MINISTRY OF HEALTH OF UKRAINE
NATIONAL UNIVERSITY OF PHARMACY
pharmaceutical faculty
department of social pharmacy

QUALIFICATION WORK

on the topic: « **CURRENT TRENDS IN PHARMACOVIGILANCE AND ADVERSE DRUG REACTIONS REPORTING IN MOROCCO »**

Performed by: higher education graduate of group Фм20 (4,10д) англ-01
specialty 226 Pharmacy, industrial pharmacy
educational and professional program Pharmacy
Ibtissam MORCHAD
Supervisor: associates professor of higher education institution of department of social pharmacy, PhD,
Iryna SURIKOVA
Reviewer: associate professor of higher education institution of department of management, marketing and quality assurance in pharmacy, PhD
Iryna BONDARIEVA

Kharkiv – 2025

ANNOTATION

The qualification work examines current trends in pharmacovigilance and ADR reporting in Morocco. It highlights CAPM's role, Morocco's participation in WHO PIDM, and pharmacist involvement. Key reporting challenges are identified, and strategic solutions are proposed to strengthen the national PV system through education, digital tools, and institutional reforms.

The qualification work consists of an Introduction, 3 chapters, conclusions, a list of used sources and is laid out on 43 pages of printed text. The work is illustrated with 8 figures and 5 tables. The bibliography includes 59 information sources.

Keywords: pharmacovigilance, adverse drug reaction, Morocco, pharmacist's role, patient safety, healthcare system.

АНОТАЦІЯ

У кваліфікаційній роботі проаналізовано сучасні підходи до фармаконагляду та звітності про побічні реакції в Марокко. Розкрито роль національного центру CAPM, участь країни в програмі ВООЗ та бар'єри для залучення фармацевтів. Визначено проблеми звітності та запропоновано шляхи покращення системи фармаконагляду в Марокко через освітні, інституційні та цифрові інструменти.

Кваліфікаційна робота складається зі вступу, 3 розділів, висновків, списку використаних джерел та розміщена на 43 сторінках друкованого тексту. Робота ілюстрована 8 рисунками та 5 таблицями. Бібліографія містить 59 джерела інформації.

Ключові слова: фармаконагляд, побічна реакція на лікарські засоби, Марокко, роль фармацевта, безпека пацієнтів, система охорони здоров'я.

CONTENT

LIST OF ABBREVIATIONS

ADE – Adverse Drug Event

ADR –Adverse Drug Reaction

AEFI – adverse events following immunization

AI – Artificial Intelligence

CAPM–The Moroccan Anti-Poison and Pharmacovigilance Center

EHR – Electronic Health Record

EMA – European Medicines Agency

FDA – U.S. Food and Drug Administration

GVP – Good Pharmacovigilance Practices

ICH – International Council for Harmonization

ICSR – individual case safety reports

ML – machine learning

NSAID– nonsteroidal anti-inflammatory drug

NCBI – National Center for Biotechnology Information

QPPV – Qualified Person for Pharmacovigilance

PIDM – Programme for International Drug Monitoring

PSUR – periodic safety update reports

PV– Pharmacovigilance

UHC – University Hospital Centers

UMC – The Uppsala Monitoring Center

WHO – World Health Organization

INTRODUCTION

Pharmacovigilance (PV), defined by the World Health Organization as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems, is a cornerstone of modern public health systems. As pharmaceutical products reach broader populations and are increasingly used outside controlled clinical trials, the importance of robust PV systems has become more critical than ever. Ensuring the safety of medicines not only protects patients but also maintains public trust in healthcare systems.

Over the past decades, global pharmacovigilance efforts have significantly evolved. High-income countries have implemented sophisticated regulatory frameworks and digital infrastructures, enabling timely signal detection, efficient ADR (adverse drug reaction) reporting, and active patient engagement. Conversely, low- and middle-income countries, including Morocco, face systemic challenges such as underreporting, limited awareness, and insufficient digital capacity.

In recent years, Morocco has made visible progress in pharmacovigilance, becoming a full member of the WHO Programme for International Drug Monitoring (PIDM) and establishing the Moroccan Anti-Poison and Pharmacovigilance Center (CAPM). Despite these achievements, the national PV system continues to experience persistent barriers, particularly in adverse event reporting and healthcare professional involvement – especially among pharmacists.

Given the increasing complexity of drug use, the rise in polypharmacy, and the introduction of new treatment modalities (e.g., biologics, vaccines, and herbal preparations), enhancing Morocco's PV capacity is a pressing need. Pharmacists, as accessible and trusted healthcare providers, are in a unique position to contribute to this effort through timely detection and reporting of adverse drug reactions (ADR). However, studies have shown a gap between their theoretical knowledge and practical

involvement. This underscores the need for research focused not only on systemic evaluation but also on professional engagement.

The purpose of the study: to analyze current trends in PV and adverse drug reactions reporting in Morocco.

Research objectives:

- to review scientific sources on global pharmacovigilance and ADR reporting practices;
- to conduct global overview international efforts in pharmacovigilance and ADR reporting;
- to analyze innovations and best practices in international PV systems;
- to evaluate the development and current state of the national PV system in Morocco;
- to assess the legal framework and identify challenges and gaps in ADR reporting;
- to examine the pharmacist's role in Morocco's PV system and propose recommendations for improvement.

The object of the research: literary sources regarding the review of the PV system and ADRs reporting, the regulatory framework regulating the safety of medicines worldwide and in Morocco, main indicators of PV activities in Morocco.

The subject of the study: Current problems and development prospects of Morocco's pharmacovigilance system, with a focus on the role of pharmacists in ADR reporting.

Research methods. The following methods were used: analytical and comparative analysis, content analysis of literature and regulatory documents, graphical and statistical methods, descriptive modeling, and generalization techniques.

The scientific novelty and practical significance of this research lie in its focused analysis of Morocco's pharmacovigilance system, combining global best practices with local challenges to highlight gaps in ADR reporting and the pharmacist's

role. By examining legal frameworks, underreporting issues, and system development, the study offers practical insights that can support improvements in drug safety monitoring and inform future policy and training initiatives in Morocco.

The study results were approved at the XXXI International scientific and practical conference of young scientists and students "TOPICAL ISSUES OF THE NEW MEDICINES DEVELOPMENT" held on April 23-25, 2025.

Structure and scope of qualification work. The qualification work consists of the introduction, three chapters, a conclusion to each chapter, a general conclusion, and a list of sources used. The results of the study are presented on 43 pages of text, the number of figures – 8, tables – 5 and the list of references – 59 titles

CHAPTER I.
THEORETICAL FOUNDATIONS AND GLOBAL PERSPECTIVES ON PHARMACOVIGILANCE AND ADVERSE DRUG REACTION REPORTING

1.1 The concept and evolution of pharmacovigilance

Pharmacovigilance (PV), as defined by the World Health Organization (WHO), is "the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems" [39]. It plays a pivotal role in safeguarding public health by ensuring the continued safety of medications, especially after they are introduced into real-world clinical use beyond the controlled settings of clinical trials. In an era of globalized pharmaceutical markets, rising patient expectations, and complex therapeutic regimens, the relevance and scope of pharmacovigilance have expanded substantially.

The historical evolution of pharmacovigilance has been shaped by notable drug-related tragedies and regulatory responses that underscored the necessity of structured post-marketing surveillance systems. Key milestones in the evolution of pharmacovigilance, as illustrated in Figure 1.1, reflect the transformation of PV into a scientific discipline with regulatory and clinical implications [49]. These milestones laid the groundwork for modern PV practices that inform public health policy, pharmaceutical regulation, and clinical decision-making.

The primary objective of pharmacovigilance is to promote the safe and effective use of medicines by continuously identifying, evaluating, and mitigating risks associated with pharmacotherapy. This process is inherently dynamic and involves the collaboration of various stakeholders, including regulatory authorities, pharmaceutical companies, healthcare professionals, and patients [32].

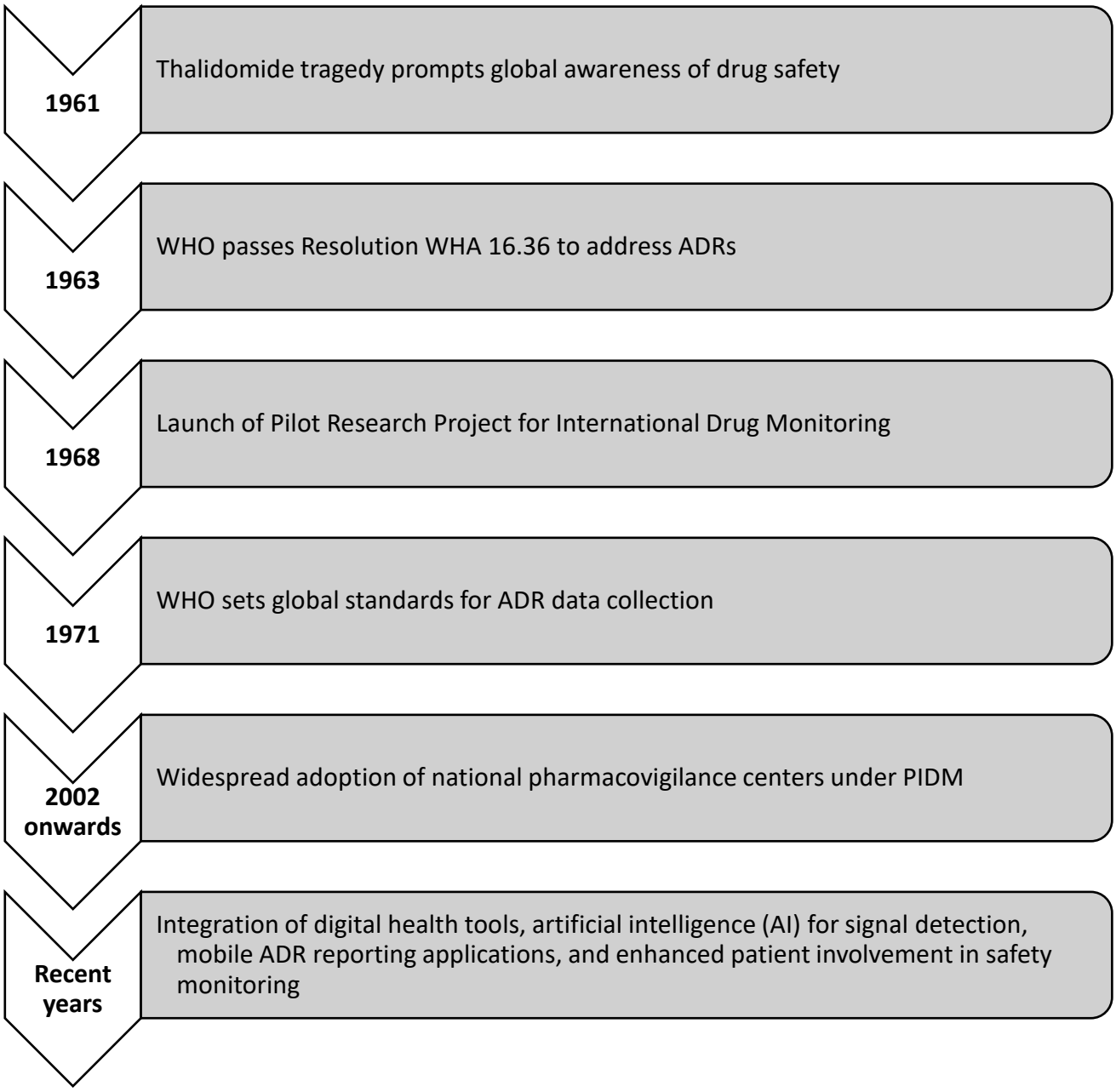

Fig. 1.1. Key Milestones in Pharmacovigilance Evolution

One of the core components of PV is the collection and analysis of safety data from diverse sources – clinical trials, spontaneous reports from healthcare professionals and patients, observational studies, and literature reviews. These reports encompass adverse drug reactions (ADRs), medication errors, and other safety concerns. As the data is aggregated and analyzed, the identification of a "signal" – defined as new or previously unrecognized information that may indicate a potential

causal association between a drug and an adverse event – becomes a critical step in the surveillance process [32].

Upon signal detection, a thorough and scientifically grounded evaluation must be conducted. This involves reviewing the scientific literature, initiating targeted epidemiological or mechanistic studies, and consulting multidisciplinary expert panels. Based on the outcomes of such assessments, regulatory decisions may be taken to update drug safety profiles, modify labeling, restrict indications, or in extreme cases, withdraw a product from the market.

Additionally, PV encompasses proactive risk management, which includes developing and implementing Risk Management Plans for newly approved medications. These plans outline risk minimization measures and monitoring strategies designed to detect and respond to safety issues in a timely manner. As illustrated in Figure 1.1, the establishment of global monitoring systems and digital tools has enhanced the effectiveness of these activities.

The evolution of PV systems over time demonstrates the transition from passive reporting mechanisms to integrated, technology-driven, proactive surveillance networks. This transformation has enabled faster signal detection and more effective responses to emerging safety concerns.

1.2 Objectives, processes and key stakeholders in pharmacovigilance systems

Pharmacovigilance is defined as the discipline concerned with the identification, evaluation, understanding, and prevention of adverse effects and other drug-related problems [4]. Its overarching goal is to enhance patient safety by promoting the rational and cost-effective use of pharmaceutical products, thereby improving public health outcomes.

The main objectives of PV systems are multifaceted. Firstly, they seek to ensure the continued safety and efficacy of medications through long-term post-marketing surveillance. This involves not only the identification of ADRs, but also the comprehensive evaluation of benefit-risk profiles across diverse patient populations. Secondly, PV serves as an educational and regulatory tool by facilitating the dissemination of safety-related information to healthcare professionals, regulatory authorities, and patients. It also guides the development of safety monitoring programs, risk communication strategies, and informed policy decisions.

By promoting the responsible use of medications, PV contributes to greater health system efficiency. The availability of timely and reliable safety data supports cost-saving interventions, minimizes avoidable hospitalizations, and reduces the incidence of medication-related harm. Furthermore, the expansion of PV education and training programs enhances awareness, strengthens pharmacotherapy competencies among health professionals, and encourages a culture of continuous quality improvement [4].

The Uppsala Monitoring Centre (UMC), a WHO Collaborating Centre for International Drug Monitoring, plays a central role in global signal detection efforts. Through tools such as VigiBase, the world's largest global database of individual case safety reports (ICSRs), the UMC employs sophisticated statistical algorithms and clinical assessment methodologies to identify potential safety concerns. Additional resources such as VigiLyze, a web-based analytical platform, and the manual review of scientific literature complement these automated processes by offering nuanced insights into drug–event associations [18].

The pharmacovigilance process typically follows a structured cycle, which begins with the identification of an adverse event and proceeds through notification, reporting, assessment, and dissemination of feedback to relevant stakeholders. Figure 1.2 illustrates the WHO pharmacovigilance cycle and highlights the essential steps involved, from data acquisition to regulatory action [53].

Fig 1.2. WHO Pharmacovigilance Cycle

Effective PV systems rely on the coordinated participation of a broad spectrum of stakeholders. Among the primary actors are:

- Regulatory authorities (e.g., the European Medicines Agency, EMA), which are responsible for defining the legal and procedural framework for PV operations. These agencies ensure the systematic collection, evaluation, and interpretation of ADR reports and implement risk minimization measures as needed [13].
- Pharmaceutical companies, particularly marketing authorization holders, are legally mandated to maintain internal PV systems. Their responsibilities include the continual monitoring of product safety, submission of periodic safety update reports (PSURs), and revision of product information in light of new data [13].
- Healthcare professionals, including physicians, pharmacists, and nurses, are frontline contributors to the detection and documentation of ADRs. Their clinical expertise and proximity to patients enable the early identification of safety signals and support evidence-based decision-making.
- Patients and caregivers increasingly play an active role in pharmacovigilance. With the advent of direct patient reporting channels, such as mobile

applications and web-based platforms, individuals can now submit firsthand accounts of suspected ADRs. This participatory approach enhances the granularity and contextual richness of PV databases [26].

The effectiveness of PV systems is also shaped by their ability to adapt to emerging challenges. For example, the integration of artificial intelligence (AI) and machine learning (ML) technologies is transforming pharmacovigilance by enabling the automated processing of large-scale datasets. Features such as real-time semantic analysis, predictive modeling, and AI-assisted triaging improve the speed, accuracy, and responsiveness of ADR signal detection [48].

Moreover, the global increase in the use of herbal and traditional medicines has prompted the inclusion of such products in PV frameworks. Given the extensive population exposure and the potential for drug–herb interactions, incorporating traditional medicine into PV systems is essential for comprehensive drug safety surveillance [58].

Recent surveys among pharmacovigilance professionals in the United States and Europe reveal a trend toward automation: while approximately 20% of case processing is currently automated, this figure is expected to exceed 60% in the near future. Despite this, the adoption of advanced AI/ML tools remains limited (only 5%). Key priorities identified by respondents include improving regulatory compliance (40%), data quality (30%), and operational efficiency (29%). However, barriers such as insufficient funding, integration difficulties, and a shortage of qualified personnel persist. These findings highlight the importance of strategic outsourcing, workforce training, and technological innovation in modern PV systems.

In summary, pharmacovigilance functions as an interdisciplinary, collaborative effort that requires the engagement of multiple stakeholders. From the early identification of ADRs to the dissemination of safety information and implementation of corrective measures, each actor plays a vital role in ensuring that pharmaceutical products are used safely, effectively, and equitably across healthcare settings.

1.3 Approaches to Classification and Mechanisms of Adverse drug reactions

Adverse drug reactions (ADRs) are defined as harmful and unintended responses to medicinal products that occur at normal therapeutic doses used for prevention, diagnosis, or treatment of disease. These reactions can vary in severity, ranging from mild skin rashes to life-threatening conditions such as hepatic failure or anaphylaxis [3]. ADRs differ from side effects, which are predictable but unintended pharmacological effects occurring during normal drug use [10].

According to the Association of Health Care Journalists, an adverse event refers to any unfavorable medical occurrence following the administration of a treatment, which may or may not be causally related to the intervention. In contrast, a side effect is a subset of adverse events directly attributable to the administered intervention. This distinction clarifies that while all side effects are adverse events, not all adverse events are necessarily side effects [18].

In the context of pharmacovigilance, ADRs represent a critical subset of adverse events with a confirmed or suspected causal link to drug therapy. They are central to evaluating the benefit–risk balance of medicinal products and are essential for post-marketing safety monitoring and regulatory decision-making [18].

Medication errors constitute another significant category within pharmacovigilance. These are preventable mistakes that occur throughout the medication use process – including prescribing, dispensing, administering, and monitoring – and which may result in harm to the patient. Contributing factors to such errors include poor communication among healthcare providers, incomplete patient information, system-level failures, and human factors such as fatigue and insufficient training. Medication errors can lead to serious ADRs, prolonged hospital stays, and, in extreme cases, patient fatalities. To mitigate such risks, many health systems have adopted technological safeguards such as computerized physician order entry CPOE, barcoding systems, and structured incident reporting mechanisms. Equally important

is fostering a safety culture that encourages error reporting and continuous professional development.

Figure 1.3 illustrates how medication errors may result in adverse drug events (ADEs), some of which qualify as ADRs if a causal relationship is established [3].

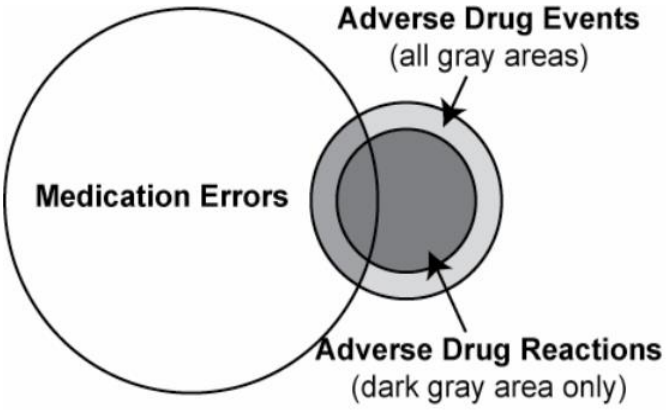

Fig 1.3. Connection between Medication errors, ADE, and ADR

To systematically evaluate ADRs, several classification frameworks have been developed.

One widely adopted approach is based on the mechanism and predictability of the reaction. According to the National Center for Biotechnology Information (NCBI) Bookshelf, ADRs can be classified into two main categories: Type A (augmented) and Type B (bizarre). This classification is summarized in Table 1.1 [4].

Another established classification method is provided by The Merck Manuals, which divides ADRs into three categories [46]:

- Dose-related ADRs: These occur when the therapeutic dose exceeds the patient's tolerance. For example, excessive doses of antihypertensive drugs may lead to hypotension.
- Allergic drug reactions: These are immune-mediated and not dose-dependent. They typically require prior sensitization and may manifest upon re-exposure.

Table 1.1

Categories of ADRs according to the NCBI Bookshelf

ADR Type	Category	Description	Examples
Type A	Drug Overdoses	ADRs occur due to excessive dosage of the drug.	• -Acetaminophen overdose leading to liver failure • Warfarin overdose causing bleeding • Oxycodone overdose causing respiratory depression
	Side Effects	ADRs are due to normal drug actions but with undesired effects.	• -Gastritis from NSAIDs • Kidney damage from aminoglycosides • Diarrhea from antibiotics • Phototoxicity from doxycycline
	Drug Interactions	ADRs resulting from interactions between drugs.	• -Macrolides increase theophylline levels • Vitamin K reduces warfarin's anticoagulant effect • Benzodiazepines and opioids cause respiratory depression
Type B	Hypersensitivity reactions	ADRs are caused by an immune or inflammatory response to a drug.	• Urticarial rash • Drug-induced hemolytic anemia • Serum sickness with equine-antitoxins and monoclonal antibodies • Contact dermatitis
	Idiosyncratic Reactions	ADRs arise because of genetic anomalies or exaggerated sensitivity at low doses.	• Dapsone-induced hemolysis in G6PD deficiency
	Pseudoallergic Reactions	ADRs are caused by direct activation of inflammatory cells without immune involvement.	• Nonimmunogenic anaphylaxis • Vancomycin flushing syndrome • Histamine release and flushing

- Idiosyncratic ADRs: These are rare, unpredictable reactions not clearly linked to dose or immune response. They may involve genetic polymorphisms affecting drug metabolism or receptor sensitivity [46].

In addition to mechanism-based classification, ADRs can also be categorized based on clinical severity, which is vital for prioritizing regulatory action and healthcare response strategies. Table 1.2 [8] outlines this severity-based classification.

Table 1.2

Classification of ADRs according to severity

Severity	Description	Examples
Mild	No antidote or treatment is required; hospitalization is not prolonged.	ACE inhibitor: Cough Antidepressants: Dry mouth Antihistamines (some): Drowsiness
Moderate	A change in treatment (e.g., modified dosage, addition of a medication), but not necessarily discontinuation of the medication, is required; hospitalization may be prolonged, or specific treatment may be required.	Hormonal contraceptives: Venous thrombosis NSAIDs: Hypertension and edema Opioids: Constipation
Severe	An ADR is potentially life threatening and requires discontinuation of the medication. Specific treatment of the ADR and extended hospitalization stay often is required. *	ACE inhibitors: Angioedema Macrolide antibiotics: Abnormal heart rhythm
Lethal	An ADR directly or indirectly contributes to a patient's death.	Acetaminophen overdosage: Liver failure Anticoagulants: Major hemorrhage

Understanding and applying such classifications help healthcare professionals and regulators to manage ADRs more effectively, prioritize patient care, and develop targeted interventions. They also aid in enhancing the predictability of ADRs and inform the design of post-marketing surveillance studies.

The use of multiple classification systems – mechanistic, severity-based, and outcome-oriented – enriches the analysis of ADRs and improves the robustness of pharmacovigilance practices. As PV continues to evolve, these frameworks remain

essential tools for interpreting adverse reaction data, guiding clinical decision-making, and shaping drug policy.

Conclusion to Chapter I

1. Pharmacovigilance has emerged as a fundamental component of modern healthcare systems, with its roots in historical challenges related to drug safety. The analysis of its conceptual foundations and evolution demonstrates a clear progression from passive reporting mechanisms to structured, proactive, and technology-driven surveillance systems. These developments have been shaped by international cooperation, regulatory reforms, and increased involvement of stakeholders at all levels.

2. The objectives of pharmacovigilance systems extend beyond mere identification of ADRs; they encompass a comprehensive strategy for ensuring the rational and safe use of medicinal products. The integration of pharmacovigilance into health systems requires collaboration among regulatory authorities, pharmaceutical companies, healthcare professionals, and increasingly, patients. As demonstrated, the effective operation of PV systems depends on structured processes such as signal detection, risk evaluation, communication, and risk minimization. Tools such as VigiBase, VigiLyze, and AI-based analytics further enhance global capacity for detecting and managing safety signals.

3. A key dimension of pharmacovigilance lies in the accurate classification of ADRs. By distinguishing between types of reactions based on mechanism, predictability, and severity, health professionals are better equipped to respond to adverse events, mitigate harm, and improve therapeutic outcomes. Medication errors, hypersensitivity reactions, dose-related effects, and idiosyncratic responses are all part of a broader safety framework that underlines the need for systematic monitoring.

CHAPTER II.
STUDY ON INTERNATIONAL PRACTICES IN PHARMACOVIGILANCE AND ADR REPORTING

2.1. Global overview of international efforts in pharmacovigilance and ADR reporting

The World Health Organization has played a central role in advancing pharmacovigilance globally. The thalidomide tragedy of the 1960s – resulting in severe birth defects due to the use of the drug during pregnancy – highlighted the critical need for systematic post-marketing surveillance of medicines [22]. This event served as a catalyst for the establishment of international pharmacovigilance mechanisms under WHO's leadership.

In 1968, the WHO initiated the Pilot Research Project for International Drug Monitoring, which marked the formal inception of global PV cooperation. This initiative led to the creation of the WHO Programme for International Drug Monitoring, designed to facilitate cross-border collaboration in monitoring ADRs, sharing safety data, and building national PV capacity [50].

Today, the PIDM functions as a global network that includes more than 180 full and associate member countries, representing approximately 99% of the world's population. The Uppsala Monitoring Centre in Sweden serves as the WHO Collaborating Centre for International Drug Monitoring and coordinates international efforts through data management, training, and technical support [51].

A core component of this system is VigiBase, the WHO's global ICSR database. As of July 2023, it contained over 35 million anonymized reports of suspected adverse effects submitted by member countries. These data are used to detect safety signals, identify potential product risks, and inform regulatory decision-making worldwide [56].

Beyond data aggregation, the WHO PIDM supports capacity-building initiatives aimed at strengthening national PV systems. This includes in-person and online training programs for healthcare professionals, development of national guidelines, technical consultations, and operational support for establishing effective ADR reporting mechanisms. Tools such as VigiFlow and VigiMobile allow for digital and offline-compatible reporting of ADRs and adverse events following immunization (AEFIs), particularly in low-resource settings [11, 53].

The geographical reach and historical development of the PIDM reflect the gradual expansion of PV efforts across regions and income levels. Figure 2.1 presents the global distribution of WHO PIDM member and associate countries as of 2025 [44].

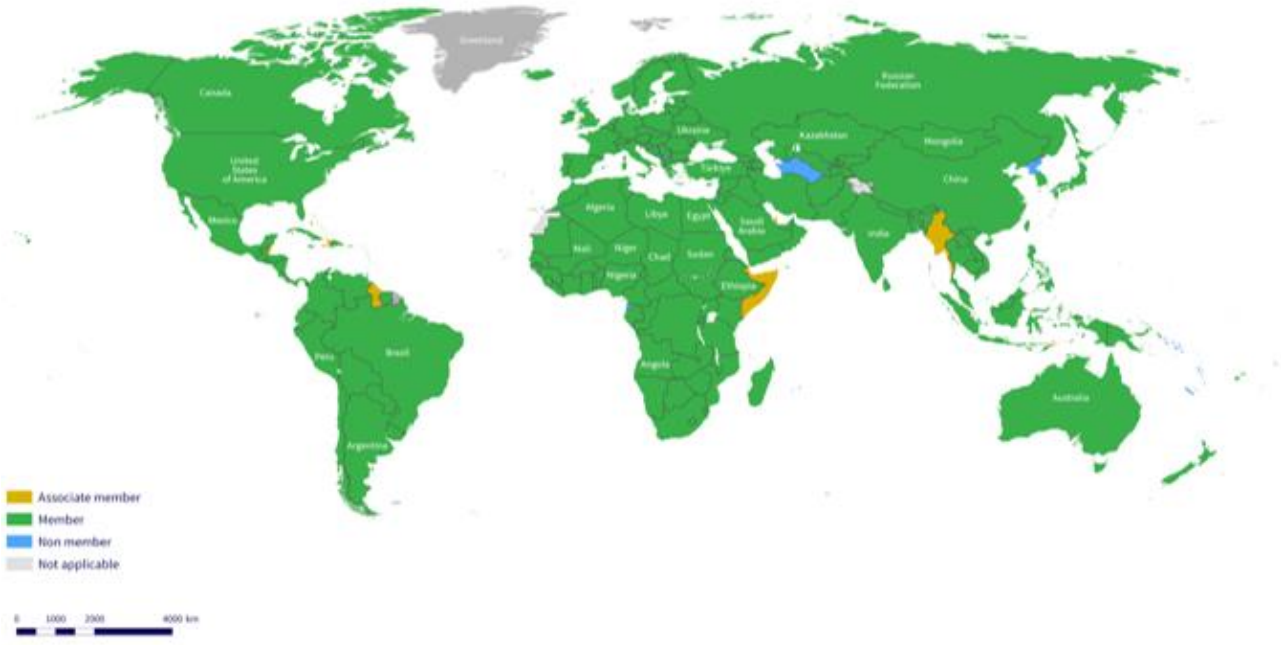

Fig 2.1. Global Distribution of WHO PIDM Member and Associate Countries

To further illustrate this progression, Table 2.1 outlines the distribution of countries joining the PIDM between 1968 and 2025, categorized by five-year intervals and world regions. This data reveals key trends, including:

- Early participation dominated by high-income countries in Europe and Oceania (e.g., Sweden, United Kingdom, Australia);

- A sharp increase in membership among low- and middle-income countries starting from the 1990s;
- Steady integration of African, Asian, and Latin American nations during the 2000s and 2010s;
- Enhanced global inclusivity, with the recent accession of countries from underrepresented regions such as Central Africa and the Caribbean between 2021–2025.

Table 2.1

Distribution countries joining the WHO Programme for International Drug Monitoring by five-year periods and regions

Period	**Africa**	**Americas**	**Asia**	**Europe**	**Oceania**
1	2	3	4	5	6
1968–1974	–	Canada, USA	Japan, Israel	Czechoslovakia, Germany, Ireland, Netherlands, Sweden, United Kingdom, Denmark, Norway, Poland, Finland	Australia, New Zealand
1975–1979	–	–	–	Bulgaria, Italy, Romania, Belgium	–
1980–1985	–	–	Thailand	Spain	–
1986–1990	–	–	France, Türkiye	Greece, Hungary, Iceland	–
1991–1995	Morocco, Tunisia, United Republic of Tanzania	Costa Rica, Argentina, Cuba, Venezuela	Republic of Korea, Singapore, Oman, Philippines	Austria, Switzerland, Croatia, Czechia, Portugal, Slovakia	–
1996–2000	–	Chile, Mexico	China, India, Iran, Viet Nam, Sri Lanka	Estonia, Russian Federation, Cyprus, North Macedonia, Serbia	Fiji
2001–2005	Egypt, Ghana, Nigeria, Mozambique	Brazil, Uruguay, Guatemala, Peru, Colombia	Jordan	Armenia, Latvia, Republic of Moldova, Ukraine, Malta, Lithuania	–

Continuation Table 2.1

1	2	3	4	5	6
2006–2010	Togo, Uganda, Ethiopia, Namibia, Sierra Leone, Sudan, Botswana, Madagascar, Senegal, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Kenya, Zambia	Suriname, Barbados	Nepal, Uzbekistan, Brunei Darussalam, Iraq, Saudi Arabia, Cambodia, Kazakhstan	Belarus, Slovenia, Montenegro, Andorra	–
2011–2015	Benin, Mali, Cabo Verde, Eritrea, Niger, Angola, Guinea, Liberia, Rwanda, Mauritius, Eswatini	Jamaica, Bolivia	Bangladesh, Bhutan, Lao People's Democratic Republic, Afghanistan, Maldives	–	–
2016–2020	Chad, Malawi	–	Pakistan, Syrian Arab Republic		Papua New Guinea
2021–2025	Algeria, Congo, Gambia, Libya, Burundi, Central African Republic, Guinea-Bissau, Gabon, Mauritania, Lesotho, South Sudan, Zanzibar, Sao Tome and Principe	Dominican Republic, Honduras, Nicaragua, Saint Vincent and the Grenadines, Ecuador, El Salvador, Paraguay	Kuwait, Lebanon, Mongolia, Yemen, Tajikistan		–

This evolution highlights both the growing global recognition of pharmacovigilance as a public health priority and the WHO's role in facilitating equitable participation through technical and institutional support.

Importantly, the integration of African countries into the PIDM has been particularly notable since the early 2000s. Morocco, which joined the PIDM in 1992, was among the first African and Arab countries to do so. Its early involvement positioned it as a regional leader in pharmacovigilance within North Africa and the broader Middle East and North Africa (MENA) region.

The increasing diversity of member countries reflects the global nature of drug safety challenges and the universal value of collaborative data sharing. By contributing case reports to VigiBase and participating in signal detection activities, member states benefit from pooled global knowledge, early warning capabilities, and shared regulatory best practices.

To qualify for PIDM membership, countries must first submit a formal application to WHO headquarters and provide at least 20 ICSRs to VigiBase [25]. This requirement ensures an initial level of national capacity and a commitment to ongoing contribution and system development.

In summary, the global expansion of the WHO PIDM demonstrates how international cooperation, supported by standardized tools and training, has become a cornerstone of modern pharmacovigilance. With over five decades of progress, this network continues to enhance global medicine safety, particularly through the active inclusion of resource-constrained countries in the collective effort to detect, evaluate, and prevent ADRs.

2.2. Analysis of best practices and innovations in the pharmacovigilance system ADR reporting

The advancement of PV has been significantly accelerated by the development and implementation of innovative technologies and regulatory practices across different countries. The WHO, in collaboration with its member states, has led efforts to standardize and optimize global ADR reporting through the introduction of advanced tools and harmonized protocols.

One of the most significant contributions in recent years is the deployment of digital solutions to support pharmacovigilance processes. Tools such as VigiFlow and VigiMobile, developed under the auspices of the WHO and the UMC, provide user-friendly, multilingual, and offline-capable platforms for collecting reports of ADRs

and AEFIs. These systems are particularly valuable in low-resource settings, allowing for the timely capture and submission of safety data from remote areas [53].

In parallel, VigiLyze, an online platform, enables signal detection by facilitating access to aggregated safety data in VigiBase. Its real-time analytics functionality supports national PV centers in identifying emerging safety signals with greater accuracy and speed. These tools are supplemented by the use of Bayesian modeling, data mining algorithms, and natural language processing, all of which enhance the predictive capacity of pharmacovigilance systems and streamline the management of large volumes of case reports [53].

WHO, in collaboration with global advisory committees such as the GACVS (Global Advisory Committee on Vaccine Safety) and ACSoMP (Advisory Committee on the Safety of Medicinal Products), has also developed standardized variables for reporting adverse events. These 25 core variables for AEFI reports aim to ensure consistent and high-quality data collection globally. A similar standardized framework for ADR reporting is under development, further supporting data interoperability and global comparison [53].

The WHO and UMC have emphasized the need for multi-stakeholder collaboration. Training programs for healthcare professionals, regulators, and patient groups are increasingly diverse and include didactic, simulation-based, and hybrid modules. Educational initiatives have also been extended to patients to foster a more participatory approach to medicine safety.

Figure 2.2 illustrates the structured process through which safety signals are identified, validated, and prioritized using automated and manual tools [53].

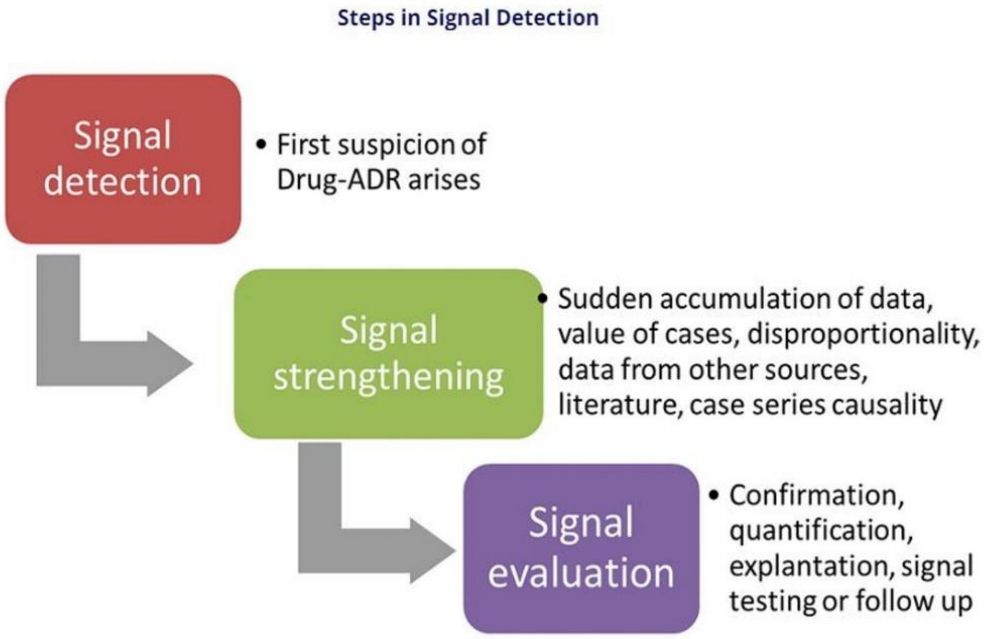

Fig. 2.2. Steps in Signal Detection.

High-income countries such as the United States, United Kingdom, and members of the European Union offer exemplary models of PV system integration. In the European Union, the EudraVigilance database, managed by the EMA, consolidates ADR reports from across member states and supports early detection of safety signals through data mining and real-time monitoring. The system's transparency is enhanced by public access to aggregated data and the "black triangle" symbol, which alerts healthcare providers and patients to products under additional monitoring.

The United Kingdom's Yellow Card Scheme, coordinated by the Medicines and Healthcare products Regulatory Agency MHRA, enables healthcare professionals and patients to report ADRs via mobile apps and web portals. This system has evolved into a comprehensive tool for regulatory action, informing label changes, market withdrawals, and public safety communications.

In the United States, the Food and Drug Administration (FDA) operates two core systems – MedWatch and FAERS (FDA Adverse Event Reporting System). While manufacturers are mandated to report all serious ADRs within a 15-day window,

healthcare professionals and consumers can contribute voluntarily. Complementary systems like VAERS (for vaccine-related events) and CDC WONDER support public access to vaccine safety data and enable transparent surveillance.

A hallmark of PV systems in high-income countries is their integration with Electronic Health Records (EHRs). These systems facilitate automated ADR detection, retrospective safety analyses, and linkages with patient demographics. Moreover, AI has been incorporated into signal detection algorithms, improving the ability to identify rare but serious safety signals from large datasets.

The role of pharmacists has expanded significantly in these countries. Positioned as accessible healthcare providers, pharmacists actively promote patient education, encourage reporting, and contribute to safety evaluations. Notably, simplified reporting interfaces, feedback loops, and recognition mechanisms have enhanced pharmacist engagement and compliance.

Digital innovations have also enabled broader patient involvement. Mobile applications and web-based tools allow patients to directly report ADRs, thereby increasing data granularity and accelerating signal detection. Patient-centered PV is seen as an important trend in strengthening the relevance and completeness of safety data.

As pharmacovigilance evolves, emerging tools and strategies continue to redefine its scope. The use of big data analytics, AI, and machine learning has facilitated the transition from reactive to predictive pharmacovigilance. These systems can analyze large volumes of structured and unstructured data, uncover patterns, and forecast potential safety concerns before they escalate.

Efforts by WHO and ICH (International Council for Harmonization) to harmonize ICSR formats and standard operating procedures ensure that safety data is comparable across countries. Regulatory authorities, pharmaceutical manufacturers, healthcare professionals, and patient organizations all contribute to this coordinated global framework.

A comparative analysis between Western and Eastern PV systems reveals key structural and operational differences. While countries in the West (e.g., U.S., U.K., Germany) benefit from mature regulatory frameworks, digital infrastructure, and strong public engagement, many countries in Asia (e.g., India, China, Japan) face challenges such as fragmented systems, underreporting, limited automation, and weak integration of traditional medicine data. Stigma, lack of awareness, and insufficient legal clarity further limit patient and provider engagement in these regions [15].

Closing these gaps requires targeted investments in infrastructure, capacity building, and legal harmonization. Adapting successful models from high-income countries while accounting for local healthcare contexts is crucial for improving global pharmacovigilance outcomes.

In sum, international experience illustrates that the effectiveness of pharmacovigilance systems depends on a combination of regulatory commitment, technological innovation, and inclusive stakeholder engagement. These insights provide a valuable foundation for evaluating the Moroccan PV system in the next chapter.

Conclusion to Chapter II

1. The analysis of international pharmacovigilance practices demonstrates the significant progress made in strengthening global medicine safety systems over the past decades. Initiated by the WHO in response to critical public health events, the establishment of the PIDM has led to the formation of a comprehensive global network encompassing over 180 countries. Through tools such as VigiBase, VigiFlow, and VigiMobile, this network facilitates the timely collection, analysis, and dissemination of safety data.

2. The gradual inclusion of low- and middle-income countries into the PIDM reflects both the growing awareness of pharmacovigilance's importance and the WHO's

efforts to promote equitable access to technical and institutional support. Morocco's early accession to the PIDM positioned it as a leader in the MENA region and illustrates how national systems can evolve through international collaboration.

3. The review of best practices shows that high-income countries have developed robust PV infrastructures supported by digital technologies, integrated reporting platforms, and public participation mechanisms. These systems benefit from strong regulatory frameworks, professional training programs, and innovative approaches such as artificial intelligence, data mining, and EHR integration. Moreover, these countries emphasize the active engagement of both healthcare professionals and patients in ADR reporting processes, which enhances the reliability and richness of pharmacovigilance data.

4. At the same time, the analysis highlights persistent challenges in some regions, including underreporting, fragmented systems, and limited use of digital tools. Addressing these disparities requires strategic investments in digital infrastructure, harmonized regulatory standards, and continuous education of all stakeholders.

CHAPTER III.
ANALYSIS OF CURRENT STATE, CHALLENGES AND ROLE OF PHARMACISTS IN PHARMACOVIGILANCE IN MOROCCO

3.1 Development and current organization of the national pharmacovigilance system in Morocco

Pharmacovigilance in Morocco has become a critical component of the national strategy for ensuring the safety and quality of medicines and other health-related products. The country's early engagement in global pharmacovigilance efforts is evidenced by its accession to the WHO Programme for International Drug Monitoring in 1992, becoming the 34th member. Since then, Morocco has emerged as a regional leader in PV within North Africa and the Arab world.

At the center of Morocco's PV system is the Moroccan Anti-Poison and Pharmacovigilance Centre (CAPM), which functions under the authority of the Ministry of Health. CAPM is responsible for the continuous collection, assessment, and management of data related to ADRs, poisonings, and other toxicological events. It operates a spontaneous reporting system that accepts inputs from healthcare professionals, pharmaceutical companies, and the general public. Through this system, CAPM monitors the benefit–risk balance of medical products, contributes to national regulatory policy, and supports international PV efforts.

A distinctive feature of Morocco's system is its broad scope, which extends beyond medicinal products to include vaccines, traditional and herbal remedies, medical devices, and toxic agents. CAPM also conducts toxicovigilance, i.e., the monitoring and evaluation of poisoning incidents from diverse sources, including industrial products, household chemicals, and biological toxins.

Between 1980 and 2014, CAPM documented 611 criminal poisoning cases, representing 2.1% of all intentional poisoning incidents. Notably, nearly 90% of these

cases occurred in urban settings, suggesting geographic disparities in exposure patterns, public awareness, or reporting infrastructure [1]. These long-term data collection activities underscore CAPM's expanded public health role.

In line with its expanded mandate, CAPM not only monitors ADRs but also compiles national data on poisoning cases from various toxic agents. The scope of surveillance includes pharmaceuticals, food, chemicals, environmental exposures, and animal toxins. This comprehensive approach enables Morocco to address a broad range of public health threats through a unified reporting system.

To illustrate the scope and distribution of toxic exposures in recent years, Table 3.1 presents the number and percentage of poisoning cases by product category in 2021 and 2022. These figures offer insight into the most common sources of toxicological incidents and highlight shifting patterns in exposure risks [35].

Table 3.1

Distribution of reports of poisoning cases by type of product

Toxic Agent Family	2021		2022	
	Cases	%	Cases	%
Medications	2,812	45.3%	1,647	39.0%
Food	341	5.5%	575	13.6%
Pesticides and Agricultural Products	785	12.7%	462	10.9%
Gas	247	4.0%	373	8.8%
Snakes and Vipers	308	5.0%	305	7.2%
Industrial Products	380	6.1%	264	6.2%
Household Cleaning Products	427	6.9%	234	5.5%
Other Venomous Animals	333	5.4%	193	4.6%
Drugs (illicit substances)	162	2.6%	84	2.0%
Plants	121	2.0%	55	1.3%
Cosmetic Products	94	1.5%	33	0.8%
Heavy Metals	25	0.4%	0	–
Foreign Bodies	3	0%	0	–
Unknown	145	2.3%	0	–
Other	19	0.3%	0	–
Total	**6,202**	**100%**	**4,225**	**100%**

The data indicate that medications remained the leading cause of poisoning in both years, though the percentage declined from 45.3% in 2021 to 39.0% in 2022. In contrast, poisonings caused by food and gas increased noticeably. The absence of heavy metal and foreign body cases in 2022 may suggest either improved prevention or underreporting. These trends emphasize the need for targeted risk communication and public health interventions, particularly regarding drug and food safety [35].

An analysis of reporting channels used by CAPM shows how data collection has evolved over time. Figure 3.1 illustrates the shift in source types for poisoning declarations submitted to CAPM between 1980 and 2022 [35].

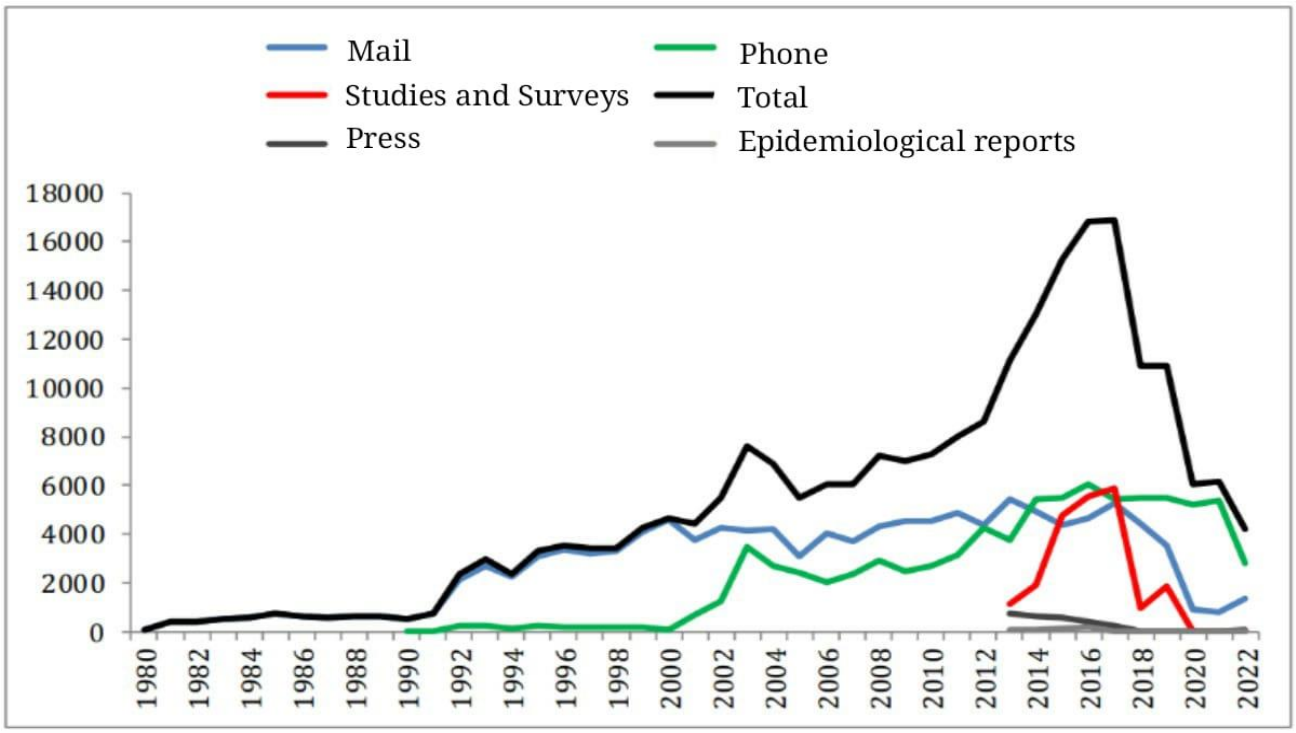

Fig 3.1 Evolution of Reported Poisoning Cases by Source of Declaration (1980–2022)

The figure 3.1 reveals that reporting by telephone has become increasingly dominant over time, surpassing older methods such as mail and press reports. This reflects both technological changes and evolving user preferences. However, reliance on certain channels over others may affect reporting quality and timeliness, necessitating periodic evaluations of communication strategies.

Morocco's early integration into the WHO PV network and its participation in collaborative international platforms have enabled the country to adopt and adapt best practices in PV. It is among the founding contributors to the development of the Arab Guidelines on Good Pharmacovigilance Practices (GVP), modeled after the European GVP framework [38].

The national PV system is structured across several operational levels. CAPM serves as the national coordinating body, while regional pharmacovigilance centers process reports and serve as local points of contact. Data from regional pharmacovigilance centers are sent to CAPM for validation and national aggregation. The system also includes a National Pharmacovigilance Commission and a Technical Committee, which provide scientific expertise, conduct case evaluations, and advise the Ministry of Health on regulatory decisions.

ADR reports can be submitted via multiple channels, including the CAPM website, email, fax, postal mail, telephone, and in-person delivery. The standardized notification form issued by CAPM captures essential information on the patient, event, suspected drug, and reporter.

The Figure 3.2 shows the organizational structure and the coordination mechanisms that underpin Morocco's national PV system [23].

The chart outlines the relationships among national, regional, and institutional actors involved in PV activities in Morocco, including governmental agencies, university hospital centers (UHCs), professional councils, public and private healthcare sectors, and academia. The multi-level structure enhances signal detection, ensures scientific oversight, and fosters inclusive participation in medicine safety.

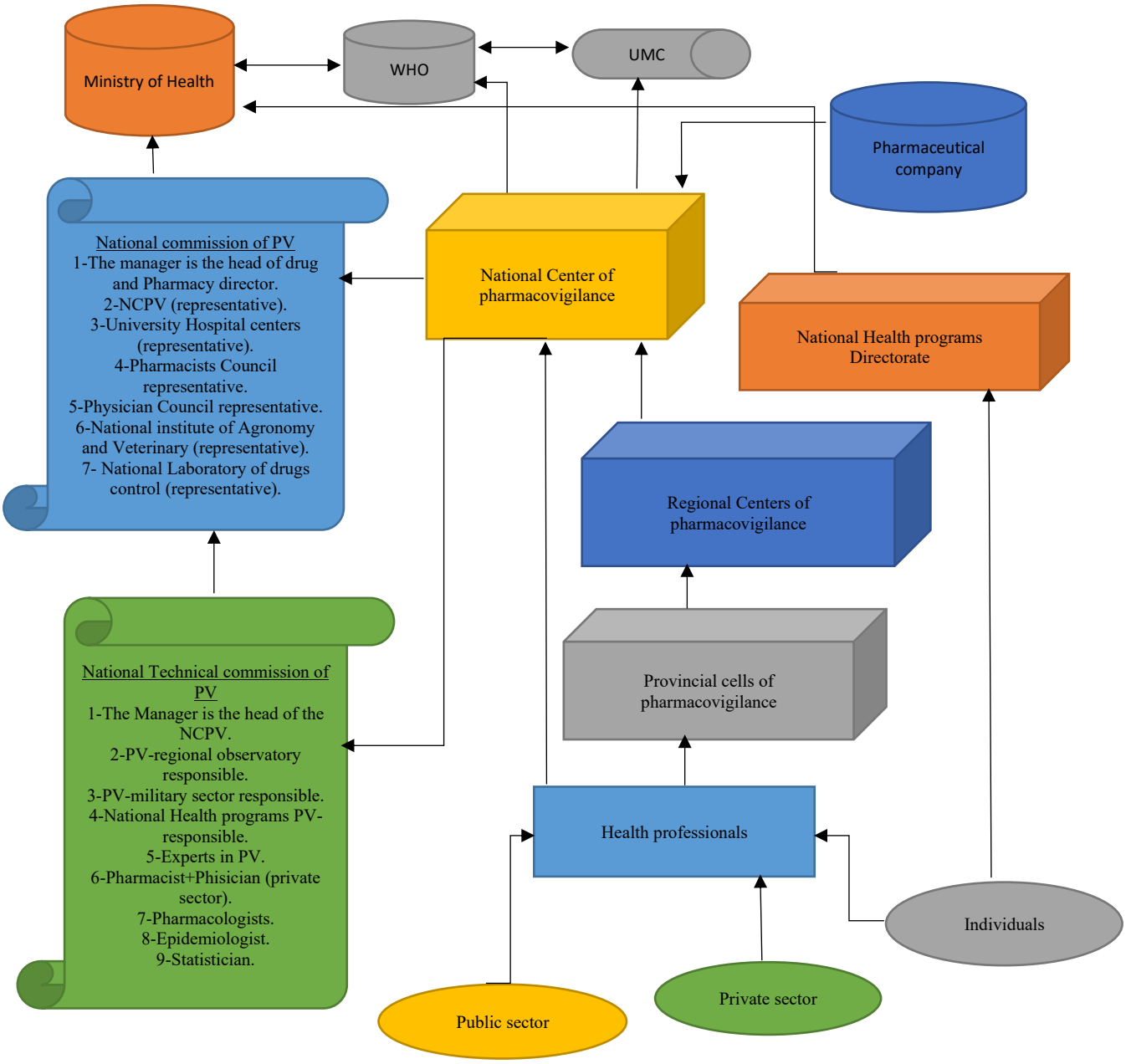

Fig. 3.2. The Moroccan system of pharmacovigilance

To evaluate Morocco's progress, a comparative analysis was conducted between Morocco and selected high-income countries. The countries chosen – United States, European Union, Japan, China, and India – represent diverse regulatory models and development levels in PV systems. The comparison focuses on legal frameworks, reporting tools, regulatory bodies, and technical capacity (Table 3.2) [38].

Table 3.2

Comparison of PV system in United States, Europe, Japan, China and Morocco

Country	Unites States	Europe	Japan	China	India	Morocco
Regulatory authority	FDA	EMA	PMDA and MHLW	CNDA and MOH	CDSCO	Ministry of Health
PV authority	CDER/CBER	EVDAS	PMDA	CNDA	NCC-IPC (PvPI)	CNPV
Guidelines followed	GVP and Pharmacoepidemiologic assessment	GVP	ICH-E2A	ICH-2EA	Schedule Y	National PV guidelines & Arab GVP
Online ADR reporting software	MedWatch	Eudravigilance	PMDA database	Chinese ADR database	Vigiflow	VigiFlow & YakadaLikah mobile app
PV database	FAERS Sentinel system	EVDAS, EVWEB	JADER database	CADRMS	Vigibase	Vigibase via VigiFlow integration & CAPM's internal database
ADR form types	3 forms: a)3500 b)3500A c)3500B	Yellow card ADR form	Online spontaneous reporting system	Online spontaneous reporting system	2 forms: a) HCP b) Consumer	CAPM's standardized notification form
PSUR timeline	15-day alert reports, quarterly for the first 3 years and annually thereafter	First two years every 6 months, once a year for two consecutive years once in 3 years thereafter	Every 6 months for the first b2 years and annually later	Annually for the first 5 years then every 5 years	First 2 years – every 6 months once a year for 2 consecutive years and thereafter annually	Annual PSURs for first 5 years, then every 5 years

This comparative overview highlights differences and similarities in regulatory authorities, implementation of GVP, reporting infrastructure, pharmacovigilance databases, and periodic safety update requirements. It provides a framework for understanding Morocco's current position within the global PV landscape and identifying opportunities for further development through alignment with international standards and innovations.

This comparison shows that while Morocco has made considerable progress, particularly with the use of VigiFlow and the development of a mobile reporting application (YakadaLikah), notable gaps remain in areas such as database integration, frequency of PSURs, and accessibility of online reporting platforms. Nonetheless, Morocco's alignment with international standards and active participation in regional initiatives signals its potential to continue strengthening its national PV infrastructure.

3.2. Legal framework, challenges and gaps in ADR reporting in Morocco

The legal and regulatory foundations of Morocco's pharmacovigilance system are established and overseen by the Directorate of Medicines and Pharmacy under the Ministry of Health. This body serves as the National Competent Authority for pharmaceutical regulation. The core legal instrument is Law No. 17-04, which governs pharmaceutical activities, including the licensing, importation, and registration of medicinal products. While the law does not explicitly require the appointment of a Qualified Person for Pharmacovigilance (QPPV), Local QPPV, or Local Contact Person for PV, Morocco has voluntarily adopted the Good Pharmacovigilance Practice Guidelines to clarify roles, responsibilities, and procedural requirements related to PV systems [39].

Additionally, Framework Law No. 34-09 on integrated health risk management mandates hospitals to implement internal safety policies, which include PV activities such as monitoring medication-related adverse events [40]. These legislative measures,

though promising, face limitations in terms of institutional enforcement and operational uniformity across healthcare institutions.

A recent national assessment of PV activities in Morocco's University Hospital Centers (UHCs) revealed a number of structural and procedural deficiencies affecting ADR reporting [41]. Despite the formal designation of PV focal points in all UHCs, underreporting remains a persistent problem. Key contributing factors include low awareness among healthcare professionals regarding reporting procedures, limited access to standardized tools, insufficient training, and lack of incentives or institutional mandates for routine reporting.

Moreover, there is no dedicated national budget specifically allocated for PV activities. The establishment and implementation of PV structures across hospitals are inconsistent. While some UHCs have relatively well-organized PV systems, others lack basic operational components, such as dedicated personnel or reporting mechanisms. This uneven development leads to variability in the quantity and quality of ADR reports submitted to the national CAPM database.

Significantly, data from the CAPM indicate that only 19% of ADR reports originate from UHCs, whereas 66% are submitted by the pharmaceutical industry, highlighting an imbalance in reporting sources. Routine ADR data transmission from hospitals to CAPM is limited, and reporting often occurs on an ad hoc basis. Prior to the COVID-19 pandemic, reporting of AEFIs – particularly in pediatric populations – was almost nonexistent. While the pandemic temporarily stimulated vaccine safety reporting, the trend was not sustained in subsequent years.

Even with national-level training programs organized by CAPM, the actual integration of PV into clinical practice remains inconsistent. For example, only 43% of UHCs consistently collected ADR data during the 2020–2022 period, and most hospitals lacked a formal PV organizational structure. The absence of clear institutional mandates and the limited inclusion of PV in medical and pharmacy curricula further impede system-wide implementation.

In response to these challenges, a thematic working group issued several recommendations aimed at strengthening PV structures within UHCs:

- Establish a PV coordination center in each UHC, led by a designated coordinator responsible for promoting and supervising pharmacovigilance activities at the institutional level;
- Create internal PV units within hospitals, which would collect, validate, and forward ADR reports to CAPM;
- Appoint ward-level PV focal points responsible for identifying and documenting ADRs, tailored to the organizational structure of each hospital.

These measures are intended to institutionalize PV practices and promote consistency across UHCs, thereby improving data quality and national coverage. Implementation of such recommendations would require sustained administrative commitment, regulatory enforcement, and resource allocation.

In summary, while Morocco's legal and regulatory framework provides a solid foundation for pharmacovigilance, numerous operational barriers – particularly within clinical institutions – continue to hinder effective ADR reporting. Overcoming these challenges will depend on the institutionalization of PV responsibilities, the standardization of tools and procedures, and the provision of targeted training and resources at the national and facility levels.

3.3 Study on pharmacist's role in ADR reporting and pharmacovigilance activities

Pharmacists represent a key stakeholder group in Morocco's pharmacovigilance system, particularly within institutional settings such as University Hospital Centers (UHCs). A 2023 national assessment found that 67% of PV focal points at Moroccan UHCs were pharmacists, many of whom were also department heads or professors of pharmacology [41]. Their responsibilities typically include the coordination of PV

activities, data collection and validation of ADRs, communication with the CAPM, and promotion of safety monitoring within their institutions.

Despite their formal involvement, recent research highlights a discrepancy between pharmacists' potential role and their actual contribution to ADR reporting, especially in community pharmacy settings. A study conducted in Casablanca among community pharmacists revealed that while 83.07% of respondents were aware of the existence of a national PV authority, only 24.62% were able to correctly name CAPM or identify its location [31]. Moreover, although 64% of respondents had been consulted by patients regarding suspected ADRs, only 10.84% had submitted formal reports to the CAPM.

When asked about the barriers to ADR reporting, the most frequently cited reasons included:

- Lack of information on reporting procedures (44.61%);
- Perceived complexity of the reporting process (32.31%);
- Absence of institutional feedback or follow-up;
- Limited time and workflow constraints in community practice.

Nonetheless, the study also found a generally positive attitude toward pharmacovigilance, suggesting that pharmacists are willing to participate more actively if systemic barriers are addressed.

Based on the identified barriers, a set of practical and evidence-informed strategies can be proposed to enhance the involvement of pharmacists in ADR reporting. These interventions are summarized in Figure 3.3. The figure 3.3 outlines core institutional, educational, and technological measures proposed to address existing gaps in pharmacists' participation in ADR reporting.

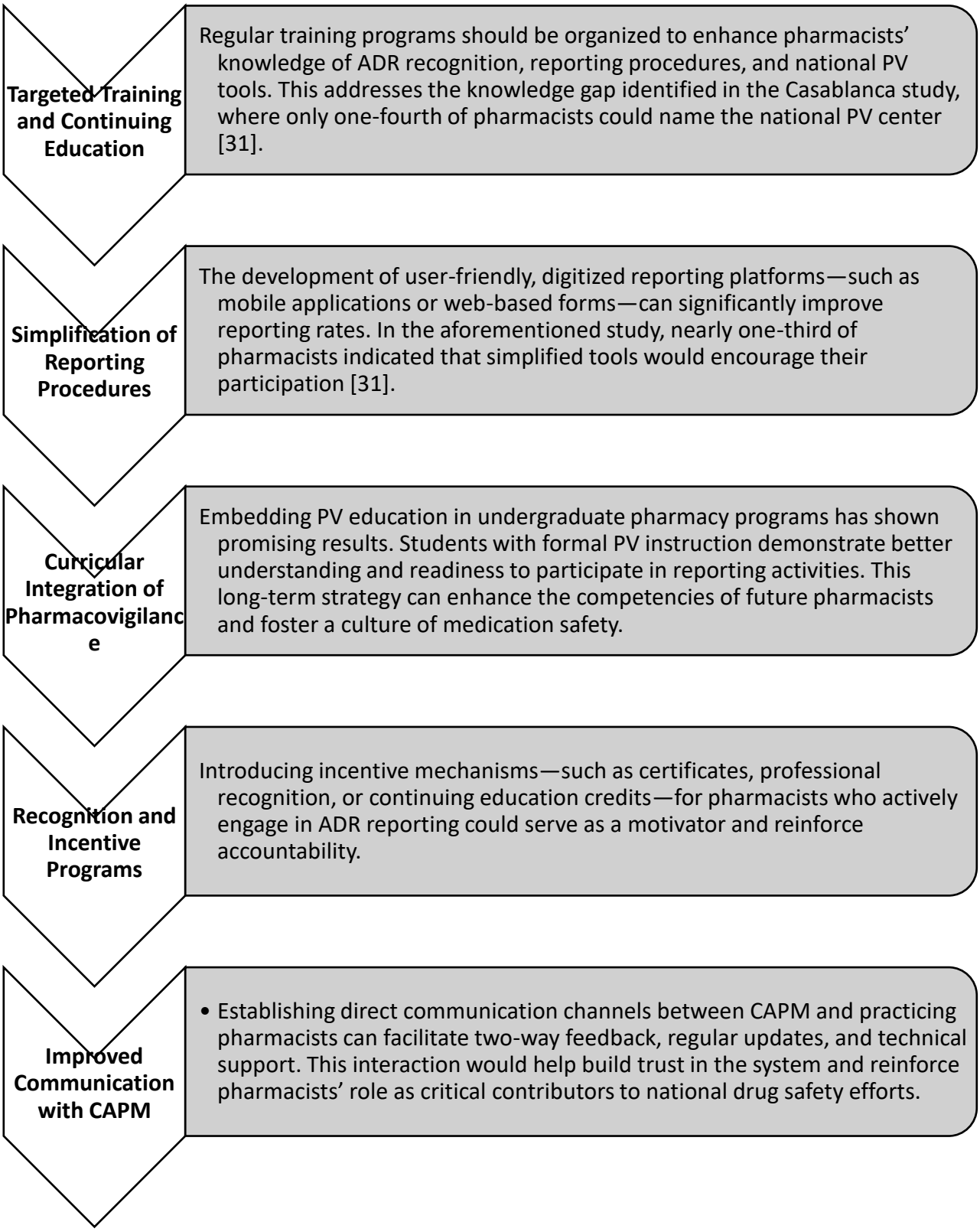

Fig. 3.3. Key Strategies to Strengthen Pharmacists' Role in the Moroccan Pharmacovigilance System

In summary, pharmacists in Morocco occupy a strategically significant position within the national pharmacovigilance infrastructure, bridging the gap between clinical care and regulatory reporting. However, their actual contribution to ADR reporting remains underutilized. Systemic improvements – particularly in professional training, operational procedures, and institutional support – are essential to unlock their full potential in advancing medicine safety.

Conclusion to Chapter III

1. The analysis of Morocco's national pharmacovigilance system reveals significant progress in establishing institutional infrastructure and aligning with international standards. The Moroccan Anti-Poison and Pharmacovigilance Centre plays a central role in the coordination of ADR monitoring and toxicovigilance, supported by regional centers and specialized technical bodies. The integration of Morocco into the WHO Programme for International Drug Monitoring and its leadership in regional GVP development demonstrate the country's commitment to global cooperation in medicine safety.

2. Nevertheless, the review identified persistent challenges that hinder the full operationalization of PV systems. Despite a robust legal framework underpinned by Laws No. 17-04 and 34-09, practical implementation remains uneven across University Hospital Centers. Structural inconsistencies, underreporting, lack of dedicated funding, and low awareness among healthcare professionals weaken the efficacy of ADR surveillance. Data from CAPM show that the majority of ADR reports originate from the pharmaceutical industry, with hospitals contributing a limited share.

3. A particularly important dimension of Morocco's PV system is the role of pharmacists. While pharmacists are formally integrated as PV focal points in institutional settings, their participation – especially in community pharmacies – remains limited due to insufficient knowledge, unclear procedures, and lack of support

mechanisms. Survey data from Casablanca confirmed these gaps but also revealed a generally positive disposition toward PV participation among pharmacists.

4. To address these issues, a set of targeted strategies has been proposed, including the establishment of PV units in all UHCs, designation of coordinators and ward-level focal points, simplification of reporting tools, curricular integration of PV education, and improved communication channels with CAPM. These interventions aim to reinforce the structural and human capacity of Morocco's PV system and enhance its responsiveness to medication safety risks.

CONCLUSIONS

1. Pharmacovigilance has become an essential pillar of global public health policy, evolving from reactive mechanisms to proactive, technology-driven systems. Theoretical and regulatory foundations underscore its role in ensuring drug safety throughout the product life cycle, from clinical trials to post-marketing surveillance. The international pharmacovigilance infrastructure – led by the WHO and supported by tools such as VigiBase, VigiFlow, and EudraVigilance – demonstrates the global commitment to medication safety and risk minimization.

2. A comprehensive review of international PV practices shows that high-income countries have successfully integrated digital technologies, real-time monitoring, and stakeholder engagement into their PV systems. The use of AI, machine learning, and EHRs has significantly improved signal detection, data analysis, and regulatory responsiveness. In contrast, countries in the Global South, including those in Asia and Africa, continue to face structural challenges such as underreporting, fragmented systems, and limited digital infrastructure.

3. Morocco's pharmacovigilance system has undergone notable development since its accession to the WHO Programme for International Drug Monitoring in 1992. The Moroccan Anti-Poison and Pharmacovigilance Centre serves as the national coordinating body and maintains a wide-ranging scope, encompassing ADRs, vaccine safety, toxicological incidents, and traditional medicine. Despite these structural advances, Morocco’s PV system still faces limitations in reporting frequency, system integration, and uniformity across healthcare institutions.

4. The legal and regulatory framework for PV in Morocco, based on Laws No. 17-04 and 34-09, aligns with international standards but suffers from weak implementation mechanisms. National assessments show persistent underreporting of ADRs from public hospitals, limited institutional PV structures, and inconsistent

data submission to CAPM. These gaps are compounded by insufficient training, lack of standardized tools, and minimal institutional accountability in pharmacovigilance reporting.

5. Pharmacists play a pivotal yet underutilized role in Morocco's PV system. While they constitute the majority of designated PV focal points in university hospitals, their participation in community settings is minimal. Survey data reveal knowledge gaps, perceived complexity of reporting procedures, and absence of institutional support as key barriers. However, pharmacists also express a generally positive attitude toward participation in PV, indicating potential for increased engagement.

6. A range of strategic interventions is recommended to enhance PV effectiveness in Morocco. These include the establishment of pharmacovigilance units in all University Hospital Centers, designation of institutional and clinical ward focal points, simplification of reporting mechanisms, integration of PV into pharmacy education, and direct engagement between CAPM and healthcare providers. Strengthening the role of pharmacists is a critical element in improving ADR reporting rates and overall system performance.

7. In conclusion, Morocco has made substantial progress in developing a national pharmacovigilance framework, supported by international collaboration and a centralized coordinating body. To realize the full potential of this system, greater emphasis must be placed on operational implementation, professional training, and stakeholder mobilization. Enhancing the contribution of pharmacists and ensuring the consistency of reporting practices across healthcare levels will be essential to advancing patient safety and aligning Morocco's PV system with global best practices.

REFERENCES

1. Criminal poisoning in Morocco: data from the Morocco Poison Control and Pharmacovigilance Centre (1980-2014)]. *Pan Afr Med J*. 2021. Vol. 38(42). DOI: 10.11604/pamj.2021.38.42.27450.

2. A Systematic Review of Pharmacovigilance Systems in Developing Countries Using the WHO Pharmacovigilance Indicators / H. Y. Garashi et al. *Ther Innov Regul* 2022. Vol. 56. P. 717–743. URL: https://doi.org/10.1007/s43441-022-00415-y. (Date of access: 20.03.2025).

3. Adverse Drug Events, Adverse Drug Reactions and Medication Errors Frequently Asked Questions. URL: https://www.pbm.va.gov/vacenterformedicationsafety/tools/AdverseDrugReaction.pdf. (Date of access: 20.03.2025).

4. *Adverse Drug Reactions* / StatPearls. 2023. URL: https://www.ncbi.nlm.nih.gov/books/NBK599521/:contentReference[oaicite:2]{index=2}. (Date of accrs; 20.03.2025).

5. *Adverse event vs. side effect* / Association of Health Care Journalists. URL: https://healthjournalism.org/glossary-terms/adverse-event-vs-side-effect/ (Date of access: 20. 03. 2025).

6. Assessment of Pharmacovigilance Across University Hospitals in Morocco / H. Hamzaoui et al. *Drug Saf*. 2025. Vol. 48(5). P. 527-539.

7. Bonnes pratiques de pharmacovigilance. URL: https://pharmacie.ma/uploads/pdfs/bonnes_pratiques_de_pharmacovigilance.pdf. (Date of access: 20.03.2025).

8. Classification of adverse drug reactions / *MSD Manuals Professional*. URL: https://www.msdmanuals.com/professional/multimedia/table/classification-of-adverse-drug-reactions (Date of access: 20.03.2025).

9. Collaborating Centres / WHO. URL: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/networks/collaborative-centers. (Date of access: 20.03.2025).

10. *Definitions of key concepts from the WHO Patient Safety Curriculum Guide* / World Health Organization. 2011. URL: https://cdn.who.int/media/docs/default-source/patient-safety/curriculum-guide/resources/ps-curr-handouts/course01a_handout_patient-safety-definitions.pdf. (Date of access: 20.03.2025).

11. *Education and Training Strengthening pharmacovigilance through capacity building* / UMC. URL: https://who-umc.org/education-and-training/ (Date of access: 23.03.2025).

12. EMA *pharmacovigilance system manual*. Version 1.3. URL: https://surl.li/rswudl (Date of access: 20. 03. 2025).

13. European Patients' Academy on Therapeutic Innovation. URL: https://www.eurordis.org/european-patients-academy-on-therapeutic-innovation-eupati/ (Date of access: 20.03.2025 .)

14. Fip statement of policy the role of the pharmacist in pharmacovigilance / International Pharmaceutical Federation. URL: https://www.fip.org/file/1464. (Date of access: 20.03.2025).

15. Gadhade J. S., Hiray R. S. Global Pharmacovigilance, challenges, and future considerations: West globe and East globe J*ournal of Pharmacovigilance and Drug Research.* 2021. Vol. 2(2). P. 2-5.

16. Grootheest A. C., de Jong-van den Berg L. T. W. The role of hospital and community pharmacists in pharmacovigilance. *Res Social Adm Pharm*. 2005 Vol. 1(1). P. 126-33. DOI: 10.1016/j.sapharm.2004.12.009.

17. Guideline on good pharmacovigilance practices (GVP) for Arab Countries. 2015. URL: https://who-umc.org/media/164038/the-good-

pharmacovigilance-practice-for-arab-countries-v3-12-2015.pdf . (Date of eccess: 20.03.2025).

18. How UMC detects signals /Uppsala Monitoring Centre. 2024 URL: https://who-umc.org/signal-work/signal-detection/ (Date of access: 20.03.2025).

19. https://www.sante.gov.ma/Pages/Accueil.aspx

20. Huntress W. T., Marov M. Ya. Key institutions ResearchGate. 2021. DOI:10.1007/978-1-4419-7898-1_3.

21. Hussain H., Siddiqui A. A review paper on pharmacovigilance: An overview. *ResearchGate*. 2024 URL: https://www.researchgate.net/publication/387737953_A_review_paper_on_Pharmacovigilance_An_Overview. (Date of access: 20.03.2025).

22. I Role of community pharmacists in pharmacovigilance: pharmacists' and patients' perceptions / I. Kazaryan et al. *European Journal of Public Health.* 2021. Vol. 31(3). P. 165.365

23. Introducing Modern Computing Methods to the Moroccan Pharmacovigilance System. *ResearchGate*. 2021. DOI:10.5530/jyp.2021.13.86.

24. Jeetu G., Anusha G. Pharmacovigilance: a worldwide master key for drug safety monitoring. *J Young Pharm*. 2010. Vol. 2(3). P. 315-20. DOI: 10.4103/0975-1483.66802. PMID: 21042493; PMCID: PMC2964775.

25. *Joining the WHO Programme for International Drug Monitoring* / Uppsala Monitoring Centre. URL: https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/how-to-join-the-programme. (Date of access: 23.03.2025).

26. Key players: Who are the stakeholders in .pharmacovigilance? *Drug-card.io*. 2023. URL: https://drug-card.io/blog/key-players-who-are-the-stakeholders-in-pharmacovigilance/. (Date of access: 20. 03.2025).

27. Khan M. A. A., Hamid S., Babar Z.-U.-D. Pharmacovigilance in high-income countries: Current developments and a review of literature. *Pharmacy. 2023.*

Vol. 11(1). URL: https://www.mdpi.com/2226-4787/11/1/10/ (Date of asccess: 20.03.2025).

28. Knowledge attitude and practice of pharmacovigilance within health professionals, pharmaceutical companies and drug regulatory organization in Cameroon. *European journal of pharmaceutical And medical research*. 2022. Vol. 9(4). URL: https://storage.googleapis.com/innctech/ejpmr/article_issue/1648707369.pdf. (Date of access: 20.03.2025).

29. National strategy for the integration of pharmacovigilance in the Moroccan TB Control Program / D. S. Tanani et al. *Pan Afr Med J*. 2017. DOI: 10.11604/pamj.2017.26.48.7394.

30. Patient safety. Pharmacists' role in medication without harm. / International Pharmaceutical Federation (FIP). 2020. URL: https://www.fip.org/file/4757. (Date of access: 20.03.2025).

31. Perception de la pharmacovigilance : enquête auprès de pharmaciens d'officine de la ville de Casablanca, Maroc / N. Nchinech et al. *Médecine Thérapeutique*. 2021. Vol. 30(2). P 119-126. DOI:10.1684/sanmt.2021.19

32. *Pharmacovigilance – Ensuring the Safety of Medications*. 2024. URL: https://gmpinsiders.com/pharmacovigilance-ensuring-safety-of-medications/ (Date of access: 20. 03. 2025).

33. *Pharmacovigilance* / CPVS. 2023. URL: http://www.cpvs.co.uk/site/pharmacovigilance/ (Date of access: 20.03.2025).

34. *Pharmacovigilance* / MTaPS (USAID). 2023. URL: /https://www.mtapsprogram.org/our-work/pharma-systems-areas/pharmacovigilance (Date of access: 20.03.2025).

35. *Pharmacovigilance* / WHO. URL: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance. (Date of access: 23.03.2025).

36. *Pharmacovigilance and Drug Safety in 2024: Insights from a Leading CRO* / TFS HealthScience. 2024. URL: https://tfscro.com/resources/pharmacovigilance-and-drug-safety-in-2024-insights-from-a-leading-cro/ (Date of access: 20.03.2025).

37. Pharmacovigilance during the COVID-19 Pandemic Era in Morocco URL: https://www.saspublishers.com/article/19862/download/ (Date of access: 20.03.2025).

38. Pharmacovigilance in the MENA Region / Biomapas. URL: https://www.biomapas.com/pharmacovigilance-in-the-mena-region/. (Date of access:20.03.2025).

39. *Pharmacovigilance strategies*. World Health Organization. Retrieved from. URL: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/strategies (Date of access: 20. 03. 2025).

40. Pharmacovigilance Systems in Arab Countries: Overview of 22 Arab Countries / T. M. Alshammari et al. *Drug Saf.* 2019. Vol.42. P. 849-868 DOI: 10.1007/s40264-019-00807-4

41. Pharmacovigilance. URL: https://www.capm-sante.ma. (Date of access:20.03.2025).

42. *Pharmacovigilance: Ensuring Drug Safety*. *Journal of Pharmacological Reports.* 2023. Vol. 7(1). URL: https://www.longdom.org/open-access/pharmacovigilance-ensuring-drug-safety-98950.html (Date of access: 20.03.2025).

43. Potential Role of Community Pharmacists in Pharmacovigilance: The Effectiveness of an Educational Intervention inGreater Cairo Province in Egypt" / Elhawary M. et al. *Acta Scientific Pharmaceutical Sciences.*2021. Vol. 5(3) P. 61-71 .

44. *Programme for International Drug Monitoring / World Health Organization. URL:* https://www.who.int/teams/regulation-

prequalification/regulation-and-safety/pharmacovigilance/networks/pidm?utm. (Date of access: 23.03.2025).

45. *Role and Responsibilities of Various Stakeholders in Pharmacovigilance (PV). ResearchGate*. 2024. Vol. 19(1). DOI: 10.2174/0115748863277574240125045459

46. *Smith Marsh D. E. Types of Adverse Drug Reactions*. 2025. URL: https://www.msdmanuals.com/home/drugs/adverse-drug-reactions/types-of-adverse-drug-reactions (Date of access: 20.03.2025).

47. Summary report on the Regional meeting on strengthening pharmacovigilance systems, Rabat, Morocco, 7–10 September 2015 / World Health Organization. URL: https://iris.who.int/handle/10665/199899. (Date of access: 20.03.2025).

48. *The Importance of Pharmacovigilance for Labs*. *ProPharmaGroup*. (2023). URL: https://www.propharmagroup.com/services/medical-information/technology-enablement/ (Date of access: 20.03.2025).

49. *The importance of pharmacovigilance: Safety monitoring of medicinal products*. URL: https://iris.who.int/bitstream/handle/10665/42493/a75646.pdf. (Date of access 20.03.2025).

50. The WHO international drug monitoring programme. *ScienceDirect*. 2002. Vol. 25. P. 589-598. URL: https://www.sciencedirect.com/science/article/pii/S0378608002800575 (Date of access: 23.03.2025).

51. The WHO Programme for International Drug Monitoring A global collaboration to advance the practice of pharmacovigilance in countries across the world.. *About the WHO Programme for International Drug Monitoring*. URL: https://who-umc.org/about-the-who-programme-for-international-drug-monitoring/ (Date of access. 23.03.2025).

52. Toklu H. Z, Mensah E. Why do we need pharmacists in pharmacovigilance systems? *J Public Health Inform*. 2016. Vol.;8(2). P. e193. DOI: 10.5210/ojphi.v8i2.6802.

53. *Tools and innovations in pharmacovigilance*. / World Health Organization URL: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance/guidance/operations/tools-innovations. (Date of access; 20.03.2025).

54. Vargesson N. Thalidomide-induced teratogenesis: history and mechanisms. *Birth Defects Res C: Embryo Today*. 2015. Vol. 105(2). P. 140-156. URL: https://pubmed.ncbi.nlm.nih.gov/26043938/ (Date of access: 20.03.2025).

55. VigiAccess Database. URL: https://www.vigiaccess.org/. (Date of access: 20.03.2025).

56. *VigiBase: WHO's global database signalling harm and pointing to safer use*. URL: https://who-umc.org/vigibase/vigibase-who-s-global-database/. (Date of access: 23.03.2025).

57. *What is the difference between an Adverse Event & Adverse Drug Reaction?* / The Pharma Daily. URL: https://thepharmadaily.com/courses/pharmacovigilance-quiz/what-is-the-difference-between-an-adverse-event-and-an-adverse-drug-reaction (Date of access: 20.03.2025).

58. *WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems*. / World Health Organization. 2024. URL: https://apps.who.int/iris/bitstream/handle/10665/43034/9241592214_eng.pdf / (Date of access: 20.03.2025).

59. WHO pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems / World Health Organization. 2015. URL; https://www.who.int/publications/i/item/9789241508254. (Date of access: 20.03.2025).

ANNEXES

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ

МАТЕРІАЛИ
XXXI МІЖНАРОДНОЇ НАУКОВО-ПРАКТИЧНОЇ
КОНФЕРЕНЦІЇ МОЛОДИХ ВЧЕНИХ ТА СТУДЕНТІВ

23–25 квітня 2025 року
м. Харків

Харків
НФаУ
2025

УДК 615.1

Редакційна колегія: проф. Котвіцька А. А., проф. Владимирова І. М.
Укладачі: Сурікова І. О., Боднар Л. А., Комісаренко М. А., Комісарова Є. Є.

Актуальні питання створення нових лікарських засобів: матеріали XXXI міжнародної науково-практичної конференції молодих вчених та студентів (23-25 квітня 2025 р., м. Харків). – Харків: НФаУ, 2024. – 515 с.

Збірка містить матеріали міжнародної науково-практичної конференції молодих вчених та студентів «Актуальні питання створення нових лікарських засобів, які представлені за пріоритетними напрямами науково-дослідної роботи Національного фармацевтичного університету. Розглянуто теоретичні та практичні аспекти синтезу біологічно активних сполук і створення на їх основі лікарських субстанцій; стандартизації ліків, фармацевтичного та хіміко-технологічного аналізу; вивчення рослинної сировини та створення фітопрепаратів; сучасної технології ліків та екстемпоральної рецептури; біотехнології у фармації; досягнень сучасної фармацевтичної мікробіології та імунології; доклінічних досліджень нових лікарських засобів; фармацевтичної опіки рецептурних та безрецептурних лікарських препаратів; доказової медицини; сучасної фармакотерапії, соціально-економічних досліджень у фармації, маркетингового менеджменту та фармакоекономіки на етапах створення, реалізації та використання лікарських засобів; управління якістю у галузі створення, виробництва й обігу лікарських засобів; суспільствознавства; фундаментальних та мовних наук.

УДК 615.1

as rotavirus and pneumococcal, but their implementation is uneven. In particular, rotavirus vaccine coverage was 18% in 2013, and tripled to 54% in 2023. The pneumococcal vaccine covered 36% of the population in 2013, and 52% in 2023, which is almost 1.5 times more.

Conclusions. The Eastern Mediterranean region has made significant progress in basic immunization coverage, but systemic challenges remain related to access to immunization in the first hours of life, uneven introduction of new vaccines, and vulnerability to external challenges. Further improvements will require investment in health infrastructure, expanded public awareness campaigns, and strengthening national immunization schedules in line with WHO global recommendations.

GLOBAL OVERVIEW OF INTERNATIONAL EFFORTS IN PHARMACOVIGILANCE

Morchad Ibtissam, Karnauh D.V.
Scientific supervisor: Surikova I.O.
National University of Pharmacy, Kharkiv, Ukraine
socpharm@nuph.edu.ua

Introduction. Pharmacovigilance plays a crucial role in ensuring the safety and effectiveness of medicinal products globally. Since the establishment of the WHO Programme for International Drug Monitoring (PIDM) in 1968, the number of participating countries has steadily increased, reflecting a global commitment to adverse drug reaction (ADR) monitoring and patient safety. Strengthening pharmacovigilance systems is particularly relevant for developing countries where healthcare infrastructures are still evolving.

Aim. The aim of this research was to analyze the dynamics of countries joining the WHO PIDM from 1968 to 2025, grouped in five-year intervals, and to characterize regional trends in the development of global pharmacovigilance collaboration.

Materials and Methods. A retrospective descriptive study was conducted using publicly available data from the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre). Information regarding the year of accession and regional affiliation was systematized. Countries were grouped by five-year periods: 1968–1974, 1975–1979, 1980–1985, and so forth, until 2025. Data were organized into a comparative table indicating new member countries from Africa, Americas, Asia, Europe, and Oceania.

Results and discussion. The WHO PIDM was launched in 1968 with 10 pioneering member countries, including Australia, Canada, Czechoslovakia, Germany, Ireland, the Netherlands, New Zealand, Sweden, the United Kingdom, and the United States. The initial goal was to facilitate international collaboration in the detection of adverse drug reactions following the thalidomide tragedy. Over the decades, the programme expanded significantly, incorporating countries from all regions of the world.

The table 1 summarizes the countries and regions that joined WHO PIDM over successive five-year periods.

In the first period (1968–1974), sixteen countries joined the PIDM, predominantly from Europe and Oceania, establishing a strong foundation for international cooperation in pharmacovigilance. During the subsequent periods of 1975–1979 and 1980–1985, the expansion slowed considerably, with only a few European countries becoming new members. A gradual acceleration of membership was observed starting from 1991, coinciding with broader global health initiatives and the recognition of the need for robust medication safety systems across different healthcare environments.

Table 1

Countries joining the WHO Programme for International Drug Monitoring (PIDM) by five-year periods and regions (1968–2025)

Period	Africa	Americas	Asia	Europe	Oceania
1968–1974	–	Canada, USA	Japan, Israel	Czechoslovakia, Germany, Ireland, Netherlands, Sweden, United Kingdom, Denmark, Norway, Poland, Finland	Australia, New Zealand
1975–1979	–	–	–	Bulgaria, Italy, Romania, Belgium	–
1980–1985	–	–	Thailand	Spain	–
1986–1990	–	–	France, Türkiye	Greece, Hungary, Iceland	–
1991–1995	Morocco, Tunisia, United Republic of Tanzania	Costa Rica, Argentina, Cuba, Venezuela	Republic of Korea, Singapore, Oman, Philippines	Austria, Switzerland, Croatia, Czechia, Portugal, Slovakia	–
1996–2000	–	Chile, Mexico	China, India, Iran, Viet Nam, Sri Lanka	Estonia, Russian Federation, Cyprus, North Macedonia, Serbia	Fiji
2001–2005	Egypt, Ghana, Nigeria, Mozambique	Brazil, Uruguay, Guatemala, Peru, Colombia	Jordan	Armenia, Latvia, Republic of Moldova, Ukraine, Malta, Lithuania	–
2006–2010	Togo, Uganda, Ethiopia, Namibia, Sierra Leone, Sudan, Botswana, Madagascar, Senegal, Burkina Faso, Cameroon, Côte d'Ivoire, Democratic Republic of the Congo, Kenya, Zambia	Suriname, Barbados	Nepal, Uzbekistan, Brunei Darussalam, Iraq, Saudi Arabia, Cambodia, Kazakhstan	Belarus, Slovenia, Montenegro, Andorra	–
2011–2015	Benin, Mali, Cabo Verde, Eritrea, Niger, Angola, Guinea, Liberia, Rwanda, Mauritius, Eswatini	Jamaica, Bolivia	Bangladesh, Bhutan, Lao People's Democratic Republic, Afghanistan, Maldives	–	–
2016–2020	Chad, Malawi	–	Pakistan, Syrian Arab Republic	Bosnia and Herzegovina, Albania, Luxembourg, Azerbaijan, Georgia	Papua New Guinea
2021–2025	Algeria, Congo, Gambia, Libya, Burundi, Central African Republic, Guinea-Bissau, Gabon, Mauritania, Lesotho, South Sudan, Zanzibar, Sao Tome and Principe	Dominican Republic, Honduras, Nicaragua, Saint Vincent and the Grenadines, Ecuador, El Salvador, Paraguay	Kuwait, Lebanon, Mongolia, Yemen, Tajikistan	–	–

Significant growth occurred between 2001 and 2010, during which the number of participating countries increased substantially. The periods 2001–2005 and 2006–2010 recorded the

largest increments, with 20 and 25 new members, respectively. This surge indicated not only the strengthening of pharmacovigilance structures in high-income countries but also the increasing engagement of low- and middle-income countries in global drug safety efforts. In the most recent periods (2016–2025), the expansion of WHO PIDM has continued steadily, marked by the inclusion of countries primarily from Africa and the Middle East, thereby further enhancing the geographic diversity and comprehensiveness of the global pharmacovigilance network.

At the inception of the programme, no African countries were among its members. The first significant steps occurred in 1992 with the accession of Morocco and South Africa, followed by Tunisia in 1993. The 2000s marked a period of intensified involvement, with countries such as Nigeria, Ghana, and others actively joining the PIDM. The period 2006–2010 was particularly notable, witnessing a surge in African membership, including Togo, Uganda, Ethiopia, Namibia, and others. This trend continued throughout the 2010s and into the 2020s, with additional countries such as Benin, Mali, Angola, and the Democratic Republic of the Congo becoming active participants. The progressive integration of African nations into the WHO pharmacovigilance network reflects concerted efforts to strengthen healthcare systems across the continent, aligning pharmacovigilance activities with international standards and enhancing patient safety initiatives on a global scale.

Conclusions. The WHO Programme for International Drug Monitoring has evolved into a robust global network, particularly expanding since the 1990s. While early participation was dominated by European and American countries, recent decades have seen a significant rise in membership from Africa and Asia. This trend underscores the growing global recognition of pharmacovigilance as an essential pillar of public health protection.

THE AVAILABILITY AND AFFORDABILITY OF MEDICATIONS AS INDICATORS OF THE EFFECTIVENESS OF NATIONAL MENTAL HEALTH POLICIES

Safi Isaam
Scientific supervisor: Surikova I.O.
National University of Pharmacy, Kharkiv, Ukraine
socpharm@nuph.edu.ua

Introduction. The burden of mental disorders continues to grow worldwide, highlighting the need for effective national mental health policies. A critical component of such policies is the pharmaceutical supply system, ensuring the availability and affordability of essential psychotropic medications. Inadequate access to necessary medications remains a major barrier to achieving the objectives of mental health programs, especially in low- and middle-income countries. Thus, assessing medication availability and affordability serves as an important indicator of policy effectiveness and provides insight into broader healthcare system gaps.

Aim. The purpose of this study is to analyze how the availability and affordability of psychotropic medications reflect the effectiveness of national mental health policies and to identify best practices for integrating pharmaceutical support into mental health programs.

Materials and Methods. The study employed a systematic review of international reports and national policy documents from selected countries (Canada, Morocco, and Kenya). Comparative and analytical methods were used to assess indicators related to medication access, pricing policies,

СЕКЦІЯ 11. СОЦІАЛЬНО-ЕКОНОМІЧНІ, ОРГАНІЗАЦІЙНІ ТА ПРАВОВІ ДОСЛІДЖЕННЯ У ФАРМАЦІЇ
SOCIO-ECONOMIC, ORGANIZATIONAL AND LEGAL RESEARCH IN PHARMACY

МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

СЕРТИФІКАТ УЧАСНИКА

Цим засвідчується, що

Morchad Ibtissam, Karnauh D.V.
Scientific supervisor: Surikova I.O.

брав(ла) участь у роботі
XXXI Міжнародної науково-практичної конференції молодих вчених та студентів
«АКТУАЛЬНІ ПИТАННЯ СТВОРЕННЯ НОВИХ ЛІКАРСЬКИХ ЗАСОБІВ»

В.о. ректора
Національного фармацевтичного
університету

Алла КОТВІЦЬКА

23-25 квітня 2025 р, м. Харків

Ф А 2.2.1–32-366

National University of Pharmacy

Faculty pharmaceutical
Department of social pharmacy

Level of higher education master

Specialty 226 Pharmacy, industrial pharmacy
Educational and professional program Pharmacy

APPROVED
The Head of Department
of Social Pharmacy

_____
Alina VOLKOVA
"11" of September 2024

ASSIGNMENT
FOR QUALIFICATION WORK
OF AN APPLICANT FOR HIGHER EDUCATION

Ibtissam MORCHAD

1. Topic of qualification work: «Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco»

supervisor of qualification work: Iryna SURIKOVA, PhD, associated professor,
approved by order of NUPh from "27th" of September 2024 № 237

2. Deadline for submission of qualification work by the applicant for higher education: May 2025.

3. Outgoing data for qualification work: data from scientific and periodical literature in accordance with research objectives; reports of international organizations, statistical data.

4. Contents of the settlement and explanatory note (list of questions that need to be developed):
- to review scientific sources on global pharmacovigilance and ADR reporting practices;
- to conduct global overview international efforts in pharmacovigilance and ADR reporting;
- to analyze innovations and best practices in international PV systems;
- to evaluate the development and current state of the national PV system in Morocco;
- to assess the legal framework and identify challenges and gaps in ADR reporting;
- to examine the pharmacist's role in Morocco's PV system and propose recommendations for improvement.

5. List of graphic material (with exact indication of the required drawings):
tables – 5, figures – 8

6. Consultants of chapters of qualification work

Chapters	Name, SURNAME, position of consultant	Signature, date	
		assignment was issued	assignment was received
1	Iryna SURIKOVA, associated professor of higher education institution of department Social Pharmacy	11.09.2024	11.09.2024
2	Iryna SURIKOVA, associated professor of higher education institution of department Social Pharmacy	21.11.2024	21.11.2024
3	Iryna SURIKOVA, associated professor of higher education institution of department Social Pharmacy	24.12.2024	24.12.2024

7. Date of issue of the assignment: «11» of September 2024.

CALENDAR PLAN

№	Name of stages of qualification work	Deadline for the stages of qualification work	Notes
1	Analysis of scientific, periodic literature on the topic of qualification work	September 2024	**done**
2	Study of international efforts in pharmacovigilance and ADR reporting	October-November 2024	**done**
3	Analyze innovations and best practices in international PV systems	December-January 2024-2025	**done**
4	Evaluate the development and current state of the national PV system in Morocco	February-March 2025	**done**
5	Summary of the results of the study	April 2025	**done**
6	Finalizing the work, preparing the report	May 2025	**done**

An applicant of higher education Ibtissam MORCHAD

Supervisor of qualification work Iryna SURIKOVA

ВИТЯГ З НАКАЗУ № 237

По Національному фармацевтичному університету

від 27 вересня 2024 року

Затвердити теми кваліфікаційних робіт здобувачам вищої освіти 5-го курсу Фм20(4,10д) 2024-2025 навчального року, освітньо-професійної програми – Фармація, другого (магістерського) рівня вищої освіти, спеціальності 226 – Фармація, промислова фармація, галузь знань 22 Охорона здоров'я, денна форма здобуття освіти (термін навчання 4 роки 10 місяців), які навчаються за контрактом (мова навчання англійська та українська) згідно з додатком № 1.

Прізвище, ім'я здобувача вищої освіти	Тема кваліфікаційної роботи		Посада, прізвище та ініціали керівника	Рецензент кваліфікаційної роботи
по кафедрі соціальної фармації				
Моршад Ібтіссам	Сучасні тенденції у системі фармаконагляду та звітності про побічні реакції в Марокко	Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco	Доцент Сурікова І.О.	Доцент Бондарєва І.В.

Ректор

Вірно. Секретар

ФА2.8-03-317

ВИСНОВОК

експертної комісії про проведену експертизу
щодо академічного плагіату у кваліфікаційній роботі

здобувача вищої освіти

«14» травня 2025 р. № 331206198

Проаналізувавши кваліфікаційну роботу здобувача вищої освіти Моршад Ібтіссам, групи Фм20 (4,10д) англ-01, спеціальності 226 Фармація, промислова фармація, освітньої програми «Фармація» навчання на тему: «Сучасні тенденції у системі фармаконагляду та звітності про побічні реакції в Марокко / Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco», експертна комісія дійшла висновку, що робота, представлена до Екзаменаційної комісії для захисту, виконана самостійно і не містить елементів академічного плагіату (компіляції).

Голова комісії,
проректор ЗВО з НПР,
професор **Інна ВЛАДИМИРОВА**

Ф А 2.2.1-32-353

REVIEW

of scientific supervisor for the qualification work of the master's level of higher education of the specialty 226 Pharmacy, industrial pharmacy

Ibtissam MORCHAD

on the topic: «Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco»

Relevance of the topic. Ensuring medication safety has become one of the central challenges for modern healthcare systems worldwide. The increasing complexity of pharmacotherapy, the widespread use of polypharmacy, and the growing number of newly introduced drugs necessitate a robust pharmacovigilance (PV) framework. In this context, Morocco, as a low-middle income country with active participation in the WHO Programme for International Drug Monitoring, presents a unique case for analysis. Despite having an established national center and a developed reporting infrastructure, the country still faces significant challenges such as underreporting, limited healthcare professional involvement, and regulatory gaps. Therefore, this topic is highly relevant to both national and international public health policy development.

Practical value of conclusions, recommendations and their validity. The work offers well-reasoned, evidence-based conclusions and proposes feasible recommendations that align with international trends in PV development. The student thoroughly analyzes systemic barriers to ADR reporting in Morocco, especially the underutilization of pharmacists in both hospital and community settings. Based on survey data and comparative analysis, the work presents a set of practical strategies that could significantly enhance PV system performance.

Assessment of work. The student demonstrates a strong ability to synthesize international and national data, critically evaluate the organization of pharmacovigilance systems, and apply comparative analytical methods. The text is illustrated with relevant figures and tables, and includes references to up-to-date,

credible sources. The level of academic writing, the analytical depth, and the presentation of findings meet the requirements.

General conclusion and recommendations on admission to defend. In general, the qualification work of Ibtissam MORCHAD on the topic: «Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco» is performed at the proper level, meets the requirements of the "Regulations on the preparation and protection of qualification works at the National University of Pharmacy" and can be recommended for defense in the Examination commission.

Scientific supervisor Iryna SURIKOVA

«14th» of May 2025

Ф А 2.2.1-32-356

REVIEW

for qualification work of the master's level of higher education, specialty 226 Pharmacy, industrial pharmacy

Ibtissam MORCHAD

on the topic: «Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco»

Relevance of the topic. The issue of pharmacovigilance has gained increasing global importance due to the rising complexity of pharmacotherapy and the need to protect patient safety in both hospital and outpatient settings. In Morocco, despite the existence of a national PV system, systemic issues such as underreporting and insufficient engagement of healthcare professionals, particularly pharmacists, still persist. The author's choice to analyze Morocco's pharmacovigilance system in the context of international trends is well-founded and reflects the urgent need to improve medication safety in low- and middle-income countries. This makes the topic not only timely, but also highly relevant for both public health policy and pharmaceutical practice.

Theoretical level of work. The thesis demonstrates a high theoretical level, grounded in a comprehensive literature review of global pharmacovigilance systems, including WHO standards, regulatory frameworks, and digital tools. The student accurately applies key concepts such as signal detection, ADR classification, and stakeholder engagement, while integrating up-to-date sources from WHO, EMA, UMC, and national legislation. The theoretical discussion is coherent, systematic, and provides a strong foundation for the applied aspects of the study.

Author's suggestions on the research topic. The author proposes a set of original and well-structured recommendations aimed at strengthening Morocco's pharmacovigilance system. These include creating hospital-based PV units, integrating

PV training into pharmacy education, improving feedback mechanisms from the national center, and promoting pharmacist participation through simplified reporting tools and institutional support. The suggestions are logically derived from the analysis and are clearly tailored to the local context.

Practical value of conclusions, recommendations and their validity. The proposed measures are based on real-world challenges identified through the author's analysis of national data and institutional reports. Recommendations are both feasible and in line with global best practices. Their implementation could enhance ADR reporting rates, improve professional engagement, and support safer medication use in Morocco. The validity of the conclusions is ensured through comparative analysis, evidence from primary and secondary sources, and the use of appropriate methodological approaches.

Disadvantages of work. Some minor stylistic inconsistencies and occasional language issues are present, but they do not significantly affect the overall quality or comprehension of the research.

General conclusion and assessment of the work. According to the relevance and the results of the research qualification work of Ibtissam MORCHAD on the topic: «Current trends in pharmacovigilance and adverse drug reactions reporting in Morocco» meets the requirements for master's works and can be recommended for official defense in the Examination commission.

Reviewer Assoc. prof. Iryna BONDARIEVA

«16th» of May 2025

Ф А2.5-32-231

ВИТЯГ
з протоколу засідання кафедри соціальної фармації
№ 22 від «26» травня 2025 року

ПРИСУТНІ: зав. каф. доц. Аліна ВОЛКОВА, проф. Ганна ПАНФІЛОВА, проф. Вікторія НАЗАРКІНА, доц. Галина БОЛДАРЬ, доц. Наталія ГАВРИШ, доц. Тетяна ДЯДЮН, доц. Юлія КОРЖ, асист. Альміра НОЗДРІНА, доц. Вікторія МІЩЕНКО, доц. Ірина ПОПОВА, доц. Олександр СЕВРЮКОВ, доц. Ірина СУРІКОВА, доц. Любов ТЕРЕЩЕНКО, доц. Наталія ТЕТЕРИЧ.

ПОРЯДОК ДЕННИЙ:

Про представлення до захисту в Екзаменаційній комісії кваліфікаційних робіт.

СЛУХАЛИ: завідувачку кафедри доц. Аліну ВОЛКОВУ з рекомендацією представити до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувачки вищої освіти спеціальності 226 Фармація, промислова фармація Ібтіссам МОРШАД на тему: «Сучасні тенденції у системі фармаконагляду та звітності про побічні реакції в Марокко».

Науковий керівник: к. фарм. н., доцент кафедри СФ Ірина СУРІКОВА.

Рецензент: к. фарм. н., доцент кафедри ММЗЯФ, доц. Ірина БОНДАРЄВА.

УХВАЛИЛИ: Рекомендувати до захисту в Екзаменаційній комісії кваліфікаційну роботу здобувачки вищої освіти Ібтіссам МОРШАД на тему: «Сучасні тенденції у системі фармаконагляду та звітності про побічні реакції в Марокко».

Завідувачка каф. СФ, доцент Аліна ВОЛКОВА

Секретар, доцент Наталія ТЕТЕРИЧ

Ф А2.2.1-32-042

НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

ПОДАННЯ
ГОЛОВІ ЕКЗАМЕНАЦІЙНОЇ КОМІСІЇ
ЩОДО ЗАХИСТУ КВАЛІФІКАЦІЙНОЇ РОБОТИ

Направляється здобувачка вищої освіти Ібтіссам МОРШАД до захисту кваліфікаційної роботи
за галуззю знань 22 Охорона здоров'я
спеціальністю 226 Фармація, промислова фармація
освітньою-професійною програмою Фармація
на тему: «Сучасні тенденції у системі фармаконагляду та звітності про побічні реакції в Марокко».

Кваліфікаційна робота і рецензія додаються.

Декан факультету _____ / Микола ГОЛІК/

Висновок керівника кваліфікаційної роботи

Здобувачка вищої освіти Ібтіссам МОРШАД під час виконання кваліфікаційної роботи продемонструвала уміння працювати з науковими даними, проводити їх узагальнення, аналізувати та узагальнювати результати дослідження. Усі поставлені завдання відповідно до мети роботи було виконано у повному обсязі. Результати дослідження належним чином оброблені і представлені.

Таким чином, кваліфікаційна робота може бути рекомендована до офіційного захисту в Екзаменаційній комісії Національного фармацевтичного університету.

Керівник кваліфікаційної роботи Ірина СУРІКОВА

«14» травня 2025 р.

Висновок кафедри про кваліфікаційну роботу

Кваліфікаційну роботу розглянуто. Здобувач вищої освіти Ібтіссам МОРШАД допускається до захисту даної кваліфікаційної роботи в Екзаменаційній комісії.

Завідувачка кафедри
соціальної фармації Аліна ВОЛКОВА

«26» травня 2025 р.

Qualification work was defended

of Examination commission on

« » June 2025

With the grade _____

Head of the State Examination commission,

DPharmSc, Professor

_____ / Volodymyr YAKOVENKO/