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Global Pharmacovigilance Today: International Programmes, Emerging Technologies And Challenges In Medicine Safety

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- **ABSTRACT**

Pharmacovigilance (PV) is essential for public health because it helps identify, evaluate, and prevent adverse effects and other medicine-related problems throughout the drug life cycle. Although drug safety monitoring began in response to major medicine-related disasters, it has now become a more proactive, global system. International programs and regulatory networks enable the collection, assessment, sharing, and interpretation of safety information across countries and healthcare settings. Key global initiatives such as the WHO Programme for International Drug Monitoring, VigiBase, EudraVigilance, and other regional and national systems have improved international cooperation in identifying potential safety issues. This review examines how global pharmacovigilance programs have developed and where they stand today, focusing on their goals, operations, international collaboration, and impact on medicine safety. It also highlights differences in pharmacovigilance infrastructure between developed and developing regions, where factors such as healthcare resources, reporting practices, regulatory strength, and public awareness can affect the quality of safety data. New methods such as electronic health records, real-world data, artificial intelligence, automated signal detection, mobile reporting, and patient-generated information are changing traditional safety monitoring. However, challenges like under-reporting, incomplete data, limited resources, fragmented systems, and cross-border data-sharing issues remain. Improving regulatory cooperation, increasing involvement from healthcare professionals and patients, adopting new technologies, and creating unified reporting standards could help build a more responsive, inclusive global pharmacovigilance system. Ultimately, pharmacovigilance's future depends on shifting from reactive adverse-event reporting to ongoing, data-driven, collaborative, patient-focused safety monitoring.

- **KEYWORDS:** Pharmacovigilance (PV), Adverse Drug Reaction (ADR), Monitoring Medicines (MM), World Health Organisation (WHO), Food and Drug Administration(FDA) Safety.

- **INTRODUCTION**

The World Health Organisation (WHO) defines pharmacovigilance (PV) as the science and activities focused on detecting, assessing, understanding, and preventing adverse effects and other drug-related problems.[1] Interest in medicine safety grew a lot after the thalidomide tragedy in 1961. At first, pharmacovigilance was mostly reactive, looking into safety problems only after a medicine was already on the market. Over time, the role of PV has grown a lot. This shift happened because of changes in the pharmaceutical industry, access, and better databases and tools for collecting and analysing safety information. Even with these improvements, pharmacovigilance continues to evolve to meet healthcare systems' needs and patients' and consumers' expectations.

Thalidomide was introduced into the market in 1957 and was subsequently widely used in several parts of the world, including Europe, Australia, Asia, Africa, and the United States. In 1961, a large number of severe congenital disabilities were observed among children whose mothers had taken thalidomide during pregnancy. These abnormalities were subsequently linked to exposure to the drug. More than 10,000 cases of congenital abnormalities were reported across more than 46 countries. The defects included absent or malformed limbs, spinal abnormalities, cleft lip and palate, abnormalities of the ears, heart, kidneys, and genital organs, as well as defects affecting the digestive system. Approximately 40% of affected infants died within their first year of life. Following these findings, many countries withdrew thalidomide from the market in 1961.[2]

The thalidomide tragedy resulted in major changes in drug-safety regulations and encouraged the development of spontaneous adverse drug reaction (ADR) reporting systems. The WHO International Programme for Adverse Reaction Monitoring was established to strengthen international monitoring of medicine-related safety problems. These systems made it possible to identify rare ADRs that might not be detected during clinical trials because of their limited duration and relatively small number of participants. Early reporting mechanisms included the British Yellow Card system and U.S. Food and Drug Administration (FDA) reporting forms. Over time, pharmacovigilance gradually moved from a mainly reactive system toward a more proactive approach. Today, medicine safety is monitored from early drug development through the entire product lifecycle, including the post-marketing period.

ADR reports remain one of the most important sources of safety information, and ADR reporting continues to form the foundation of many pharmacovigilance systems. Safety monitoring now extends from early clinical development to long-term post-marketing surveillance. During clinical trials, researchers systematically record and evaluate adverse events. After marketing, spontaneous reports and post-marketing study data help identify uncommon or rare adverse effects that may not have been detected during clinical development. This information also helps detect potential safety signals that require further investigation.

Initiatives developed by the Council for International Organisations of Medical Sciences (CIOMS) and the International Council for Harmonisation (ICH) have further strengthened pharmacovigilance, particularly through risk-management approaches. Risk management involves systematically identifying, evaluating, communicating, and addressing both known and potential risks associated with medicines. It also includes developing strategies to reduce or control these risks and protect patients.

Today, pharmacovigilance is an ongoing, active process, not just a way to collect adverse event reports. It includes gathering and analysing safety data, finding possible risks, sharing safety information clearly, and taking steps to protect public health. Changes in regulations and international projects over the years show a better understanding of medicine-related risks and the need for stronger safety monitoring. Still, current regulations, technologies, databases, and monitoring methods can be improved. Ongoing development of pharmacovigilance systems is important to make sure medicines are used safely and effectively throughout their life cycle. [3]

The Monitoring Medicines Project: A Multinational Pharmacovigilance and Public Health Project:

Spontaneous reporting of suspected adverse drug reactions (ADRs) has been one of the most important methods used in pharmacovigilance for many years. It helps healthcare professionals and regulatory organisations identify early warning signals of possible medicine-related safety problems.

These reporting systems work at different levels, including individual pharmaceutical companies, regional pharmacovigilance centres, and national pharmacovigilance programmes. At the international level, large databases also collect and analyse safety reports. Two important examples are EudraVigilance, coordinated by the European Medicines Agency (EMA) together with EU Member States, and VigiBase, the World Health Organisation's global database of individual case safety reports (ICSRs), managed by the Uppsala Monitoring Centre (UMC).

Monitoring Medicines Project

The Monitoring Medicines (MM) project, officially titled "Optimising drug safety monitoring to enhance patient safety and achieve better health outcomes," was launched in 2009. It involved 11 organisations and partners from Africa, Asia, and Europe. The project received financial support through the EU Seventh Framework Programme (FP7) and was conducted from September 2009 to July 2013.

The major aims of the project were:

1. To encourage patients and consumers to report suspected adverse drug reactions and strengthen consumer participation in pharmacovigilance.

2. To strengthen national pharmacovigilance centres and increase their ability to detect, investigate, and prevent medication errors.

3. To make better use of existing pharmacovigilance information so that safety data could contribute more effectively to protecting patients.

4. To develop additional pharmacovigilance approaches that could complement traditional spontaneous reporting systems and provide a broader understanding of medicine-related safety problems.[4]

Major Pharmacovigilance Initiatives

Pharmacovigilance initiatives have been designed at different geographical levels. Some programmes have focused mainly on individual countries, such as Sentinel in the United States, while others have operated at the regional level, such as PROTECT in Europe. The Monitoring Medicines (MM) project was broader and involved several regions. Financial support for these initiatives has differed considerably. The Monitoring Medicines (MM) project received about €2 million from the European Commission, while SALUS received about €3.3 million, for a total budget of about €5 million. The EU-ADR project received around €4.5 million in funding and spent approximately €5.88 million. PROTECT had a budget of about €20 million, with about half of this support provided as in-kind contributions by participating EFPIA pharmaceutical companies. The European Union provided government-level support through the Innovative Medicines Initiative. In comparison, the US Sentinel programme operated with a much larger budget of approximately US$135 million.

Several of these programmes—including SALUS, EU-ADR, OMOP, PROTECT, and MM—were based on collaboration between public-sector organisations and commercial partners. However, unlike some of the other initiatives, MM did not involve direct participation from the pharmaceutical industry.

Although each programme had its own specific goals, their objectives overlapped considerably. Their major areas of focus included the following:

1. Expanding Sources of Drug-Safety Information :

The initiatives aimed to obtain safety information from a wider range of sources. This included:

- Encouraging patients and consumers to report suspected ADRs, either voluntarily or through structured reporting approaches, as demonstrated by MM and PROTECT.

- Making greater use of safety-related information already available in healthcare databases and electronic health records, as used in SALUS, Sentinel/Mini-Sentinel, PROTECT, EU-ADR, and OMOP.

2. Improving Pharmacovigilance Methods:

Another important objective was to strengthen existing methods and develop new approaches for pharmacovigilance and pharmacoepidemiological research. Examples included:

- Improving techniques for detecting and confirming potential safety signals, as explored by MM, PROTECT, EU-ADR, OMOP, and Mini-Sentinel.

- Developing approaches for evaluating the balance between the benefits and risks of medicines, particularly through PROTECT.

- Introducing or improving methods used in pharmacovigilance and pharmacoepidemiology, with contributions from PROTECT, OMOP, and MM.

- Developing approaches that could help predict medicine-related risks at the individual patient level, an objective of MM.

3. Creating New Data Resources and Research Tools:

Several initiatives also contributed new resources that could support drug-safety research. These included:

- PROTECT: Development of resources containing information on established ADRs and European medicine-use/consumption data.

- EU-ADR: Development of a computerised platform to support pharmacovigilance activities.

- ENCePP: Creation of research-resource databases and tools such as checklists for developing study protocols.

- Mini-Sentinel: Development and use of large-scale electronic healthcare data resources for safety monitoring.

4. Improving the Quality of Pharmacovigilance Activities:

Improving the overall quality and consistency of pharmacovigilance work was another common goal. This involved:

- Providing education, training, and improved communication related to medicine safety, particularly through MM and PROTECT.

- Encouraging the sharing and dissemination of project findings through initiatives such as PROTECT, OMOP, and MM.

- Developing guidelines and standards to improve pharmacovigilance and pharmacoepidemiological research. Examples include the ENCePP Study Seal, ENCePP Code of Conduct, and guidance developed through MM.[5]

Adverse Drug Reactions and Pharmacovigilance

The World Health Organisation (WHO) describes an adverse drug reaction (ADR) as an unwanted and harmful response to a medicine when it is administered at doses normally used for preventing, diagnosing, or treating diseases, or for modifying normal physiological functions. ADRs are an important clinical concern because they can contribute considerably to illness, complications, hospitalisation, and, in severe cases, death.[6] Pharmacovigilance refers to the scientific activities involved in identifying, evaluating, understanding, and preventing adverse effects and other problems associated with medicines. Its primary purpose is to continuously assess medicine safety and identify potential risks not recognised during early drug development.

Need for Pharmacovigilance

The safety information available when a medicine first enters the market is based largely on clinical trial data. Although clinical trials provide valuable information on efficacy and common adverse effects, they generally involve a relatively small, carefully selected population.[7] Consequently, uncommon or delayed adverse reactions may go undetected until a much larger, more diverse population uses the medicine. Rare adverse events can be particularly difficult to identify during clinical trials because follow-up periods may be limited. In addition, interactions with other medicines, existing diseases, age-related factors, and individual differences may influence the occurrence of adverse effects.[6,7] Therefore, the overall balance between a medicine's benefits and risks becomes clearer only after extensive use in routine clinical practice and continued safety monitoring.[6]

Observation of medicines under real-world conditions provides important information about their long-term safety. Pharmacovigilance plays an essential role by collecting and evaluating safety information from routine healthcare settings.[7] Pharmacovigilance findings can alert healthcare professionals, regulatory authorities, and pharmaceutical manufacturers to emerging safety concerns. Depending on the evidence, appropriate actions may include updating product information, restricting use, strengthening safety warnings, or, when necessary, withdrawing a medicine from the market.

Pharmacovigilance Systems and Spontaneous Reporting

Pharmacovigilance uses several approaches to monitor medicine safety, with spontaneous reporting remaining one of the most widely used methods. In this system, healthcare professionals, patients, or other individuals report an event when they suspect it may be associated with a particular medicine. Pharmacovigilance databases then collect and store these suspected ADR reports for further assessment.

One major challenge of spontaneous reporting is under-reporting. Although reporting suspected ADRs is an important part of medicine-safety monitoring, many events may never be reported to the relevant pharmacovigilance authorities.[6] Despite this limitation, spontaneous reports are highly valuable because they can reveal unexpected patterns and generate hypotheses about possible relationships between medicines and adverse events.

Combining spontaneous reporting with well-designed post-marketing studies, active surveillance, and systematic analysis of healthcare databases can strengthen it. Linking information from different sources can improve pharmacovigilance systems' ability to identify and investigate potential safety concerns early.[8]

Global Role of Pharmacovigilance

Pharmacovigilance can also provide useful information about the quality and safety of clinical care within a healthcare system.[8] Each country may require a pharmacovigilance approach suited to its own population because factors such as disease patterns, prescribing behaviour, genetic characteristics, dietary habits, and cultural practices can affect how adverse drug reactions occur and are reported.[9] The thalidomide tragedy of 1961 highlighted the importance of international cooperation in medicine safety. Following this event, the WHO established the Programme for International Drug Monitoring (PIDM). The WHO Collaborating Centre for International Drug Monitoring, based in Uppsala, Sweden, supports international efforts to strengthen pharmacovigilance and promote medicine safety.[10]

Information generated through pharmacovigilance activities can contribute to several aspects of healthcare, including safer medicine-use practices, essential medicines programmes, standard treatment guidelines, and the development of national and institutional formularies.[8] Regulatory authorities also maintain databases of suspected adverse event reports. These data can be systematically analysed to identify potential safety signals.

A safety signal may emerge from an unusual individual case, a recurring pattern of similar adverse events, or several reports higher than would normally be expected. Such findings can prompt further investigation, detailed evaluation, and, when appropriate, regulatory action.[7]

The IWG

The International Working Group (IWG) was formed by inviting professionals from different sectors involved in medicine safety and pharmacovigilance. As a result, the group brings together individuals from regulatory agencies, pharmaceutical organisations, and academic institutions. Its members represent several countries and regions, including the Netherlands, France, New Zealand, Japan, Iraq, the United States, Canada, and the United Kingdom.

The IWG members' multidisciplinary background allows the group to approach pharmacovigilance-related issues from different perspectives. Its expertise spans clinical medicine, biological sciences, epidemiology, biostatistics, and other disciplines relevant to medicine safety. The IWG also maintains collaborations with various institutions, stakeholders, and organisations involved in pharmacovigilance and medicine-safety activities. These professional relationships strengthen the group's ability to examine a wide variety of issues and contribute knowledge from different areas of the field.

Mission and Objectives of the IWG

The IWG began its mission in 2019 to improve pharmacovigilance methods and support the safe, appropriate use of medicines and vaccines, ultimately strengthening public health protection. Pharmacovigilance continues to evolve, especially with the introduction of new therapeutic products and increasingly complex sources of safety information. Key challenges include monitoring medicines introduced through accelerated development pathways, ensuring consistency in data and terminology, and determining how to appropriately apply advanced analytical approaches, including machine-learning methods, to pharmacovigilance.[11]

As part of its mission, the IWG identifies areas where existing pharmacovigilance methods or practices may need further evaluation and development. The group works toward improving methods for detecting, monitoring, and analysing medicine-safety information. It also seeks to develop and communicate evidence-based approaches to help healthcare professionals and other decision-makers interpret safety information.

The IWG's activities extend beyond conventional medicines to include combination products, medical devices, and gene therapies. When the group identifies limitations or gaps in existing pharmacovigilance processes, it may conduct methodological research to understand these issues better and explore possible improvements. The knowledge generated through this work can be shared through peer-reviewed scientific publications, IWG reports, blogs, conferences, and other scientific meetings.

The Drug Safety Research Unit (DSRU) in the United Kingdom serves as the IWG's coordinating centre. It also supports the IWG coordinator, who facilitates meetings, coordinates activities, conducts research related to the group's work, and contributes to publications with IWG members.

The IWG follows a collaborative and multidisciplinary model. Members actively review emerging or established areas of pharmacovigilance to identify where additional research, methodological assessment, or recommendations could be useful. The group discusses potential topics during plenary meetings, after which members may choose to join topic-specific subgroups based on their expertise and interests. This approach enables the IWG to combine knowledge from different disciplines and work collectively toward improving pharmacovigilance practices.[12]

"PHARMACOVIGILANCE IN TRANSITION: EMERGING CHALLENGES AND FUTURE PROSPECTS"

Medicine safety monitoring is an ongoing process throughout a drug's life cycle, from early development to clinical use. During drug development, safety is assessed at different stages to identify potential risks and establish appropriate monitoring measures. In preclinical studies, the main objective is to determine a dose likely to be safe for human use and identify key safety parameters to monitor in subsequent clinical studies. Once a drug enters clinical development, each phase has a specific safety-related purpose. Phase I trials primarily assess tolerability and safety across dose levels, generally in healthy volunteers. Phase II studies are conducted in patients with the condition being treated and help determine an appropriate therapeutic dose range while providing further safety information. Phase III trials involve larger patient populations and help establish the medicine's overall benefit–risk balance and detect adverse drug reactions not identified in earlier phases.

Despite extensive safety assessments during drug development, clinical trials before marketing have inherent limitations. Their relatively short duration, selected study populations, and controlled conditions may prevent researchers from fully recognising certain safety concerns. Therefore, the complete safety profile of a medicine may only become clearer after wider use in the general population.[13]

Pharmacovigilance in Healthcare Emergencies

During the early stages of the COVID-19 pandemic, the lack of specifically approved vaccines and effective medicines created an urgent need for potential treatment and preventive options. As a result, researchers rapidly considered and used several medicines approved for other diseases for COVID-19, often outside their officially approved indications. Drugs such as hydroxychloroquine, ivermectin, and azithromycin were widely used in some settings despite limited and uncertain evidence regarding their effectiveness. Much of the initial evidence came from laboratory-based or in vitro studies rather than well-established clinical data. This situation highlighted the importance of continuous pharmacovigilance and careful assessment of medicine-related risks during public health emergencies.[14]

Database Networks for Post-Marketing Surveillance of Vaccines and Medicines

The growing availability of large, interconnected healthcare databases has created valuable opportunities to monitor vaccine and medicine safety after they enter the market. These databases can also generate real-world evidence, helping healthcare professionals and regulatory authorities make better-informed decisions about the safety and use of medical products.

One important development in this area was the launch of the FDA's Sentinel Initiative in May 2008. The initiative was established to use electronic healthcare information to continuously evaluate the safety of approved medical products in real-world settings. Over time, Sentinel has developed into a major distributed database network for post-marketing safety assessment. Its activities include the Sentinel System, which applies standardised data models and analytical methods to existing real-world healthcare data, and FDA-Catalyst, which obtains additional safety information through routine data queries and direct interactions or interventions involving health plan members and healthcare providers. Together, these approaches strengthen the ability to identify and evaluate potential safety concerns after medicines and vaccines are introduced into routine clinical use. [15]

Artificial Intelligence in Pharmacovigilance

Healthcare-related data has increased rapidly in recent years and is expected to grow further as digital technologies that continuously collect and store patient-related information become more widespread. This growing volume of data creates new opportunities to apply artificial intelligence (AI) to improve the detection, evaluation, and monitoring of medicine-related safety concerns.

AI-based approaches can help researchers extract useful information from large and complex datasets. In particular, natural language processing (NLP) and text-mining techniques can analyse extensive amounts of unstructured information and identify clinically relevant patterns that may otherwise be difficult to detect manually. In pharmacovigilance, these technologies can help identify adverse drug reaction (ADR) reports, potential drug–drug interactions, and other safety signals across different textual sources. Such applications can help healthcare professionals and researchers conduct more efficient, timely drug-safety monitoring. [16]

Governmental and private organisations are increasingly exploring AI-based systems that can automatically process and evaluate ADR-related information. These developments could make pharmacovigilance faster, more scalable, and better suited to the growing volume of healthcare data. [17]

ECOPHARMACOVIGILANCE

Ecopharmacovigilance is an emerging area of pharmaceutical safety that focuses on identifying, evaluating, understanding, and preventing harmful effects caused by pharmaceutical substances present in the environment. These substances may pose risks to humans, animals, and other living organisms (Velo and Moretti, 2010). This topic has gained importance because pharmaceutical residues are increasingly recognised as environmental contaminants that can affect ecosystems and potentially threaten public health. Medicines and their residues can enter the environment through several pathways. For example, patients may excrete unchanged drugs or their metabolites, which can pass into sewage systems. Pharmaceutical manufacturing facilities and hospitals may also release drug-containing wastewater, while pharmaceutical residues deposited on land provide another route of environmental contamination. These pathways highlight the need for effective monitoring and responsible pharmaceutical waste management to minimise the environmental impact of medicinal products. [19]

PV IN ASEAN COUNTRIES

(Myanmar), Cambodia, Laos, and Vietnam. Indonesia

The first steps toward pharmacovigilance in Indonesia began between 1975 and 1978, when six public facilities took part in a hospital pilot project. Then, in 1980, a national program was created to monitor ADRs through voluntary reporting by HCPs, with support from an advisory board. In 1990, the National Agency of Drug and Food Control (NADFC) became part of the WHO Program for International Drug Monitoring in Uppsala, Sweden. In 2004, the Directorate of Distribution Control of Therapeutic and Household Healthcare Products established a PV unit. Between 2008 and 2011, a stronger legal framework for PV was put in place, requiring the pharmaceutical industry to conduct PV.

However, the goal set for 2012 to 2014 is to make the risk management program stronger, connect the National Regulatory Authority (NRA) with public health programs, and build a dedicated subsite for PV work that covers e-ADR reporting and building connections with the right stakeholders to advance PV efforts, along with running PV workshops that strengthen what HCPs do and are responsible for and get them engaged in reporting for PV.[20] The PV system in Indonesia consists of voluntary reporting by HCPs in hospitals and

public health centres; in general and private practices; by pharmacists in pharmacies; and by other HCPs. This happens by submitting Yellow forms. Mandatory reporting is by the pharmaceutical industry and Marketing Authorisation Holders (MAH) occurs through spontaneous reporting by submitting a Council for International Organisations of Medical Sciences (CIOMS) form. Drug companies need to set up a PV unit, headed by a PV manager.

- **Malaysia**

In 1987, Malaysia established its own PV system and became a participant in the WHO Program for International Drug Monitoring in 1990. The Malaysian Adverse Drug Reaction Committee (MADRAC), under the Malaysian MOH, has supervised and managed the PV program since then. HCPs sent 5850 ADR reports to MADRAC in 2009. Yet, based on WHO advice on an ideal national PV centre, this figure is considered low. The Malaysian PV system, like most systems worldwide, is affected by HCP underreporting of ADRs. Information on the reasons for this underreporting overall, especially by community pharmacists, is scarce, and only a few studies have examined this in Malaysia.[21] MADRAC urges healthcare professionals (HCPs) to report every suspected adverse reaction, yet the marketing authorisation holder (MAH) of a product must notify the DCA about any adverse reactions linked to that product, as set out in the Malaysian rules for monitoring adverse drug reactions (ADRs)

- **Philippines**

The ADR reporting system in the Philippines was established in August 1994; it gained recognition as a national centre.
a member of the WHO International Drug Monitoring program based in Uppsala
Monitoring Centre, in February 1995. The pharmacovigilance (PV) system of the
Philippines created several communication and training materials, aiming to promote safer medicines and the rational use of drugs. It is widely known that, in the Philippines, traditional folk medicines are used more and more, and these are
being prescribed. Like many Asian countries, the culture of reporting ADRs is extremely poor, partly because AEs go unrecognised; sometimes practitioners mistake an AE for part of the healing effect and are unlikely to report it. Those who turn to herbal medicines generally come from the poorer part of the population, and they tend to trust unscientific claims and are unlikely to report whatever harm they experienced. Promoting herbal medicines as natural and safe substitutes overlooks the potential for adverse events.[22] Even though they are not regulated, traditional Chinese medicines are permitted in the Philippines when ethnic Chinese use them, and this raises worry, since many interactions can occur with these medicines when they are taken alongside modern drugs. The oversight of health supplements has likewise not worked well. Together, these two issues have created gaps that let harmful products slip through.

- **Singapore**

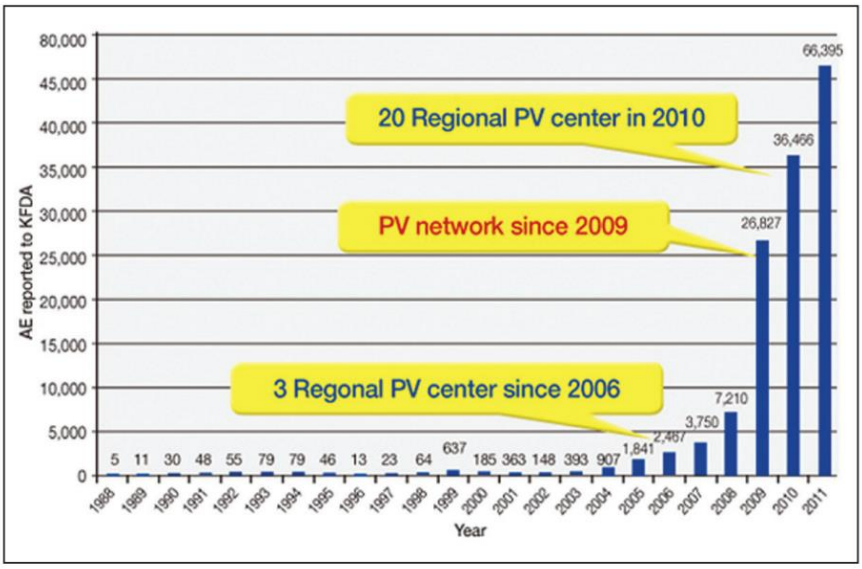
The pharmacovigilance unit (PVU), formerly the Adverse Drug Reaction Monitoring Unit (ADRMU), is based in Singapore and was established in 1993. This unit became part of the WHO in 1994, joining as the 40th member of the WHO International Drug Monitoring Program, which works on drug safety through international collaboration. The unit acts as the country's national centre for gathering and examining ADR reports. The Health Sciences Authority has also established a Pharmacovigilance Advisory Committee (PVAC) made up of experts in medicine, pharmacy, pharmacology, and forensic sciences. A key part of their

job is to evaluate how major drug safety issues affect people and recommend appropriate regulatory steps to improve drug safety. In Singapore, a license holder may send the ADR report to the PVU using the unit's reporting form or the CIOMS I form. PSURs can be requested for certain registered medicinal products. PSURs must be sent to the Product Evaluation and Registration Branch (PERB) every 6 months for the first 2 years after marketing approval; after that, they must be sent once a year for the next 3 years. This schedule may change to align with international periodic safety updates.[23]

- **Thailand**

In 1983, the Thai National ADR Monitoring eCentre was established under the Thai Food and Drug Administration, Ministry of Public Health, working with hospitals nationwide. Initially, 18 regional centres were established, and this continued until 1992. In 1997, the regional centres expanded to cover all health products and were limited to hospitals; Thailand now has 23 such centres. Yet in 2010, the focus shifted away from monitoring ADRs in hospitals to monitoring ADRs in the community for every drug-related problem. The

After that, the scope of monitoring was broadened to cover non-medicinal products, including narcotic substances, food, cosmetics, medical supplies, and dangerous substances used in the home. The national ecentre was then renamed the Health Product Vigilance eCentre, which operates under the FDA. ADR reporting is a national program, and every hospital sends its ADR reports to this centre. You can also report ADRs online through this website: http://thaipvc.fda.moph.go.th/thaihvc/index.jsf. Each year, the centre receives thousands of ADRs from hospitals across Thailand.[24] Every NCE registered and approved for sale in Thailand must undergo a required SMP of about 2 years, and sometimes it can last up to 4 years. During the SMP, only doctors working in hospitals and clinics can prescribe these medicines, and only pharmacies inside hospitals and clinics can dispense them. These medicines also cannot be sold in drug stores, and they cannot be added to the national list of essential medicines (NLEM). Each year, the ecentre holds a conference where it asks pharmacists to share their academic work, such as research and interesting case reports. The ecentre collects, reviews, and summarises the reports, then produces an annual report and sends it to all hospitals for use in later tasks. In addition, the centre provides resources to help track and prevent ADRs, including patient information sheets, ADR cards, report forms, and similar items. From time to time, the centre also arranges meetings with outside experts when the US FDA provides evidence about ADRs, so they can discuss whether the drug should be pulled from the market in Thailand.



Operating system of Regional Pharmacovigilance Countries.[25]

- **CONCLUSION**

Pharmacovigilance has become an essential part of modern healthcare by helping identify, assess, and prevent medicine-related risks throughout the life cycle of pharmaceutical products. International initiatives, including the WHO Programme for International Drug Monitoring, VigiBase, EudraVigilance, and national surveillance systems, have strengthened the collection and evaluation of safety information across healthcare settings. Collaborative projects and regional programmes have also improved adverse drug reaction reporting, safety-signal detection, and evidence-based regulatory decision-making.

Despite this progress, several challenges continue to affect pharmacovigilance effectiveness worldwide. Under-reporting of adverse drug reactions, differences in regulatory infrastructure, limited resources, incomplete safety information, and difficulties in sharing data between countries remain important concerns. These limitations can be particularly challenging in regions where awareness, training, and access to reporting facilities are inadequate. Therefore, strengthening medicine-safety monitoring requires greater involvement from healthcare professionals, patients, researchers, pharmaceutical organisations, and regulatory authorities.

New technologies are opening up ways to improve pharmacovigilance. Artificial intelligence, electronic health records, real-world data, automated signal detection, and digital reporting tools can help spot safety concerns earlier and make it easier to analyse large amounts of information. However, these methods require reliable data, robust checks, human oversight, and careful handling of patient information. Ecopharmacovigilance is also important, since pharmaceutical residues in the environment add another layer to medicine safety.

In conclusion, the future of global pharmacovigilance depends on combining scientific advances, international teamwork, better reporting, and greater public involvement. A more organised, open, and patient-focused approach can help healthcare systems handle new drug safety issues more effectively. Ongoing improvements

in monitoring and regulatory collaboration will remain key to ensuring medicines are used wisely and protecting both public health and the environment.

- **DECLARATION**

Declaration of Originality and Conflict of Interest:

The authors declare that this review article, titled "Global Pharmacovigilance in Transition: Programmes, Practices and Emerging Directions in Drug Safety," has been prepared for academic and scientific purposes. The manuscript reviews and synthesises relevant published literature to provide an overview of global pharmacovigilance programmes, current practices, major challenges, and emerging developments in drug-safety monitoring.

The authors acknowledge the importance of giving appropriate credit to the sources used in preparing this review. All references should be cited and listed in accordance with the applicable academic or journal guidelines. The authors are responsible for ensuring the accuracy of the information presented and for making appropriate revisions wherever required.

Conflict of Interest: The authors declare no conflict of interest, provided that this statement accurately reflects their circumstances.

Originality and Publication Status: The authors should confirm that the manuscript is their original scholarly work, that any material derived from other sources has been appropriately acknowledged, and that the manuscript has not been published previously or submitted elsewhere for publication, if this is consistent with its actual submission history.

Author Approval: Both authors should confirm that they have reviewed and approved the final manuscript and agree to its submission for academic or publication purposes.

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