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STRENGTHENING DRUG SAFETY ON A GLOBAL SCALE: PRACTICE AND PROSPECTS

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Abstract

Drug safety has become one of the central priorities of public health systems worldwide, as the globalization of pharmaceutical manufacturing, distribution, and trade has multiplied the pathways through which unsafe, substandard, or falsified medicines can reach patients. This article examines the current state of global drug safety practice, including international regulatory harmonization efforts led by the World Health Organization (WHO) and the International Council for Harmonisation (ICH), national pharmacovigilance systems, good manufacturing and distribution practices, and the ongoing struggle against substandard and falsified medical products. Particular attention is given to the

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role of digital technologies, artificial intelligence, and track-and-trace systems in modernizing adverse-event monitoring and supply-chain security. The article concludes with an assessment of prospective directions for strengthening drug safety, including deeper international cooperation, capacity building in low- and middle-income countries, and the harmonization of regulatory standards. The analysis is intended to be useful for pharmacy students, practicing pharmacists, and regulatory professionals seeking a concise overview of global drug safety practice and its future trajectory.

Keywords: drug safety, pharmacovigilance, WHO, ICH, good manufacturing practice, falsified medicines, regulatory harmonization, adverse drug reactions, global health.

1. Introduction

The safety of medicines is a cornerstone of modern healthcare. Every year, millions of patients around the world depend on medicines that are expected to be effective, correctly manufactured, properly labeled, and free from harmful contamination or falsification. Yet the pharmaceutical supply chain today is genuinely global: an active pharmaceutical ingredient may be synthesized in one country, formulated into a finished dosage form in another, packaged in a third, and distributed across dozens of national markets before it ever reaches a patient. This complexity creates enormous opportunities for innovation and access to medicines, but it also creates new vulnerabilities — regulatory gaps between jurisdictions, inconsistent quality standards, weak post-marketing surveillance, and criminal networks that exploit fragmented oversight to introduce substandard or falsified products into legitimate supply chains.

Drug safety, in the broad sense used in this article, encompasses several interconnected domains: the quality assurance of manufacturing and distribution (good manufacturing practice and good distribution practice), the scientific

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evaluation of a medicine's benefit-risk balance before and after approval (pharmacovigilance), the prevention and detection of substandard and falsified medical products, and the education of healthcare professionals and patients in the rational and safe use of medicines. Strengthening drug safety at a global level therefore requires coordinated action across regulatory science, public health policy, industry practice, and international diplomacy.

2. International Regulatory Frameworks and Harmonization

Historically, national drug regulatory authorities developed their own, often quite different, standards for the approval and monitoring of medicines. This fragmentation created duplicative testing requirements, slowed patient access to new therapies, and left gaps that could be exploited by producers of substandard products. Over the past three decades, harmonization initiatives have sought to close these gaps.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory authorities and the pharmaceutical industry to develop unified scientific and technical guidelines covering quality, safety, and efficacy testing. Its guidelines on good clinical practice, stability testing, and pharmacovigilance reporting are now used as reference standards well beyond its founding member regions, including by many national authorities in Asia, Africa, and Latin America that have adopted ICH-aligned requirements to streamline registration and strengthen oversight.

The World Health Organization plays a complementary and, in many respects, foundational role. Through its prequalification programme, WHO evaluates medicines, vaccines, and diagnostics intended for procurement by United Nations agencies and international donors, providing an independent quality assurance mechanism that many countries with limited regulatory capacity rely on directly. WHO also supports countries in building functional national regulatory systems through its Global Benchmarking Tool, which allows regulatory authorities to

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assess their own maturity against internationally agreed indicators and to plan targeted capacity-building. According to WHO's first Global Patient Safety Report, published in 2024, almost all countries surveyed reported having a functioning pharmacovigilance programme, reflecting the scale of institutional progress achieved since the WHO Programme for International Drug Monitoring was established in the 1960s; at the same time, the same report found that only a minority of countries were systematically addressing all priority areas of the WHO Global Patient Safety Challenge on Medication Without Harm, underscoring that formal structures do not always translate into full operational effectiveness.

Regional harmonization bodies add a further layer of coordination. The Pharmaceutical Inspection Co-operation Scheme (PIC/S) harmonizes good manufacturing practice inspection standards among dozens of member authorities, while regional bodies in Africa, the Gulf states, and the Commonwealth of Independent States work to align registration dossiers and inspection procedures among neighboring countries, reducing duplication and pooling scarce regulatory expertise.

3. Current Practices in Pharmacovigilance and Quality Assurance

Pharmacovigilance — the science of detecting, assessing, understanding, and preventing adverse effects of medicines — remains the primary tool through which drug safety is monitored once a product reaches the market. National pharmacovigilance centers collect spontaneous reports of suspected adverse drug reactions from healthcare workers and, increasingly, directly from patients, and transmit this information to WHO's global database, VigiBase, which now contains tens of millions of individual case reports contributed by more than 150 member countries. Signal-detection algorithms applied to this database allow early identification of safety concerns that might not be apparent from clinical trials conducted on comparatively small and homogeneous patient populations.

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Quality assurance during manufacturing and distribution is enforced through good manufacturing practice (GMP) and good distribution practice (GDP) standards, which specify requirements for facility design, personnel training, documentation, equipment qualification, and product traceability. Regulatory inspectorates conduct periodic on-site inspections of manufacturing facilities, both domestically and, for imported products, abroad, to verify ongoing compliance. Risk-based inspection planning — prioritizing facilities and product categories associated with higher public-health risk — has become standard practice among mature regulatory authorities, allowing limited inspection resources to be allocated more effectively.

Hospital and community pharmacists also play a frontline role in drug safety through medication reconciliation, dose verification, interaction screening, and patient counseling. Clinical pharmacy services that actively monitor high-risk medications, transitions of care, and polypharmacy in older patients have been shown to reduce preventable medication-related harm, which the WHO Global Patient Safety Challenge on Medication Without Harm has identified as a leading cause of avoidable injury in health systems worldwide.

4. The Challenge of Substandard and Falsified Medical Products

Substandard and falsified (SF) medical products remain one of the most persistent threats to global drug safety. WHO estimates, based on a systematic review of over one hundred studies covering more than 48,000 medicine samples from 88 countries, that approximately one in ten medical products circulating in low- and middle-income countries fails to meet quality standards or is deliberately falsified. Antimalarials and antibiotics are among the most frequently reported categories, and the consequences extend beyond individual patient harm: substandard antimicrobials contribute directly to the global rise of antimicrobial resistance by exposing pathogens to sub-therapeutic drug concentrations.

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WHO's Global Surveillance and Monitoring System for substandard and falsified medical products, established in 2013, allows national authorities to report suspect products through a centralized portal, enabling faster alerts and coordinated cross-border response. Nevertheless, reporting remains geographically uneven, with certain WHO regions historically contributing a disproportionately small share of reports relative to the likely scale of the problem, suggesting that the true burden of substandard and falsified medicines is significantly underestimated in official statistics.

Combating this threat requires a combination of strengthened border and market surveillance, secure packaging and authentication technologies, criminal-law enforcement against falsification networks, and public awareness campaigns that help patients and healthcare workers recognize warning signs. Increasingly, national regulators are also investing in portable and field-deployable analytical devices — such as handheld spectrometers and paper-based colorimetric test kits — that allow rapid on-site screening of suspect products without requiring full laboratory analysis.

5. Digital Technologies and Innovation in Drug Safety

Digital transformation is reshaping nearly every dimension of drug safety practice. Electronic track-and-trace systems, which assign a unique serialized identifier to each medicine package and record its movement through the supply chain, are being adopted or piloted in an increasing number of countries, allowing pharmacists and regulators to verify product authenticity at the point of dispensing. Some national systems now integrate this serialization data with mobile applications that allow patients to scan a package and confirm its authenticity directly.

Artificial intelligence and machine-learning methods are being applied to pharmacovigilance signal detection, enabling regulators to identify unusual patterns in large volumes of adverse-event reports, electronic health records, and

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even social media data far more quickly than traditional manual review. Mobile reporting applications have also lowered the barrier to adverse-event reporting for both healthcare workers and patients in resource-limited settings; a cluster-randomized trial of a mobile pharmacovigilance reporting application in Uganda, published in 2025, illustrated how such tools can measurably increase the volume and quality of adverse-drug-reaction reporting in a low-resource environment.

Blockchain-based supply-chain platforms, though still at an early stage of adoption, offer a further potential safeguard by creating tamper-resistant, distributed records of product movement that are more difficult for falsifiers to manipulate than centralized databases. Combined with big-data analytics for demand forecasting and stock-out prevention, these technologies point toward a future drug-safety infrastructure that is more transparent, more responsive, and less dependent on manual, paper-based processes.

6. Prospects for Global Cooperation

Looking forward, several directions appear likely to shape the next phase of global drug safety practice. First, further convergence of regulatory requirements — through mechanisms such as reliance and recognition procedures, in which one national authority formally relies on the assessment of another trusted regulator — can reduce duplication of effort and allow scarce regulatory expertise to be deployed more efficiently, particularly benefiting countries with smaller regulatory agencies.

Second, sustained investment in regulatory capacity building remains essential, particularly in low- and middle-income countries where regulatory authorities may still lack the laboratory infrastructure, trained personnel, or legal authority needed for effective oversight. WHO's Global Benchmarking Tool and its regional capacity-building programmes provide a structured pathway for such investment, but political will and sustained financing at the national level remain the limiting factors in many settings.

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Third, the integration of pharmacovigilance with broader digital health infrastructure — including electronic health records, national health information exchanges, and genomic and real-world-evidence databases — promises to make post-marketing surveillance faster, more precise, and better able to detect rare or delayed adverse effects. Fourth, continued international cooperation against substandard and falsified medical products, including intelligence sharing among customs, law-enforcement, and health authorities, will remain necessary as counterfeit networks adapt to new detection technologies.

Finally, public and professional education must keep pace with technological change. Pharmacists, physicians, nurses, and patients alike need to understand how to use new reporting tools, how to recognize signs of substandard or falsified products, and how to interpret and act on safety communications issued by regulators. Pharmacy education programmes, including those preparing the next generation of clinical and industrial pharmacists, have an important role to play in embedding this awareness early in professional training.

7. Conclusion

Global drug safety has advanced substantially over the past several decades, from the establishment of the first international adverse-drug-reaction monitoring programme to today's interconnected system of regulatory harmonization, risk-based inspection, digital pharmacovigilance, and cross-border surveillance of substandard and falsified products. Yet the same forces that have made pharmaceutical manufacturing and distribution more efficient — long, globalized, multi-tiered supply chains — continue to create new vulnerabilities that outpace the regulatory capacity of many countries. Strengthening drug safety on a global scale will require continued harmonization of standards, sustained investment in regulatory and pharmacovigilance capacity, wider adoption of digital authentication and monitoring technologies, and close international cooperation among regulators, industry, healthcare professionals, and patients.

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Pharmacy students and early-career professionals, as future stewards of medicine safety, have a particular responsibility to understand these systems and to contribute actively to their continued improvement.

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