulation. The pre and post ICDRA conference, aimed to strengthen regulatory capacities, foster international collaboration, and address key issues impacting the safety, quality, and accessibility of medical products. As part of the pre-ICDRA and post-ICDRA sessions, one of the key areas of focus was the enhancement of pharmacovigilance systems worldwide.

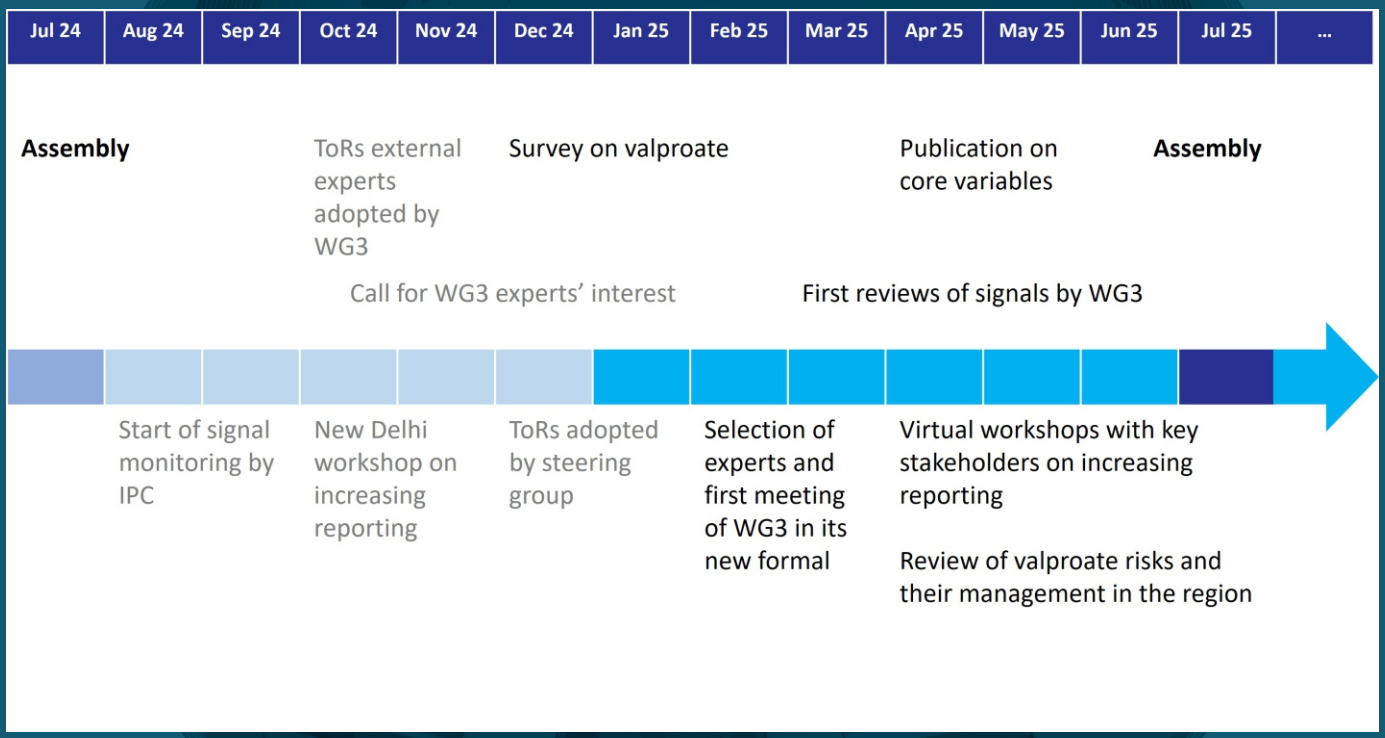
The Pharmacovigilance sessions, titled "Building Bridges for Effective Pharmacovigilance Systems," highlighted the importance of collaboration between various stakeholders in ensuring the safety of medical products. The session featured insightful moderated panel discussion, where experts emphasized how regulatory authorities, healthcare professionals, pharmaceutical companies, and patients must work together to detect, assess, and manage risks related to medicines. Real-world case studies were presented, showcasing successful collaborations that led to significant improvements in

Discussions revolved around practical solutions to strengthen pharmacovigilance systems globally, with recommendations for enhanced information sharing, building trust among stakeholders, and expanding the scope of pharmacovigilance activities. These sessions underscored the importance of a unified, global approach to pharmacovigilance in addressing emerging safety concerns, ensuring that medicines remain safe and effective, and ultimately improving public health outcomes worldwide. Through this collaborative dialogue, participants reaffirmed the critical role of strong pharmacovigilance systems in maintaining the safety of medical products in an increasingly complex and interconnected healthcare environment.

Dr. Rajeev Singh Raghuvanshi inaugurating the 19th ICDRA, organized by WHO in collaboration with the CDSCO

SOUTH-EAST ASIA REGULATORY NETWORK

SEARN: WHERE ARE WE IN THE WORKPLAN?



INDIAN PHARMACOPOEIA COMMISSION

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Ministry of Health & Family Welfare, Government of India