Strengthening pharmaceutical systems in Sub-Saharan Africa: Bridging the gap in medication safety and healthcare quality

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Abstract

Medication errors and adverse drug events represent a leading cause of preventable harm in health systems globally, with Sub-Saharan Africa (SSA) bearing a disproportionate burden. Pooled inpatient medication error rates exceed 8% across the region, compounded by fragmented regulatory frameworks, underfunded pharmacovigilance systems, workforce constraints, and unreliable medicine supply chains. Up to 13% of medicines circulating in low-and-middle-income countries are substandard or falsified, while clinical pharmacy practice remains largely confined to dispensing roles, limiting the profession's contribution to patient safety. These systemic weaknesses collectively undermine medication safety and erode public trust in healthcare. This paper proposes a coherent, systems-based framework to strengthen pharmaceutical systems in SSA, drawing on the Systems Engineering Initiative for Patient Safety (SEIPS) and the Consolidated Framework for Implementation Research (CFIR). The framework integrates six interconnected pillars: regulatory and governance reform, workforce development, technology adoption, supply chain reliability, safety culture transformation, and patient engagement. Proposed strategies include competency-based clinical pharmacy training and interprofessional education; hybrid mandatory-voluntary incident reporting systems aligned with non-punitive safety cultures; offline-capable e-prescribing, clinical decision support, and digital pharmacovigilance platforms; electronic Logistics Information Management Systems to reduce medicine stock-outs; and leveraging the African Medicines Agency to harmonize regional regulatory standards. Successful implementation requires phased deployment beginning with high-risk pilot sites, sustained leadership commitment, and alignment with national Universal Health Coverage agendas. With coordinated investment across regulatory, organizational, and technological dimensions, SSA can substantially reduce preventable medication-related harm, improve patient outcomes, and advance equitable health systems.

Keywords: medication safety; pharmaceutical systems strengthening; pharmacovigilance; sub-Saharan Africa; patient safety

Introduction

Medication errors (MEs) and adverse drug events (ADEs) are among the leading causes of preventable harm in health systems globally. The World Health Organisation (WHO) estimates that unsafe medication practices cost nearly $42 billion annually, with low-and-middle-income countries (LMICs) carrying a disproportionate share of this burden.[1] In Sub-Saharan African (SSA), which comprises of over 45 countries, the problem is particularly acute. A systematic review reported pooled inpatient medication error rates exceeding 8%, with prescribing and administration errors especially common.[2]

Pharmacovigilance systems, which study the science and activities relating to the detection, understanding, and prevention of ADEs or any other medicine-related problems are weak, further compounding safety challenges.

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In SSA, pharmacovigilance centers exist in most countries but operate with significant constraints. In developed systems like United States of America (USA), reporting to regulatory authorities (e.g., Food and Drug Administration (FDA)) is voluntary but encouraged. In SSA, the regulatory environment is fragmented, with all 55 African Union member states having National Medicines Regulatory Authorities (NMRAs) functioning at varying maturity levels, many as departments within Ministries of Health.[3] The Africa Medicine Regulatory Harmonization (ARMH) programme, established in 2009, coordinates harmonization efforts across Regional Economic Communities such as the East African Communities.[4] Unlike the centralized FDA system in United States, SSA faces structural challenges including weak or absent regulatory policy, inadequate post-marketing systems, lack of standardized ME classification, and under-reporting and limited feedback mechanisms to healthcare facilities.[5,6,7] However, the 2025 landmark agreement among National Regulatory Authorities (NRAs) rated at WHO Maturity Level 3 established a framework for regulatory reliance, allowing countries with limited resources to rely on stronger agencies decision.[8]

Additionally, MEs rarely represent isolated mistakes; instead, they emerge from complex interactions between healthcare workers, workflows, tools, organizational factors, and wider system pressures.[9,10] In SSA, these interactions are shaped by

systemic weakness: underfunded health services, low pharmacist-to-high patient ratios, high prevalence of substandard and falsified (SF) medicines, and fragile supply chains.[5,11] These deficiencies undermine patient trust in healthcare and contribute to preventable morbidity, mortality, and economic waste.

Global health actors have emphasized the urgency of addressing this challenge. The WHO's *Medication Without Harm* challenge, launched in 2017, set an ambitious target of reducing severe, avoidable medication-related harm by 50%.[1] However, translating this goal into reality in SSA requires more than technical fixes; it demands a systems-based approach. Frameworks such as the Systems Engineering Initiative for Patient Safety (SEIPS)[9] and the Consolidated Framework for Implementation Research (CFIR)[12] provide useful lenses to understand the interdependencies across workforce, processes, technology, and governance.

This paper argues that pharmaceutical systems in SSA can be strengthened through a coherent framework integrating workforce development, regulatory and governance capacity, technology adoption, supply chain reliability, safety culture, and patient engagement. Drawing on implementation science and global best practices, it proposes strategies to bridge existing gaps in medication safety and healthcare quality. The ultimate aim is to reduce preventable harm, improve patient outcomes, and restore public trust in health systems across the region.

Current Challenges in Pharmaceutical Systems in SSA

Healthcare systems in SSA face persistent underfunding, with per capita expenditure in many countries far below the global average.[2] Pharmacist density is low, and clinical pharmacy practice remains underdeveloped with most pharmacists confined to dispensing roles.[13] Task overload and lack of structured medication reconciliation compromise patient safety. Pharmacovigilance and ME reporting systems are fragile. Although most SSA countries have designated pharmacovigilance centers, under-reporting is widespread, and standardised ME classification is lacking.[6] Weak regulatory oversight further undermines quality control, particularly for imports and informal drug markets.[11] Organizational hierarchies and a pervasive blame culture discourage incident reporting, limiting learning from errors.[10,12] Leadership commitment to safety is inconsistent, and frontline staff often lack the tools or incentives to participate in safety initiatives.

Errors occur across the medication-use continuum. In Ethiopia, pooled data show frequent administration errors among nurses, with wrong-dose and omission errors prominent.[14] Paediatric and critical care units face particular risk due to complex dosing. Substandard and Falsified medicines further compound harm. A meta-analysis estimated that up to 13% of medicines in LMICs are SF, with antibiotics and antimalarials most affected.[5] Unreliable supply chains contribute to frequent stock-outs, substitutions, and therapeutic compromises that increase ME risk.[15]

At the system-level, medication-related inefficiencies contribute to wasteful expenditure, prolong bed-days, and erode patient trust in healthcare.[1,2] While broader system inefficiencies exist beyond pharmaceutical systems, medication-related issues represent a significant and addressable component, with preventable ADEs accounting for substantial healthcare utilization and cost. Collectively, these gaps underscore the urgency of pharmaceutical systems reform in SSA.

Sub-Saharan African Context and Regulatory Landscape

Sub-Saharan Africa comprises over 45 countries with diverse economic, cultural, and healthcare system contexts. The region includes countries from the Southern African Development Community (SADC) such as South Africa, Botswana, Zimbabwe, and Tanzania; the East African Community (EAC) including Kenya, Uganda, Rwanda, and Burundi; the Economic Community of West African States (ECOWAS) encompassing Nigeria, Ghana, Senegal, and Côte d'Ivoire; and the Economic Community of Central African States (ECCAS) including Cameroon, Democratic Republic of Congo, and Gabon, among others. This geographic and political diversity creates a complex regulatory environment where medication safety challenges manifest with varying intensity across different sub-regions and country income levels. The regulatory framework governing pharmaceutical systems across SSA is characterized by significant fragmentation and heterogeneity. All 55 African Union member states have established NMRAs, though these agencies function at vastly different maturity levels as classified by the World Health Organization's Global Benchmarking Tool.[16] Many NMRAs operate as departments within Ministries of Health rather than as independent regulatory bodies, limiting their authority, resources, and technical capacity. Unlike centralized systems such as the United States FDA or the European Medicines Agency (EMA) which operate with substantial budgets, specialized staff, and sophisticated post-marketing surveillance infrastructure, most SSA regulatory authorities face chronic underfunding, inadequate human resources with limited technical expertise, and minimal capacity for quality control testing and inspections.[17]

The AMRH programme, established in 2009 under the African Union Development Agency-NEPAD, represents a continent-wide initiative to address regulatory fragmentation by coordinating harmonization efforts across Regional Economic Communities. This initiative has achieved notable successes including development of harmonized guidelines for medicine registration, joint assessment procedures, and information-sharing platforms, though implementation remains variable across regions.[3] The African Medicines Agency (AMA), which came into legal effect in November 2021 following ratification

by the requisite 15 African Union member states and appointed its inaugural Director General in June 2024, aims to further strengthen regulatory harmonization continent-wide.[17] However, it is critical to understand that the AMA will complement and support national regulatory authorities rather than replace them, functioning as a coordinating and capacity-building mechanism rather than a supranational regulator like the EMA. Regarding pharmacovigilance specifically, while most SSA countries have established designated pharmacovigilance centers often linked to national NMRAs or academic institutions, these systems operate quite differently from those in high-income countries. In the United States, for example, medication error and adverse drug reaction reporting to the FDA through mechanisms like MedWatch is voluntary for healthcare professionals, though many healthcare institutions have internal mandatory reporting policies. Similarly, reporting to national pharmacovigilance centers in SSA is generally voluntary at the healthcare professional level. However, SSA faces more fundamental challenges including severe under-reporting due to lack of awareness about pharmacovigilance systems, absence of standardized medication error classification frameworks limiting comparability across facilities and countries, fragile feedback mechanisms where reporters rarely receive information about actions taken based on their reports, and limited analytical capacity to detect safety signals from submitted reports.[6] These structural weaknesses mean that even when reporting systems exist on paper, they often fail to function as effective learning systems that drive medication safety improvements.

This regulatory landscape creates an environment where the "particularly acute problem" of medication safety referenced in the introduction manifests through multiple interconnected pathways. Weak regulatory oversight enables circulation of substandard and falsified medicines that directly cause patient harm through therapeutic failures and toxicity. Fragmented pharmacovigilance means that safety signals go undetected for extended periods, allowing preventable harm to continue unchecked. Limited post-marketing surveillance capacity prevents identification of medication errors at the system level, hindering evidence-based policy responses. The absence of standardized medication error taxonomies across countries makes it impossible to benchmark performance or share lessons learned effectively across the region. Understanding this complex regulatory context is essential for appreciating why pharmaceutical system strengthening requires not merely technical interventions at the facility level, but coordinated reforms spanning national regulatory capacity, regional harmonization mechanisms, and international support for capacity building. The recent establishment of the AMA and the February 2025 regulatory reliance agreement among WHO-listed Maturity Level 3 authorities represent promising developments, but transforming this fragmented landscape into an integrated, effective regulatory system capable of ensuring medication safety will require sustained political commitment, substantial investment, and long-term capacity development across the continent.[18] (Table 1).

Pharmaceutical Systems Strengthening: A Framework to Bridge the Gap

Pharmaceutical systems strengthening involves coordinated improvements in policies, organizational capabilities, workforce, technologies, and supply chains oriented toward safe and effective medication use.[1,9] Guided by SEIPS, which conceptualises safety as an outcome of interactions within work systems,[9] and CFIR, which provides an implementation lens[12] addresses both technical and cultural determinants of safety. Expanding clinical pharmacy practice is central. Modular, competency-based training should equip pharmacists to conduct medication review, reconciliation, and dose optimization, particularly for high-risk medicines.

Interprofessional education (IPE) with physicians, pharmacists, and nurses can reduce calculation errors and improve paediatric safety, demonstrating improvements in role clarity, communication skills, and teamwork dynamics.[2,13,19] However, significant barriers impede translation of IPE to practice, including scheduling coordination difficulties, high workload in clinical settings, curriculum centralization, and lack of attention to interprofessional capabilities in current curricula.[20,21]

For IPE to translate into sustainable practice change, educational intervention must be accompanied by system-level changes that recognize and legitimize different professional roles, organizational structures that support interprofessional collaboration, and continuing professional development beyond undergraduate education. Training must also embed safety science, incident analysis, human factors, and non-punitive reporting.[22] Also, regular workshops and continuing professional development can foster a workforce oriented toward safety and quality improvement.[9] Key implementation success factors includes administrative commitment allocating resources to IPE despite competing demands, addressing “turf battles” and attitudinal differences among profession, and ensuring protected time for collaboration practice in clinical stings.[23]

Robust governance is also critical to institutionalise safety. However, the relationship between mandatory reporting and errors disclosure is complex. The Joint Commission’s position notes that providers forced to report errors may not describe event details fully, as they are motivated by compliance requirement rather than learning.[24] Additionally, healthcare workers fear career-threatening disciplinary actions and malpractice litigation to selective reporting only when patients harm occurs or error cannot be concealed. Rather than blanket mandatory reporting, SSA system should consider a hybrid approach: mandatory reporting for sentinel events (serious harm or death) to regulatory health authorities, combined with protected voluntary reporting for near-misses

and lower-severity events within facilities. Such systems should include prompt, full disclosure to patients and families, disclosure to regulatory agencies, and institutional committees for organizational learning, while carefully avoiding individual blame.[24] National Pharmacovigilance systems must harmonise ME definitions (e.g., National Coordinating Council for Medication Error Reporting and Prevention, NCC MERP), provide timely feedback to facilities, and create legal protections for reports to engage learning-oriented reporting culture.[6] Further, at the regional level, the AMA offers an opportunity to align regulatory standards, strengthen inspections, and coordinate responses to SF medicines.[11] This nuanced approach balances accountability for serious events with psychological safety that enables continuous learning from daily errors and near-misses.

E-prescribing and clinical decision support systems can prevent common prescribing errors by flagging drug interactions, contraindications, and incorrect doses.[9,25] Offline-capable solutions adapted to resource constraints should be prioritised. Telepharmacy, increasingly validated in LMICS, can extend pharmacist counseling to rural communities and improve quality of care.[25,26] Digital pharmacovigilance platform, which includes simplified mobile or web-based portals with analytic dashboards, can increase reporting volumes and improve data use for learning.[6] Safe care requires reliable access to quality medicines. Electronic Logistics Information Management Systems (eLIMS) with real-time dashboards reduce stock-outs and improve planning,[15] as well as procurement reforms, serialization technologies, and targeted quality surveillance can deter SF circulation.[5]

Learning systems must replace punitive environments. Non-punitive incident reporting, regular safety huddles, and feedback cycles can normalise learning from errors.[10,12] Leadership sponsorship and protected time for clinical pharmacy activities are perquisites for success. Voluntary reporting encourages practitioners to report near-misses and errors, producing important information to reduce future errors, while mandatory reporting may lead providers to withhold event details.[24]

Patients should be active partners, but merely providing visual aids, plain-language counselling, and SMS reminders does not automatically ensure engagement.[25] However, engagement is influenced by multiple interdependent factors beyond educational materials alone: health system structure and accessibility, attitudes and communication approaches of healthcare professionals , health literacy levels, and local cultural context regarding patients-provider relationship.[27] Given resource variability, a tiered approach is essential. For instance. high-risk areas such as paediatrics can serve as pilots, with gradual expansion. Offline-first tools and fallback paper protocols ensure resilience to infrastructural constraints.[25]

Implementation Strategies

The CFIR framework offers a structured approach to implementation. Intervention characteristics should emphasize simplicity, adaptability, and cost transparency.[12] Outer-setting alignment with national Universal Health Coverage (UHC) strategies and donor investments ensures policy coherence.[1,6] Inner-setting factors, including leadership sponsorship and protected time for clinical pharmacy, are prerequisites for success.[9] At the individual level, role clarity and incentives empower pharmacists and technicians. Peer champions can accelerate adoption. Process-wise, participatory co-design with frontline staff builds ownership, while phased pilots and rapid-cycle evaluations support scaling.[12] SEIPS mapping should guide workflow redesign, addressing usability pain points, reducing alert fatigue, and standardizing high-risk processes (e.g., paediatric double-checks).[9,10]

Case Studies and Global Best Practices

Evidence from SSA and comparable regions demonstrates feasible pathways for strengthening pharmaceutical systems, though the evidence base remains limited and geographically skewed.[25,26] Telepharmacy has shown promise in low- and middle-income countries for improving access to pharmacist counseling and adherence monitoring. A systematic review examining telepharmacy applications found positive outcomes including improved medication adherence, patient satisfaction, and accessibility, though the authors acknowledged that the vast majority of included studies originated from high-income countries, with limited representation from Sub-Saharan Africa.[26] During the COVID-19 pandemic, Bashshur et al. noted that telepharmacy reduced barriers to continuity of care in resource-limited contexts, though this was primarily documented through expert commentary rather than empirical SSA data.[25] The scarcity of rigorous telepharmacy research conducted specifically in SSA settings represents a significant evidence gap that must be addressed through context-specific implementation studies before widespread adoption can be confidently recommended. Supply chain strengthening has been better documented within the region; in Ethiopia, eLIMS deployments reduced tracer medicine stock-outs and improved supply visibility.[15]

Further, evidence from SSA and comparable regions demonstrates feasible pathways for strengthening pharmaceutical systems. Telepharmacy has shown promise in LMICS, improving access to pharmacist counselling and adherence monitoring with positive usability outcomes.[25,26] While most robust telepharmacy evidence derives from developed countries, the COVID 19 pandemic demonstrated telepharmacy potential in maintaining continuity of care and expanded pharmacist reach in resource-limited contexts.[25] Pharmacovigilance reforms have yielded gains: a 2022 review found that simplified digital reporting supply chain strengthening has been demonstrated in Ethiopia, where

eLIMS deployments reduced tracer medicine stock-outs and improved visibility.[15] These reforms gained further momentum with February 2025's regulatory reliance agreement among leading NRAs, establishing frameworks for shared regulatory decisions.[28] While limited, these examples underscore the feasibility of combining digital innovation with governance reform to enhance medication safety in resource-constrained settings, though sustained implementation outcomes require longer-term evaluation.

Evaluation Plan

Evaluation should adopt mixed methods anchored in Donabedian's structure–process–outcome logic and implementation outcomes framework,[29] which provides a comprehensive logic model for assessing healthcare quality, combined with implementation science outcomes.[30] The Donabedian framework recognises that quality healthcare depends on adequate structures (organizational capacity and resources), effective processes (actual delivery activities), and positive outcomes (changes in health status). Structure indicators must address fundamental capacity issues that enable all downstream improvements, including pharmacist-to-population ratios and skill mix, availability of essential tracer medicines, functionality and connectivity of pharmacovigilance centers, and regulatory maturity levels of NMRAs. Without adequate structural foundations, process improvements cannot be sustained. Process indicators should measure the actual activities and workflows, including the proportion of patients receiving medication reconciliation at care transitions, medication error reports submitted per 1,000 prescriptions or patient-days, clinical decision support alert response rates distinguishing between accepted and overridden alerts, pharmacist counseling sessions conducted per 100 prescriptions, and time elapsed from medication error report submission to facility-level feedback.[9,6] Output measures represent the immediate tangible results of interventions, such as reductions in stock-out days for tracer medicines, substandard and falsified medicine detection rates from quality surveillance activities, pharmacovigilance signal generation and regulatory response times, and healthcare worker training completion rates with competency assessments. Outcome measures capture the ultimate patient and system impacts, including preventable adverse drug events per 1,000 patient-days, medication administration error rates specifically in high-risk units such as pediatrics and intensive care, medication adherence rates in chronic disease cohorts including non-communicable diseases and HIV programs, patient-reported medication safety experiences captured through validated instruments, and 30-day hospital readmissions attributable to medication-related causes.[14,25]

Medication reconciliation quality requires particular attention beyond simple completion rates. As emphasized by Mueller et al.[31] in their systematic review of hospital-based medication reconciliation practices, effective evaluation must assess not merely the number of reconciliations completed, but rather the quality and clinical meaningfulness of the process. This includes measuring the percentage of reconciliations that successfully identify medication discrepancies, the drug-related problems identified and clinically resolved through the reconciliation process, the clinical significance of identified discrepancies using standardized severity classification, time from patient admission to reconciliation completion, and inter-rater reliability among different healthcare professionals conducting reconciliations. Kwan et al. demonstrated in their systematic review that medication reconciliation's effectiveness as a patient safety strategy depends critically on these quality dimensions, not simply on documentation completion.[32] Furthermore, equity-sensitive metrics should disaggregate all indicators by facility level (tertiary, secondary, primary care), geographic location distinguishing urban and rural settings, and patient demographic characteristics to ensure interventions do not inadvertently widen existing health disparities. Sustainability indicators are essential for assessing long-term viability, including cost per medication error prevented and cost per preventable ADE averted to demonstrate economic value, institutionalization of reporting systems measured longitudinally at 12, 24, and 36 months post-implementation, staff turnover and retention rates among trained clinical pharmacy cadres, and continued leadership commitment evidenced through sustained resource allocation. This comprehensive evaluation approach, grounded in established quality frameworks while incorporating implementation science principles, enables both accountability for patient safety improvements and organizational learning for continuous system strengthening.

Limitations and Research Gaps

The evidence base in SSA remains limited. Many ME studies are single-site with heterogeneous definitions, limiting comparability.[2,6] Standardized ME metrics and linkage of pharmacovigilance databases with health information systems are urgently needed. Telepharmacy and clinical decision support (CDS) evidence in SSA is promising but small-scale and short-term.[25,26] Cost-effectiveness and equity outcomes remain underexplored. Similarly, while eLIMS demonstrates supply visibility gains, direct causal links to reduced patient harm are less well established.[15] Future research should prioritize pragmatic trials of pharmacist-led reviews, paediatric dosing safety bundles, and pharmacovigilance uptake strategies, as well as evaluating AMA's impact on regional safety governance.

Conclusion

Medication-related harm in SSA reflects deep systemic weaknesses in pharmaceutical systems requiring coordinated reform across multiple levels. This paper proposed systems-based approach integrating: regulatory harmonization through AMA and national pharmacovigilance strengthening; organizational transformation fostering non-punitive safety culture and protected time for clinical pharmacy; workforce development through competency-based training and realistic

interprofessional collaboration models; technology adoptions prioritizing offline-capable, context-appropriate solutions; and supply chain reliability through eLIMS and quality surveillance mechanism.

Successful implementation requires phased, sequential deployment beginning with high-risk pilot sites, strong local ownership, and leadership commitment. National governments must prioritize strengthening pharmaceutical systems within broader UHC agendas, while regional mechanisms such as the AMA, can harmonize standards and enhance enforcement. By embedding safety science into pharmaceutical systems and aligning reforms with patient-centered care, SSA can significantly reduce preventable harm, improve quality of care, and advance equitable health outcomes.

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Table 1. Comparison of Pharmaceutical Regulatory Landscape in Sub-Saharan Africa and Developed Systems

Regulatory Aspect	Sub-Saharan Africa (e.g., Nigeria, Ghana)	Developed Systems (e.g., USA, EU)	Key Implications for Medication Safety
Geographic Scope	46-49 countries across multiple Regional Economic Communities	Single jurisdictions or harmonized regional bloc	Coordination challenges across borders; SF medicines can exploit regulatory gaps
NMRAs Structure	55 national authorities; many within Ministries of Health; WHO maturity levels vary from 1-3	Independent, well-resourced agencies (FDA, EMA); Maturity Level 4	Limited independence and authority; resource constraints affect all regulatory functions
Regulatory Harmonization	AMRH programme (2009); AMA operational (2021); gradual progress	EMA established 1995; mutual recognition agreements; mature systems	Fragmentation allows substandard products; slow approval processes
Pharmacovigilance Systems	Designated centers exist but under-resourced; severe under-reporting; limited feedback	Robust systems (FDA MedWatch, EudraVigilance); systematic reporting; rapid signal detection	Medication errors and ADEs under-detected; limited organizational learning
ME Reporting Policy	Generally voluntary; inconsistent implementation; no standardized classification	Voluntary to regulatory bodies; often mandatory within institutions; standardized taxonomies (NCC MERP)	Poor data quality; inability to benchmark or compare rates
Post-Market Surveillance	Minimal capacity; limited inspections; weak supply chain monitoring	Extensive inspection programmes; serialization; real-time monitoring	High prevalence of SF medicines; quality failures go undetected
Regulatory Reliance	Emerging (2025 WHO ML3 agreement among leading African NRAs)	Well-established mutual recognition and reliance pathways	Potential to accelerate approvals and strengthen capacity through collaboration
Technology Infrastructure	Limited electronic systems; paper-based processes common	Advanced electronic submission and review systems	Slower processes; limited data analytics capability

Abbreviations: AMA, African Medicines Agency; AMRH, African Medicines Regulatory Harmonization; ADRs, adverse drug reactions; FDA, Food and Drug Administration; EMA, European Medicines Agency; EU, European Union; ME, medication errors; ML3, Maturity Level 3; NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention; NRAs, National Regulatory Authorities; SF, Substandard and Falsified; USA, United States of America; WHO, World Health Organization