WHITE PAPER

Pharmacovigilance in Africa: Strengthening Safe Use of Medicines

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Contents

Executive Summary

Pharmacovigilance (PV) plays a crucial role in ensuring drug safety, protecting public health, and improving healthcare outcomes. Africa's growing pharmaceutical market, increasing clinical trial activity, and expanding access to medicines make robust pharmacovigilance systems essential. Despite progress, challenges such as limited infrastructure, underreporting of adverse drug reactions (ADRs), and fragmented regulatory frameworks persist. This white paper explores the current landscape, challenges, and opportunities for strengthening pharmacovigilance in Africa. It highlights strategic approaches, including regulatory harmonization, digital solutions, and public-private partnerships, to enhance drug safety across the continent.

1. Introduction

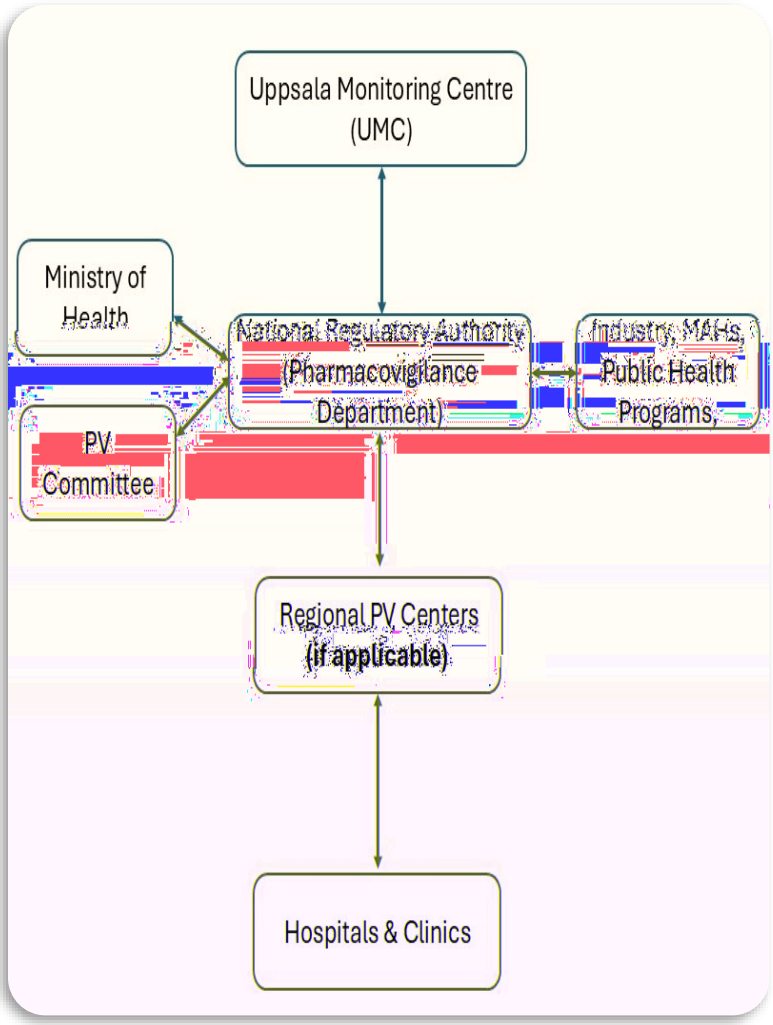
Pharmacovigilance (PV) is defined by WHO as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or or any other medicine/vaccine related problem. As Africa's healthcare sector continues to evolve with increasing access to medicines, vaccines, and medical devices, the importance of PV becomes even more pronounced in ensuring patient safety.

However, pharmacovigilance remains underdeveloped in many African countries. Therefore, strengthening PV systems is crucial for protecting patients, supporting regulatory decision-making, and fostering public trust in healthcare interventions.

2. Current State of Pharmacovigilance in Africa

2.1. Key Pharmacovigilance Systems

- **Uppsala Monitoring Centre (UMC),** the WHO Collaborating Centre for Pharmacovigilance, is responsible for global ADRs data collection through the WHO Programme for International Drug Monitoring (PIDM). Forty-six of the fifty-five African countries are full members of UMC, with an additional four holding associate membership. Their reports are submitted to VigiBase, the WHO's global database for adverse events related to medicines and vaccines.
- **African centers** such as the African Collaborating Centre for Pharmacovigilance and Surveillance (ACC) in Ghana, and the *Centre Anti-Poison et de Pharmacovigilance du Maroc* (CAPM)[1]in Morocco, serve as key WHO collaborating centers for pharmacovigilance in Africa.



General illustration of PV systems in Africa

These centers play a crucial role in supporting the monitoring of adverse drug reactions and training healthcare professionals in pharmacovigilance practices across the continent.

- **National PV Centers:** African countries have made substantial progress in building national pharmacovigilance systems within their National Regulatory Authorities (NRAs). These systems actively collaborate with healthcare providers to collect, analyze, and report adverse events. National PV centers play a critical role in ensuring drug safety through robust surveillance and reporting mechanisms. As of 2024, eight countries have achieved WHO Maturity Level 3, marking a significant increase from just two in 2021[2].

[1] "WHOCC - CAPM Plateforme."
[2] "Statement from Africa CDC on Rwanda and Senegal National Regulatory Authorities Achieving WHO Maturity Level 3"; "Senegal and Rwanda Achieve WHO Maturity Level 3 in Medicines Regulation."

2.2. Regulatory frameworks and harmonization efforts

- Regional initiatives such as the East African Medicines Regulatory Harmonization (EAC-MRH) and most importantly, the recently launched African Medicines Agency (AMA) are strengthening regulatory collaboration and harmonizing pharmacovigilance (PV) systems across Africa.
- Many African regulatory bodies are aligning their practices with the World Health Organization's (WHO) pharmacovigilance guidelines and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards. This includes adopting ICH E2E pharmacovigilance guidelines, along with other widely used ICH guidelines.

2.3. The Growing Significance of Pharmacovigilance

- Recent scandals involving substandard and unsafe medicines have underscored the need for stronger surveillance and reporting systems; systems that, if properly implemented, could have prevented these issues[3] [4].
- As access to medications and vaccines increases, African countries are placing greater emphasis on developing robust pharmacovigilance systems to monitor adverse drug reactions and ensure patient safety.

2.4. ADRs Reporting

- Underreporting of adverse drug reactions remains a significant challenge due to a lack of awareness and inadequate reporting mechanisms. Many countries still rely on paper-based reporting, which results in delays and data inconsistencies.
- There is limited engagement of healthcare professionals and the general public in ADR reporting. As noted by Wang et al., "Although local pharmacovigilance institutions enjoy legal support and have established systems and structures, limited stakeholder involvement and engagement in these systems are reflected in low reporting rates"[5].
- However, the number of reports has increased significantly as more countries join Uppsala Monitoring Centre (UMC) and strengthen their pharmacovigilance systems. From 2,695 reports by five countries in 2000, the number rose to about 25,000 (0.4%) in 2010 as the number of reporting countries grew to 24[6]. By 2016, reports from Africa accounted for 1% of all ADRs reports in VigiBase[7], despite Africa having the highest disease burden. For example, reports on Artemether-Lumefantrine from Africa have surged, with nearly 80% of all reports related to the drug in VigiBase by January 2025 being submitted in the past 10 years. This upward trend in reporting is evident across the majority of medicines and various countries albeit some differences.

[3] "Gambia Cough Syrup Scandal: Police Investigate Deaths Linked to Indian Medicine."
[4] "Exposing an Indian Pharma Firm Fuelling West Africa's Opioid Crisis."
[5] Wang et al., "Safety Monitoring of Medicines and Vaccines."
[6] Isah et al., "Specific Features of Medicines Safety and Pharmacovigilance in Africa."
[7] Wang et al., "Safety Monitoring of Medicines and Vaccines."

3. Challenges and Opportunities

3.1. Challenges

Data Collection and Reporting: Ensuring comprehensive ADR reporting remains a challenge, particularly in rural and underserved regions. Low internet access and inadequate technological infrastructure impede the real-time reporting of adverse events, with many countries relying on paper-based reporting.

Regulatory Gaps: While harmonization efforts are in progress, Africa's regulatory landscape remains fragmented, with each country maintaining its own guidelines, processes, and timelines.

Limited Resources: Inadequate funding and resources hinder pharmacovigilance (PV) implementation. Some African countries struggle to maintain comprehensive PV systems due to insufficient funding, shortage of trained personnel, and limited digital infrastructure for ADR reporting.

3.2. Unlocking Opportunities in Drug Safety

3.2.1. Enhancing ADRs reporting and PV systems

Given limited ADR reporting, pharmaceutical companies and CROs can spearhead initiatives to enhance engagement with both the public and healthcare professionals. These efforts would be beneficial:

For pharmaceutical companies & MAHs

- ✓ Enhanced drug safety and strengthened regulatory compliance.
- ✓ Lowered risk of litigation and legal exposure.
- ✓ Greater trust and credibility among regulators, healthcare providers, and patients.
- ✓ New opportunities for CROs to provide value through PV consulting and training.
- ✓ Accelerated regulatory response through early detection of unknown side effects and counterfeit medicines.
- ✓ Growth of materiovigilance, which remains a developing but important focus in the African regulatory landscape.

For patients & healthcare providers

- ✓ Increased access to safer medications and improved treatment outcomes.
- ✓ Early identification and management of drug safety concerns, helping to minimize adverse effects.
- ✓ Improved awareness among healthcare professionals and the public, enabling patients to report adverse events and make better-informed decisions.
- ✓ Strengthened development of safer, more effective therapies through enhanced real-world data collection.

For Africa

- ✓ Increase African representation in clinical trials thereby closing critical gaps in genetic diversity.
- ✓ Identification of region-specific drug safety concerns, enabling development of medicines tailored to African genetic profiles.
- ✓ Contribution to the advancement of personalized medicine through the integration of real-world data and pharmacogenomics.
- ✓ Improved patient safety and public trust in the continent's healthcare systems.

3.2.2 Strengthening Regulatory, Data Sharing and Public-Private Partnership

Pharmaceutical companies and CROs can leverage regulatory collaboration, data sharing, and private-public partnerships to expand their operations and strengthen pharmacovigilance (PV) across Africa. These opportunities include:

- Expanding AMA's role in coordinating PV efforts across Africa will enhance cross-border data sharing and improve signal detection.
- Adopting standardized reporting formats and guidelines for harmonized data collection.
- Public-private partnerships to build PV infrastructure and fund capacity-building initiatives, including joint projects to raise awareness among the public and healthcare providers.

3.2.3 Leveraging Technology

- Africa’s improving mobile penetration enables mobile app-based ADR reporting, reducing reliance on paper-based systems and thereby improving ADR collection and response times.
- AI-powered signal detection tools can help pharma companies analyze large Adverse Drug Reaction data from diverse African populations.
- Electronic Health Records (EHR) integration with PV systems for real-time Adverse Drug Reaction monitoring, ensuring better data collection, accuracy, and efficiency.

4. Case Studies: Successful Pharmacovigilance Initiatives in Africa

South Africa: SAHPRA (South African Health Products Regulatory Authority)

South Africa's SAHPRA has integrated a robust national pharmacovigilance system with electronic ADR reporting and public-private partnerships. The implementation of a digital reporting platform has significantly improved Adverse Drug Reaction reporting rates, particularly for antiretroviral (ARV) drugs.

A practical example is the 2012 reports of maternal deaths due to severe nevirapine (NVP)-induced adverse drug reactions (ADRs), which raised safety concerns about ARVs in pregnancy and led to a change in the first-line ARV regimen for pregnant women from NVP to an efavirenz (EFV)-based regimen[8].

The agency have also developed an app for prompt and efficient safety reporting[9]. These efforts are complemented by regular training programs and awareness campaigns, resulting in a more engaged community.

Rwanda: Rwanda Food and Drug Authority

Rwanda FDA, established by law in February 2018, achieved WHO Maturity Level 3 (ML3) in December 2024; just 7 years after its inception[10].

ARDs reporting increased significantly, with the number of vaccine-related adverse events following immunization (AEFI) reports surging from 89 in the first two years[11] to 456 in 2023[12]. Similarly, quality complaints about medical products increased from 21 in 2021 to 52 in 2023[13]. The authority has also strengthened post-market surveillance. A four-year assessment highlighted its proactive approach to drug recalls, reducing the percentage of all recalled products from 51.9% in 2020 to just 8.5% in 2024[14].

To enhance ADR reporting, Rwanda FDA, like South Africa, has introduced a digital tool for efficient reporting .

These initiatives demonstrate that strong post-market surveillance, coupled with regulatory compliance, significantly contributes to ensuring safer medicines for patients.

"Safer Medicines, Healthier Africa"

[8] "Maternal Deaths Due to Adverse Drug Reactions to Nevirapine-Containing HAART."
[9] "Medsafety X SAHPRA."
[10] "Senegal and Rwanda Achieve WHO Maturity Level 3 in Medicines Regulation."
[11] "Vigilance Medicine Safety Bulletin – Rwanda FDA."
[12] "Vigilance Medicine Safety Bulletin – Rwanda FDA."
[13] "Vigilance Medicine Safety Bulletin – Rwanda FDA."
[14] Bahizi et al., "A Four-Year Assessment of the Characteristics of Rwandan FDA Drug Recalls."

5. The future of pharmacovigilance (PV)

Pharmacovigilance is being shaped by rapid advancements in technology, adaptive regulatory landscapes, and the increasing need for proactive drug safety monitoring. Below are some notable trends:

- Digital & AI-Driven Pharmacovigilance
  - **Artificial Intelligence (AI) & Machine Learning (ML):** AI-powered platforms to enhance case processing, signal detection and risk assessment by analyzing vast data more efficiently.
  - **Natural Language Processing (NLP):** The use of NLP algorithms is improving adverse event (AE) intake from unstructured data sources such as social media, electronic health records (EHRs), and scientific literature, and also facilitating automated case narrative writing.
  - **Automated ADR Reporting:** Mobile apps and electronic reporting systems to enable real-time data collection from healthcare professionals and patients.

- **Real-World Evidence (RWE) & Big Data Utilization.** Integration of big data analytics will allow continuous monitoring of drug safety across diverse populations.

- **Global regulatory harmonization:** Regulatory agencies are increasingly adopting data-driven approaches. Harmonizing global standards will improve drug safety by facilitating data sharing and enabling faster signal detection, ultimately strengthening patient safety worldwide.

- **Patient-Centric Pharmacovigilance:** Increased patient engagement can be achieved by enhancing patient involvement in ADR reporting through digital tools, mobile apps, and social media monitoring. Additionally, emphasizing pharmacovigilance literacy can empower patients and communities to report and understand drug safety concerns effectively.

- **Partnerships:** Public-private partnerships and collaboration among healthcare professionals, regulators, and researchers are poised to drive advancements in pharmacovigilance.

- **Precision pharmacovigilance:** The rise of personalized medicine presents new opportunities in pharmacovigilance. This will require adaptive PV strategies that integrate pharmacogenomics to enhance drug safety, with an emphasis on post-marketing monitoring for long-term safety risks.

6. Closing Note

A robust pharmacovigilance system is critical for ensuring drug safety, maintaining regulatory compliance, and fostering public trust in healthcare interventions. While challenges persist, Africa is making significant strides toward strengthening its pharmacovigilance landscape. By leveraging technology, enhancing regulatory harmonization, engaging stakeholders, and fostering collaborations, Africa can build sustainable and efficient pharmacovigilance systems that benefit public health. THESYL remains dedicated to supporting these efforts and driving excellence in pharmacovigilance across the continent.

How THESYL supports Pharmacovigilance in Africa

THESYL is committed to enhancing pharmacovigilance across Africa by leveraging innovative solutions, local market understanding, and extensive industry expertise. Our key approaches include:

- ✓ **Advanced PV Solutions:** The company provides safety database for storing, processing, analyzing, and reporting adverse events related to drugs, devices, and vaccines. Our solutions include seamless ADR management, automated pharmacovigilance processes, and AI-powered signal detection and risk assessment tools to enhance drug safety monitoring.
- ✓ **End-to-End PV Services:** THESYL's PV covers the full PV lifecycle including QPPV/LPPV, clinical trial safety, post-marketing surveillance, periodic safety reports, risk management plans (RMPs), and signal detection for all categories (generics, biologics, and vaccines).
- ✓ **Strong Network:** Partnering with hospitals, private clinics, universities, and local regulatory bodies to strengthen PV implementation and reporting.
- ✓ **Cost-Effective & Scalable Solutions:** Offering scalable and cost-effective PV services with flexible pricing, tailored to meet the needs of both small biotech startups and large pharmaceutical companies. Whether you require support for individual projects or full outsourcing, our services are ideal for MAHs looking to streamline compliance and reduce operational burdens.
- ✓ **Global Alignment & Regulatory Expertise:** We support clients in aligning with international pharmacovigilance (PV) standards while adapting to evolving global and regional trends. With our in-depth expertise in African PV regulations, we facilitate seamless communication and accelerate regulatory approvals.

"Driven by Data, Committed to Safety"

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