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Review Article

Regulatory Assessment of Pharmacovigilance and ADR Reporting Systems in ROW Market

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ABSTRACT

Pharmacovigilance (PV) plays a vital role in monitoring the safety of medicines after marketing and ensuring patient safety through effective adverse drug reaction (ADR) reporting systems. While well-regulated markets maintain advanced pharmacovigilance frameworks, Rest of the World (ROW) countries continue to face challenges such as infrastructure limitations, ADR underreporting, lack of awareness, inadequate training, weak digitalization, and non-harmonized regulatory guidelines. The maturity of PV systems varies significantly across ROW regions. India's Pharmacovigilance Programme of India (PvPI) is a major contributor to the Uppsala Monitoring Centre (UMC), whereas Singapore utilizes expert advisory committees and advanced NLP-based text mining for signal detection. In contrast, Malaysia and the Philippines continue to experience low ADR reporting, while Thailand and Indonesia focus on community-based and mixed reporting systems. African countries such as Ethiopia, Kenya, and Tanzania are strengthening their PV systems through WHO-supported initiatives, while GCC, Latin American, and CIS nations are progressing toward regional harmonization through collaborations such as PANDRH and EAEU. Unlike previous studies focused on individual regions, this review provides a comparative regulatory assessment of multiple ROW markets, identifies existing pharmacovigilance gaps, and highlights future improvement strategies including AI, machine learning, electronic reporting systems, and global regulatory collaboration to improve medicine safety and public health protection.

INTRODUCTION

Pharmacovigilance (PV) plays a pivotal role in ensuring the continued safety, efficacy, and quality of medicinal products once they are introduced into the market. The science of pharmacovigilance involves the systematic monitoring, detection, assessment, understanding, and prevention of

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adverse drug reactions (ADRs) or any other drug-related problems. It not only safeguards public health but also supports informed decision-making by regulatory authorities, healthcare professionals, and pharmaceutical industries. In recent years, the importance of PV has grown substantially due to the increasing complexity of therapeutic agents, expanding global drug markets, and the emergence of new safety concerns even after product approval[1].

Globally, well-established regulatory authorities such as the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) have implemented robust and transparent pharmacovigilance systems. These systems are supported by clear regulatory frameworks, advanced electronic reporting mechanisms, and active participation from healthcare professionals and the public. However, in many Rest of the World (ROW) countries which typically include regions across Asia, Africa, Latin America, and parts of the Middle East the pharmacovigilance infrastructure remains underdeveloped or inconsistently implemented[2].

The challenges faced by these regions are multifaceted. A significant proportion of healthcare professionals and patients remain unaware of the importance of ADR reporting, leading to widespread underreporting. Limited human resources, inadequate training, lack of financial support, and weak coordination between regulatory agencies and healthcare institutions further contribute to the inefficiency of existing PV systems. Additionally, the absence of harmonized regulatory guidelines, poor data management, and insufficient adoption of digital technologies restrict the ability to identify and respond to potential safety signals promptly[3].

Given the globalization of pharmaceutical manufacturing and distribution, medicines are increasingly developed in one region and marketed in many others. This interconnectivity necessitates that all countries, including those in ROW regions, maintain efficient pharmacovigilance systems aligned with international standards such as those outlined by the World Health Organization (WHO) and the International Council for Harmonization (ICH). Strengthening pharmacovigilance capacity in these countries is therefore not only a local public health priority but also a global responsibility[4].

IMPORTANCE OF PHARMACOVIGILANCE

Pharmacovigilance is the scientific discipline concerned with understanding and explaining the complex nature of adverse drug reactions (ADRs) that occur in patients receiving oral, parenteral, or intravenous (I.V.) medications for various illnesses. Before being marketed globally, medicines undergo extensive laboratory testing and clinical trials in both animals and humans to evaluate their safety, efficacy, and potential side effects. However, not all ADRs are identified during these preclinical and clinical studies, and many reactions become evident only during post-marketing surveillance. ADRs are known to significantly affect patients by reducing quality of life, prolonging hospital stays, and increasing mortality rates. A landmark study conducted by Lazarou in 1998 reported that ADRs were among the fourth to sixth leading causes of death in the United States and were responsible for approximately 3–7% of all hospital admissions[5].

AIMS OF PHARMACOVIGILANCE

Pharmacovigilance (PV) plays a significant role in evaluating the side effects associated with medicines administered through oral, parenteral,

or intravenous (I.V.) routes. Although these drugs undergo extensive testing for adverse drug reactions (ADRs) before being introduced into the global market, some reactions may only become evident during post-marketing use. PV is essential for the detection, assessment, and identification of drugs responsible for specific ADRs, as well as for understanding the mechanisms involved in causing such reactions. Effective identification and prevention of side effects require the combined efforts of physicians, nurses, healthcare workers, residents, and informed patients, all of whom contribute to addressing and minimizing the root causes of ADRs[6].

METHODS OF PHARMACOVIGILANCE

Several researchers have developed various methods for causality assessment of adverse drug reactions (ADRs) using different evaluation criteria. These include the time relationship between drug administration and the onset of the ADR, exclusion of non-drug related causes, confirmation through in vivo or in vitro testing, and previous evidence of similar reactions associated with the suspected drug or its therapeutic class. These approaches help classify ADRs into different categories. At present, there is no universally standardized method for ADR causality assessment. Although numerous algorithm-based assessment methods are available, none has been recognized as the definitive gold standard due to their individual limitations and inconsistencies among the results. This research article aims to conduct a comprehensive regulatory assessment of pharmacovigilance and ADR reporting systems in ROW countries, with the objective of identifying the existing gaps, evaluating their impact on drug safety monitoring, and proposing practical improvement strategies. The study will compare the regulatory frameworks, reporting mechanisms, and compliance practices of ROW countries with those of well-regulated markets. Furthermore, it will explore opportunities for improvement through enhanced stakeholder training, integration of digital reporting tools, and international collaboration to promote harmonization and efficiency in ADR monitoring[7].

RATIONALE AND NOVELTY OF THE PRESENT REVIEW

Several published review articles and research studies have discussed pharmacovigilance systems, ADR reporting practices, and challenges in individual developing countries or specific regions such as Asia, Africa, GCC, or Latin America. Previous studies mainly focused on general pharmacovigilance frameworks, underreporting issues, WHO pharmacovigilance indicators, or country-specific regulatory systems.

However, the present review article is different from the previously published literature because it provides a comprehensive regulatory assessment of pharmacovigilance and ADR reporting systems specifically across Rest of World (ROW) markets by collectively analyzing multiple regions including Asia, Africa, GCC countries, Latin America, and CIS nations.

Unlike earlier references that discuss isolated pharmacovigilance systems, this article comparatively evaluates:

- ADR reporting structures in different ROW countries
- Existing regulatory gaps and implementation challenges
- Variations in pharmacovigilance maturity levels
- Issues such as underreporting, lack of awareness, poor infrastructure, inadequate

training, weak digitalization, and non-harmonized guidelines
- The role of WHO-UMC, VigiFlow, and international collaborations in strengthening pharmacovigilance systems.

In addition, this review emphasizes practical improvement strategies for ROW markets, including:

- strengthening healthcare professional training,
- improving spontaneous ADR reporting culture,
- implementation of electronic and AI-based pharmacovigilance systems,
- integration of NLP and machine learning for signal detection,
- harmonization of global regulatory frameworks,
- and enhancement of stakeholder collaboration.

Therefore, the novelty of this article lies in its integrated and comparative approach toward identifying pharmacovigilance gaps across ROW markets and proposing future-oriented solutions to improve global medicine safety and patient protection.

The ROW region broadly encompasses diverse countries with varying levels of regulatory development and pharmacovigilance maturity.

1) In Asia, this includes nations such as China, India, Sri Lanka, Bangladesh, and several ASEAN members like Singapore, Malaysia, and Thailand.

2) Across Africa, countries such as Algeria, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania are strengthening their PV systems through WHO-supported initiatives.

3) In the Middle East, the Gulf Cooperation Council (GCC) countries — Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates — have made notable progress toward harmonized regulatory standards.

4) Within Latin America, nations including Mexico, Brazil, Peru, Argentina, and Chile have developed regionally coordinated frameworks under PAHO guidance.

5) Similarly, in the Commonwealth of Independent States (CIS), countries such as Russia, Ukraine, Kazakhstan, and Uzbekistan are working toward enhanced ADR reporting and regulatory convergence[8].

OVERVIEW OF PHARMACOVIGILANCE & ADR REPORTING SYSTEMS ACROSS IN ROW MARKET.

The Pharmacovigilance landscape across ROW Countries shows significant diversity in terms of structure, regulatory responsibility and maturity of ADR reporting systems. While some nations have established national pharmacovigilance centers integrated with the WHO Programme for International Drug Monitoring (PIDM), others are still developing basic reporting frameworks[9].

A) PV System in India

National Programme of Pharmacovigilance was launched in 2005 and was renamed as the Pharmacovigilance Programme of India (PvPI) in 2010. The PvPI works to safeguard the health of the Indian population by ensuring that the benefit of medicines outweighs the risks associated with their use. The culture of reporting of ADRs has achieved remarkable success, with 250 PvPI-established adverse drug monitoring centres all over India and provision of training to healthcare professionals[10]. Currently, almost hundred

thousand case reports are submitted to NCC PvPI each year through its 250 ADR Monitoring Centres (AMCs) located across India, and India is the one of the top contributor countries under WHO-Uppsala Monitoring Centre since 2012 and start issuing drug safety alerts from March 2016. The ADRs collected by the ADR monitoring Centres and MAHs are communicated to NCC PvPI in the form of Individual Case Safety Report (ICSR). The annual database accounts 64, 441 ICSRs for the period APR-2018 to MAR-2019. Reporting patterns are on the increase every year and have shot up in recent years[11].

B) PV System in Malaysia

The number of ADR reports received from HCPs by MADRAC reached 5850 in 2009. However, according to WHO guidelines for the optimal national PV centres, this number of ICSR is considered low. The Malaysian PV reporting system, like most others countries around the world, suffers from underreporting of ADRs by HCPs.2 All ADR associated with the use of CAM (Complementary and alternative medicine) products (including health supplements) submitted to the Malaysian Centre for ADR Monitoring, National Pharmaceutical Regulatory Agency over a 15-year period were reviewed and analysed. From a total number of 74 997 ICSR reports in the database, 930 involved CAM products[13]. Malaysia started consumer reporting to improve compliance level from recent times. Various guidance documents are being prepared with the aim of developing a uniform framework towards assuring patient safety while expediting the availability of biosimilar products. Pharmacy student of several Malaysian universities confirmed that they had taken courses on the concept of pharmacovigilance during their current pharmacy curriculum.

C) PV System in Singapore

The Health Sciences Authority (HSA) has also appointed a Pharmacovigilance Advisory Committee (PVAC), which comprises experts in the fields of medicine, pharmacy, pharmacology, and forensic sciences for proper implementation of PV system in Singapore. Their main roles are to assess the impact of major drug safety issues and give advice on the appropriate regulatory actions to be taken to enhance drug safety[14]. The spontaneous adverse event (AE) reports submitted by HCPs and companies remain a critical information source for pharmacovigilance surveillance system. In Singapore, the Health Sciences Authority (HSA) is responsible for the management of the spontaneous reporting system (SRS). One of the important decision-making examples in recent time is to make HLA-B*1502 testing the standard of care prior to first use of CBZ (carbamazepine) in Asians and to subsidize the genotyping test at public hospitals. Expert configured natural language processing (NLP) framework in Hospital discharge summaries which offers a potentially resource of adverse event to evaluate drug safety in real-world practice. Major positive attributes of the Risk management programs include active involvement of independent expert clinical advisory committees in identifying and evaluating risks through the assessment of reports of serious and unusual reactions, and regular communications about risks from HSA to HCPs by means of bulletins[15].

D) PV System in Thailand

Initially, 18 regional centres were set up until 1992. However, in 1997, the regional centres were expanded to cover all the health products, and currently there are 23 centres in Thailand. However, in 2010, the focus changed from hospital-based ADR monitoring to community-based ADR monitoring. The vigilance system in

Thailand started in 1983 with focus on drugs, known as "Pharmacoviglance System", and was later expanded to include other health products (e.g. herbal medicines, vaccines, and medical devices) and became "Health Product Vigilance System" in 2008. The national centre's name was then changed to Health Product Vigilance Centre. Reporting of ADRs is a national program and all hospitals send reports of ADRs to this centre. The centre receives thousands of ADRs annually from various hospitals in Thailand. The reports received at Health Product Vigilance Centre (HPVC) grew steadily from a few hundred in the beginning to 50,000 reports per year nowadays. The adverse events were reported mainly from governmental hospitals.13 Research showed outpatients reported a high proportion of potential ADRs with high confidence and accuracy in Thailand.14 Survey conducted involving rural communities showed nearly half of community living experienced ADRs, and has implications for other rural elderly persons of low education.15 Thai National Pharmacovigilance Centre (NPVC) has been operational since 1983, but its performance has never been formally audited. The risk communication function was evaluated to be unsatisfactory in one of the studies recently[16].

E) PV System in Indonesia

In 2004, the PV unit was established under the Directorate of Distribution Control of Therapeutic and Household Healthcare Products. From the year 2008 to 2011, strengthening PV framework was happened, making it mandatory for the pharmaceutical industry to perform PV system. However, the agenda from the year 2012 to 2014 is to strengthen the risk management program, linking National Regulatory Authority (NRA) with public health program, development of dedicated website for PV activities including e-ADR reporting, collaborating with stakeholders (e.g. HCPs, pharmaceutical companies) to promote PV activities. The PV system in Indonesia consists of voluntary reporting through HCPs in hospitals and public health centres, general and private practices, through pharmacists in pharmacy. Mandatory reporting through Marketing Authorization Holders (MAH) was done through spontaneous ICSR by submitting Council for International Organizations of Medical Sciences (CIOMS) form[17].

F) PV System in Philippines

The PV system in the Philippines developed with the intention of promoting safer medicines and rational drug use. It is well known that in the Philippines, there is an increased level of traditional medicines use. As with several ASEAN countries, the culture of reporting ADRs is low, and this is perhaps in part because the AEs are unrecognized, sometimes the AE is misinterpreted as part of the healing action, and practitioners of these remedies are unlikely to report them. People who resort to herbal medicines are usually from the poor segment of the population and are likely to believe in unscientific claims and unlikely to report them. Recently Reporting of ADRs via texting was initiated with an existing ADR paper-based system[18].

G) PV System in Ethiopia

Ethiopia has developed a comprehensive pharmacovigilance (PV) system supported by a strong legal and regulatory framework to ensure the safety, efficacy, and quality of medicines. The system is governed by Proclamation No. 661/2009 and Regulation No. 299/2013, which define the regulatory responsibilities of the Ethiopian Food and Drug Authority (EFDA). The Ethiopian Health Policy (2000) emphasizes drug safety and rational medicine use, while the Guideline for Adverse Drug Events Monitoring

(Pharmacovigilance), 2014, provides detailed procedures for monitoring and reporting adverse drug reactions (ADRs)[19]. The ADR reporting system in Ethiopia operates under the coordination of the EFDA, serving as the National Pharmacovigilance Center. It follows a spontaneous (voluntary) reporting system, where healthcare professionals, pharmacists, and other stakeholders submit reports using standardized ADR reporting forms. Reports are collected through hospital-based pharmacovigilance focal points and directly by the EFDA. Marketing Authorization Holders (MAHs) are also mandated to report ADRs as part of post-marketing surveillance. The EFDA compiles and evaluates the reports in Bigalow, linked to the WHO-Uppsala Monitoring Centre (UMC) global database (VigiBase). This system enables early detection of safety signals, supports regulatory decisions, and contributes to global efforts in improving patient safety and drug quality monitoring[20].

H) PV System in Kenya

Kenya has established a structured pharmacovigilance (PV) system to ensure the safe and effective use of medicines, guided by several legislative and policy frameworks. The foundation of drug regulation in the country is provided by the Pharmacy and Poisons Act, Chapter 244 (1956), which regulates the manufacture, distribution, and use of pharmaceutical products. The Health Act (2017) and the Health Sector Policy (2015) further emphasize patient safety and the need for monitoring the quality and safety of medical products. To strengthen post-marketing surveillance, Pharmacovigilance Guidelines (2009) were developed, later complemented by the 2018 Pharmacovigilance Guidelines (Draft), providing updated procedures for adverse drug reaction (ADR) reporting and risk management[21]. The Pharmacy and Poisons Board (PPB) serves as Kenya's National Pharmacovigilance Center, overseeing the ADR reporting and monitoring system. The country primarily employs a spontaneous (voluntary) reporting system, where healthcare professionals, pharmaceutical companies, and consumers report suspected ADRs using standard forms or online platforms. The collected data is managed through VigiFlow, which connects Kenya to the WHO-Uppsala Monitoring Centre (UMC) global database (VigiBase). Through this system, Kenya actively identifies and evaluates safety signals, implements risk minimization measures, and promotes the rational and safe use of medicines across the healthcare system[22].

I) PV System in Tanzania

Tanzania has established a well-structured pharmacovigilance (PV) system to promote the safety, efficacy, and quality of medicines through an organized regulatory framework. The foundation of this system is rooted in the Food, Drug and Cosmetics Act of 2003, which empowers the Tanzania Medicines and Medical Devices Authority (TMDA) to regulate and oversee pharmaceutical activities. The Tanzania National Drug Policy (1991) underscores the importance of monitoring medicine safety as part of ensuring rational drug use. To strengthen post-marketing surveillance, the Regulations on Registration of Medicinal Products (2015) and the Pharmacovigilance Regulations (2018) were enacted, defining clear roles and responsibilities for stakeholders in medicine safety monitoring. Furthermore, the National Guidelines for Monitoring Medicines Safety (2018) provide practical procedures for adverse drug reaction (ADR) reporting, signal detection, and risk management[23].

The TMDA functions as the National Pharmacovigilance Centre, coordinating ADR reporting from healthcare professionals, pharmaceutical companies, and the public through a spontaneous reporting system using standardized ADR forms and online submission platforms. All collected reports are entered into VigiFlow, which is linked to the WHO-Uppsala Monitoring Centre (UMC) global database (VigiBase). Through this integrated system, Tanzania continuously monitors and evaluates medicine safety, enabling timely regulatory actions, strengthening patient protection, and contributing to global pharmacovigilance efforts.

J) PV System in GCC Countries

The Gulf Cooperation Council (GCC)—comprising Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates (UAE)—has developed robust and harmonized pharmacovigilance (PV) systems to ensure medicine safety, quality, and efficacy across the region. Pharmacovigilance activities in the GCC are coordinated both at the national level by individual drug regulatory authorities and regionally through the GCC-Drug Regulatory Committee (GCC-DR) under the GCC Health Council. Each member state has established its own national pharmacovigilance center responsible for monitoring and managing Adverse Drug Reactions (ADRs) and promoting the rational use of medicines.

In Saudi Arabia, the Saudi Food and Drug Authority (SFDA) overseas pharmacovigilance activities through the National Pharmacovigilance and Drug Safety Centre, which collects and evaluates ADR reports via VigiFlow and contributes to the WHO-Uppsala Monitoring Centre (UMC) global database (VigiBase). The United Arab Emirates (UAE) implements its PV system under the Ministry of Health and Prevention (MOHAP), which established national guidelines for ADR reporting and post-marketing surveillance. Qatar, through the Pharmacy and Drug Control Department (PDCD) under the Ministry of Public Health, encourages healthcare professionals and companies to report ADRs via structured reporting forms and electronic systems. Oman has a well-developed PV framework led by the Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC), which has implemented national pharmacovigilance guidelines aligned with WHO standards. Kuwait and Bahrain have also strengthened their systems through national reporting centers managed by their respective Ministries of Health, focusing on spontaneous ADR reporting and regional data sharing[24].

Collectively, the GCC countries promote pharmacovigilance collaboration through shared databases, harmonized reporting standards, and coordinated safety signal assessments within the region. These efforts support early detection of adverse drug effects, informed regulatory actions, and continuous improvement in public health and patient safety across the Gulf region.

K) PV System in Latin America

The Latin American region has made significant progress in developing and strengthening pharmacovigilance (PV) systems to enhance the safety, efficacy, and quality of medicines. Nearly all countries in the region have established National Pharmacovigilance Centers (NPCs) that coordinate Adverse Drug Reaction (ADR) monitoring, reporting, and evaluation in collaboration with the World Health Organization (WHO) and the Uppsala Monitoring Centre (UMC) through the global database VigiBase. The countries that actively operate pharmacovigilance systems include Argentina, Brazil, Chile, Colombia, Costa Rica, Cuba, Dominican

Republic, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Uruguay, and Venezuela[25].

Among these, Brazil plays a leading role through the National Health Surveillance Agency (ANVISA), which manages ADR reporting via its national system Notivisa and conducts signal detection and risk management. Mexico, through the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), coordinates pharmacovigilance activities under the National Pharmacovigilance Center (CNFV). Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT) operates a comprehensive PV network linked to hospitals and healthcare institutions. Chile's Institute of Public Health (ISP) and Colombia's National Institute for Food and Drug Surveillance (INVIMA) also maintain active reporting systems and participate in regional harmonization efforts[26].

Across Latin America, pharmacovigilance follows mainly a spontaneous (voluntary) reporting model, complemented by targeted post-marketing studies and active surveillance programs. Regional collaboration is promoted through organizations such as the Pan American Network for Drug Regulatory Harmonization (PANDRH), which supports standardization of PV guidelines and capacity building. Collectively, Latin American countries are working toward greater integration and harmonization of pharmacovigilance systems to strengthen medicine safety surveillance and ensure public health protection across the region[27].

L) PV System in CIS Countries

The Commonwealth of Independent States (CIS)—which includes Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan—has progressively developed pharmacovigilance (PV) systems to monitor and ensure the safety, quality, and efficacy of medicines. These systems are primarily guided by national drug regulatory authorities, many of which align their practices with the World Health Organization (WHO) pharmacovigilance framework and the standards of the Uppsala Monitoring Centre (UMC) through participation in VigiBase, the global ADR database[28].

Overall, the CIS countries employ a spontaneous (voluntary) reporting system supported by healthcare professionals, pharmaceutical companies, and healthcare institutions. Ongoing regional cooperation under the Eurasian Economic Union (EAEU) has significantly enhanced the harmonization of pharmacovigilance regulations, ensuring consistent safety monitoring, efficient signal detection, and timely regulatory actions across the CIS region.

M) Pharmacovigilance in Argentina

Argentina established the National Administration of Drugs, Foods and Medical Devices (ANMAT) in 1992 under National Decree No. 1490/1992. Later, in September 1993, the National Pharmacovigilance System was introduced through Resolution 706/1993 within the ANMAT framework. Argentina became a member of the WHO-Uppsala Monitoring Centre (UMC) in 1994 and gained access to the Vigimed international network in 1999 for global drug safety communication and information exchange[29].

The Argentine National Pharmacovigilance System is responsible for collecting, evaluating, and organizing information related to adverse drug reactions (ADRs) during post-marketing use of medicines. Its functions include monitoring the safety and efficacy of drugs, identifying adverse effects from acute and chronic drug use, evaluating medicine-related risks, studying

pharmacoepidemiological profiles, and implementing regulatory and control measures. The system is coordinated by the Pharmacovigilance Department under ANMAT through a National Centre and regional representatives located across the country[30].

System has a Committee of Honor and a National Commission of Pharmacovigilance (Resolution 706/1993, article #4), both exercise their functions adhonorem and have neither executive nor management attribute

Table 1: Comparison of Pharmacovigilance Systems in ROW Countries

Sr. No.	Country/ Region	Regulatory Authority	ADR Reporting System	Key Strengths	Major Challenges
01	India	PvPI / CDSCO	Spontaneous reporting via AMCs	Large ADR network, WHO-Uppsala contribution	Underreporting in rural areas
02	Malaysia	MADRAC	Voluntary reporting	Consumer reporting introduced	Low ADR reporting rate
03	Singapore	HSA	Electronic spontaneous reporting	NLP and AI integration	Limited public participation
04	Thailand	HPVC	Community-based vigilance	Strong hospital participation	Weak risk communication
05	Indonesia	National PV Unit	Mandatory + voluntary reporting	E-ADR reporting initiatives	Limited awareness
06	Philippines	FDA Philippines	Paper + SMS reporting	Traditional medicine monitoring	Underreporting of herbal ADRs
07	Ethiopia	EFDA	Spontaneous reporting via VigiFlow	WHO-supported framework	Resource limitations
08	Kenya	PPB	Online + voluntary reporting	VigiFlow integration	Technical barriers
09	Tanzania	Tanzania	Standard ADR forms + online reporting	Strong regulations	Limited trained manpower
10	GCC Countries	GCC-DR / National Authorities	Harmonized regional reporting	Regional collaboration	Regulatory variability
11	Latin America	ANVISA, ANMAT, COFEPRIS etc.	National PV networks	PANDRH harmonization	Uneven infrastructure[31]
12	CIS Countries	National Regulatory Authorities	Spontaneous reporting	EAEU harmonization	Limited digitalization

THE UPPSALA MONITORING CENTRE

The Uppsala Monitoring Centre serves as the operational centre for the World Health Organization Programme for International Drug Monitoring and is responsible for managing the global database of adverse drug reaction (ADR) reports. Established in 1978 through a collaboration between the WHO and the Swedish government, the centre primarily focuses on collecting and evaluating ADR data submitted by member countries participating in the international

monitoring programme. By mid-2002, the programme included 68-member nations[32].

According to the Uppsala Report 22, the number of ADR reports associated with herbal medicines in the WHO database increased from 8,986 in 1997 to 11,716 in 2002. Although this number remained significantly lower than reports related to conventional medicines, the rise highlighted the growing importance of continuous safety monitoring for herbal products. Between 2001 and 2002, the UMC received approximately 162,336 ADR reports, bringing the total number of records in the global database to nearly 2.85 million by 2002[33].

WHO Programme for International Drug Monitoring

The WHO Programme for International Drug Monitoring (PIDM) is a global pharmacovigilance programme established by the World Health Organization in 1968 after the Thalidomide Tragedy to improve medicine safety and monitor adverse drug reactions (ADRs) worldwide[34].

The programme aims to:

- Detect and prevent adverse drug reactions
- Improve patient safety
- Promote safe and rational use of medicines
- Support international collaboration in pharmacovigilance[35]

The programme is coordinated by the Uppsala Monitoring Centre (UMC), Sweden, which manages VigiBase, the global database of Individual Case Safety Reports (ICSRs).

Key Functions

- Collection and analysis of ADR reports
- Signal detection of new drug safety issues
- Sharing safety information globally
- Supporting regulatory authorities in risk assessment
- Strengthening pharmacovigilance systems in member countries [36]

Importance in ROW Markets

WHO PIDM helps developing and ROW countries strengthen ADR reporting systems, improve regulatory decisions, and access global medicine safety data.

Challenges

- Underreporting of ADRs
- Lack of awareness and trained professionals[37]

WHO-Uppsala monitoring centre (UMC) causality assessment criteria

The WHO-UMC causality assessment method includes the following criteria

- Certain-adverse event and the time relationship associated with it
- Probable/likely-unlikely to attribute the other drugs or diseases \
- Possible-this can be explained by the drug intake or another disease[38]
- Unlikely-adverse event can be explained with the time relationship associated with it but it's not impossible
- Conditional/unclassified data in needed to make a proper assessment

- Unassessable /unclassifiable-and adverse event is suggested but more data are needed to make an assessment[39].

ARTIFICIAL INTELLIGENCE IN PHARMACOVIGILANCE

The exponential growth of healthcare data, fuelled by the widespread adoption of patient-tracking digital tools, offers a major opportunity to leverage artificial intelligence (AI) for enhanced drug safety assessment[40]. In clinical research, natural language processing (NLP) and text mining have become vital for extracting meaningful insights from massive amounts of unstructured text. Within pharmacovigilance, these technologies allow public and private entities to automate the tracking of adverse drug reactions (ADRs) and drug-drug interactions from diverse sources. Furthermore, AI and machine learning are transforming drug safety by automating case report data entry, identifying clusters of side effects that indicate specific syndromes, strengthening pharmacoepidemiological studies, linking disparate datasets through probabilistic matching, and utilizing real-world data models to predict and prevent adverse events[41].

Table 2: Major Gaps and Improvement Strategies in ROW Pharmacovigilance Systems

Sr. No.	Identified Gap	Impact on PV System	Suggested Improvement Strategy
01	Underreporting of ADRs	Delayed signal detection	Awareness programs for HCPs and patients
02	Lack of trained professionals	Poor ADR assessment quality	Regular pharmacovigilance training
03	Weak digital infrastructure	Slow data processing	Implement e-reporting systems
04	Limited regulatory harmonization	Inconsistent safety standards	Adoption of WHO & ICH guidelines
05	Poor stakeholder coordination	Delayed regulatory actions	Strong inter-agency collaboration
06	Low public awareness	Reduced consumer reporting	Public ADR awareness campaigns
07	Resource constraints	Weak monitoring systems	Government funding and WHO support
08	Manual case processing	Increased workload and errors	AI and automation integration
09	Limited signal detection capability	Missed safety concerns	Machine learning-based analytics
10	Weak post-marketing surveillance	Unsafe medicine continuation	Strengthen PMS activities[42]

FUTURE PROSPECTIVE

The future of pharmacovigilance in ROW markets depends on strengthening ADR reporting systems through digital technologies, AI, machine learning, and improved regulatory frameworks. Increasing awareness among healthcare professionals, enhancing international collaboration, and adopting harmonized guidelines will improve drug safety monitoring. Future efforts should focus on identifying existing gaps and improving them through the development of effective regulatory, technological, and reporting strategies to ensure better patient safety and global pharmacovigilance practices.

CONCLUSION

Strengthening pharmacovigilance capacity in ROW countries is both a critical local public health

priority and a shared global responsibility in an increasingly interconnected pharmaceutical market. Aligning regional systems with international standards set by the WHO and ICH requires addressing foundational weaknesses, including low reporting awareness among healthcare professionals and weak coordination between regulatory agencies.

Moving forward, the integration of digital technologies and Artificial Intelligence (AI) presents a transformative path to overcome these resource barriers. Implementing machine learning, text mining, and Natural Language Processing (NLP) allows regulatory bodies to automatically process unstructured healthcare data and execute case-report entries efficiently. By leveraging these AI capabilities alongside enhanced stakeholder training and regional collaborations (such as the EAEU, PANDRH, and GCC frameworks), ROW markets can drastically optimize safety signal detection, bridge current infrastructure gaps, and ensure robust patient safety on a global scale.

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CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

REFERENCES

1. Garashi H Y, Steinke D T, Schafheutle E I. A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators. Therapeutic Innovation & Regulatory Science. 2022;56(5):717-743.
2. Campbell J E, Gossell-Williams M, Lee M G. A Review of Pharmacovigilance. West Indian Medical Journal. 2015;63(7):771-774.
3. Walsh M, et al. Challenges and Solutions for Pharmacovigilance in Developing Countries. (Open-access).
4. Sharif M A, Kazi A, Rweyemamu M A. Why Pharmacovigilance and Adverse Drug Reaction Reporting Practices Lacks in Developing Countries: A Study from Pakistan. Sys Rev Pharm. 2021;12(11):604-610.
5. Oosterhuis M, et al. Adverse-Drug-Reaction-Related Hospitalisations in Developed and Developing Countries: A Review. (2016) British / Int'l journal.
6. Tan MK, et al. Barriers to Adverse Drug Reaction Reporting in Malaysia: a narrative review based on the theoretical domain's framework. Journal of Pharmaceutical Health Services Research. 2021;12(4):626-6278229.
7. Kalaiselvan V, Srivastava S, Singh A, Gupta SK. Pharmacovigilance in India: Present Scenario and Future Challenges. Drug Saf. 2019;42(3):339–46. doi:10.1007/s40264-018 0730-7.
8. Biswas P. Pharmacovigilance in Asia. J Pharm Pharmacother. 2013;4(1):7.
9. Thota P, Thota A, Medhi B, Sidhu S, Kumar P, Selvan V, et al. Drug safety alerts of pharmacovigilance programme of India: A scope for targeted spontaneous reporting in India. Perspect Clin Res. 2018;9(1):51. doi:10.4103/picr.picr_29_17.

10. Pharmacovigilance Programme of India (PvPI) Performance Report ; 2018-19.
11. Shaikh A, Aziz Z. Complementary and alternative medicine: Pharmacovigilance in Malaysia and predictors of serious adverse reactions. J Clin Pharm Ther. 2020;45(5):946–58. doi:10.1111/jcpt.13106.
12. Sawanpanyalert P, and WS. Health Products Vigilance in Thailand: Past, Present and Future. J Health Sci. 2016;25(3):444–55.
13. Endale S., Marew W., Fenta T. G. Implementation Status and Challenges of Pharmacovigilance Program in Ethiopia: A Mixed-Methods Study. PMC. 2024.
14. Sisay E. Pharmacovigilance System in Ethiopia: Implementation Status and Challenges. Thesis, Addis Ababa University, 2021.
15. Tekel M. T., Bekalu A. F., Sema F. D. Knowledge, Attitude, and Practice of Pharmacovigilance and ADR Reporting at University of Gondar, Ethiopia. Advances in Medical Education and Practice. 2021. 16) Achalu D. L., Mamo G. M. Practices and awareness of pharmacovigilance in ALERT hospital, Addis Ababa, Ethiopia: a pilot study. PAMJ Clinical Medicine. 2024.
16. Garashi H. Y., Steinke D. T., Schafheutle E. I. A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators. Therapeutic Innovation & Regulatory Science. 2022.
17. Barry A., Olsson S., Minzi O., et al. Comparative Assessment of the National Pharmacovigilance Systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania. Drug Safety. 2020.
18. Agoro O. O., Kibira S. W., Freeman J. V., Fraser H. S. F. Barriers to the success of an electronic pharmacovigilance reporting system in Kenya: an evaluation three years post implementation. J Am Med Inform Assoc. 2017.
19. Toroitich A. M., Armitage R., Tanna S. Suspected poor-quality medicines in Kenya: a retrospective descriptive study of medicine quality-related complaints reports in Kenya's pharmacovigilance database. BMC Public Health. 2024.
20. Garashi H. Y., Steinke D. T., Schafheutle E. I. A qualitative exploration of pharmacovigilance policy implementation in Jordan, Oman, and Kuwait using Matland's ambiguity-conflict model. Globalization and Health. 2021.
21. 22)Alsheikh M. Y., Alasmari M. M. A National Survey of Community Pharmacists' Viewpoints about Pharmacovigilance and ADR Reporting in Saudi Arabia. Frontiers in Pharmacology. 2022.
22. Short-Term Training, a Useful Approach for Sustainable Pharmacovigilance Knowledge Development in Tanzania, Kenya, Ethiopia and Rwanda. Drug Safety. 2024.
23. Garashi, H. Y., Steinke, D. T., & Schafheutle, E. I. (2022). A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. Therapeutic Innovation & Regulatory https://doi.org/10.1007/s43441-022-00415-y (Open access) Science, 56(5), 717–743.
24. Al-Abdulrhman, Z. (2022). The development of a pharmacovigilance system in Bahrain. [Journal Name]. (Note: citation details need to be completed when full text accessed)
25. Hamid, A. A. & Mohamed Ibrahim, M. I. (2017). A systematic scoping review of the state of pharmacovigilance and governance in the MENA region: Challenges and Opportunities. [Master/PhD thesis]. Qatar University.

26. AlSheikh, M. Y., & Alasmari, M. M. (2022). A national survey of community pharmacists' viewpoints about pharmacovigilance and ADR reporting in Saudi Arabia. Frontiers in Pharmacology. (Proceed to retrieve full citation)
27. Al-Saoud, A., … (2022). Strengths and weaknesses of the pharmacovigilance systems in three Arab countries: A mixed-methods study using the WHO pharmacovigilance indicators. [Journal]. https://pubmed.ncbi.nlm.nih.gov/35270208/
28. Hoffmann, E., Fouretier, A., Vergne, C., & Bertram, D. (2012). Pharmacovigilance regulatory requirements in Latin America. Pharmaceutical Medicine, 26(3), 153-164. https://doi.org/10.2165/11631470-000000000-00000
29. Castañeda-Hernández, G., Sandoval, H., Coindreau, J., Rodriguez-Davison, L. F., & Pineda, C. (2019). Barriers towards effective pharmacovigilance systems of biosimilars in rheumatology: A Latin American survey. Pharmacoepidemiology & Drug Safety, 28(8), 1035 1044. https://doi.org/10.1002/pds.4785 (Open access)
30. Olivera, M. E., Uema, S. A. N., Romañuk, C. B., Caffaratti, M., Mastroianni, P. d. C., Varallo, F. R., … Vega, E. M. (2014). Regulatory issues on pharmacovigilance in Latin American countries. Pharmaceuticals Policy & Law, 16, 289-312. https://doi.org/10.3233/PPL 140390 the
31. Pan American Health Organization (PAHO). (2011). Good Pharmacovigilance Practices for Americas. Pan American Health Organization / https://www.paho.org/en/documents/good-pharmacovigilance-practices-americas-2011 WHO.
32. Rodrigues, L. F., et al. (2021). Statin-associated adverse reactions in Latin America: A scoping review. [Journal]. https://pubmed.ncbi.nlm.nih.gov/34598987/
33. Garashi, H. Y., Steinke, D. T., & Schafheutle, E. I. (2022). A systematic review of pharmacovigilance systems in developing countries using the WHO pharmacovigilance indicators. (same as GCC list)
34. PharmExpert LLC. (2023). The pharmacovigilance in the CIS, EAEU. https://pharmex.co/the-pharmacovigilance-in-the-cis-eaeu/ (review article online)
35. Centralized Pharmacovigilance: Ensuring Compliance and Efficiency Across Global Markets" (Biomapas). Biomapas. (2024). https://www.biomapas.com/centralized pharmacovigilance-ensuring-compliance-and-efficiency-across-global-markets.
36. Available from: www.paho.org/hq/index.php?option=com_content&view=article&id=1592&Itemid=40147 [Last accessed 8 March 2015]
37. van Hunsel FPAM. The contribution of direct patient reporting to pharmacovigilance. thesis Groningen: Rijsuniversiteit Groningen; 2011
38. Avery AJ, Anderson C, Bond CM, et al. Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys. Health Technol Assess 2011;15:20
39. Hartigan-Go K. Empowering consumers as contributors for health product safety: lessons from the Philippines. Drug Saf 2015;38(4):329-3
40. Bate, A., and Hobbiger, S. F. (2021). Artificial Intelligence, Real-World Automation and the Safety of Medicines. Drug Saf. 44 (2), 125–132. doi:10.1007/s40264 020-01001-7
41. Wong, A., Plasek, J. M., Montecalvo, S. P., and Zhou, L. (2018). Natural Language

Processing and its Implications for the Future of Medication Safety: A Narrative Review of Recent Advances and Challenges. Pharmacotherapy 38 (8), 822–841. doi:10.1002/phar.2151.

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