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Strengthening post-market drug surveillance in Nepal: evidence, gaps, and pathways forward

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Abstract

Nepal has experienced a rising number of pharmaceutical recalls due to quality failures, regulatory non-compliance, and the circulation of substandard and falsified medicines, highlighting critical weaknesses in post-market drug surveillance. Evidence from national recall data shows a persistent increase in recalled products over the past decade, with antimicrobials, analgesics, gastrointestinal medicines, and supplements most frequently affected. However, recall notices alone underestimate the true burden of poor-quality medicines, as delayed detection, limited laboratory capacity, and reactive regulatory processes allow many products to be consumed before corrective action. National surveys and field reports further indicate that quality failures extend across both public and private supply chains. Drawing on Nepal-specific evidence and global literature, this perspective argues that strengthening post-market surveillance requires a shift from recall-driven responses to proactive, risk-based systems. Key pathways forward include expanding routine sampling, enhancing laboratory capacity, improving transparency, adopting traceability tools, fostering regional collaboration, and supporting continuous national medicine-quality research to better protect public health.

Keywords: Post-market surveillance; Drug recalls; Substandard and falsified medicines; Pharmacovigilance

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Introduction

Nepal has witnessed a concerning trend of pharmaceutical products being recalled due to quality failures and regulatory non-compliance, reflecting both systemic weaknesses in post-market surveillance and broader challenges common to low- and middle-income countries.[1] Drug recall data are an essential lens through which regulatory performance can be evaluated, but recall notices alone do not reveal the full extent of substandard and falsified medicines in circulation.[1,3] A comprehensive understanding that bridges recall frequency with systemic causes is urgently needed to safeguard public health.

Evidenced trends in Nepal's drug recalls

A decade-long evaluation of recall notices in Nepal revealed that 346 pharmaceutical products were recalled between 2010 and 2020, and that this number increased significantly over time, suggesting that quality assurance issues persistently challenge the market. Among these recalled products, 62% were classified as substandard, 11% as falsified, and 27% were unregistered with the national regulator (Department of Drug Administration, DDA), indicating persistent regulatory vulnerabilities and breaches of basic quality standards.[2]

Detailed analysis of the same recall data highlighted that the most frequently recalled drugs included antimicrobials, gastrointestinal medicines, vitamins and supplements, and pain-management drugs, with imported products only slightly less recalled than domestically produced ones, emphasizing that both local and global supply chains contribute to quality lapses.[2]

A more recent study analyzing recall notices from April 17, 2023 to May 14, 2025 found 50 drug recalls in just two years, with antibiotics being the most frequently recalled class, followed by NSAIDs and ulcer-healing formulations - mirroring historic patterns and indicating ongoing systemic quality gaps in essential medicines.[1]

Regulatory weaknesses and market dynamics in Nepal

Recall notices alone do not fully capture the prevalence of substandard drugs in the Nepalese pharmaceutical market. For example, a national survey of essential medicines discovered that over 15% of tested medicine batches failed to meet pharmacopeial quality standards, with both government-supplied and locally procured products implicated, underscoring that poor-quality medicines are not limited to private markets but extend into public supply chains.[3]

Recall notices are often issued several months after the medicines' manufacturing date, suggesting that substandard products may have already been sold and consumed well before regulatory action is taken. Officials have acknowledged this gap, noting that products found substandard are often identified only after they have circulated widely, risking preventable harm to patients.[1,4]

Similarly, recent recalls of contaminated intravenous solutions revealed that sterility failures persisted until testing was completed - a process that may take months due to laboratory capacity constraints within the DDA - illustrating how testing delays can blunt the protective effect of recall actions.[5]

Connection to global evidence on substandard and falsified medicines

International research underscores that substandard and falsified (SF) medicines are a widespread global problem, particularly in regions with weaker regulatory systems. A systematic review of drug recall patterns across countries (including Nepal) identified diverse contributing factors, such as gaps in surveillance, inconsistent enforcement, and deficits in proactive quality monitoring, suggesting that recall systems often remain reactive rather than preventive.[6]

Global integrative reviews highlight that effective market surveillance and control of SF medicines require hybrid models combining surveillance, enforcement, reporting transparency, and interagency collaboration rather than isolated recall notices. Such models improve detection and response but are resource-intensive and require political will and technical investment.[7]

Recall data alone are insufficient

Recall frequencies - even if increasing - do not equate to accurate prevalence estimates of poor-quality medicines because recall notices depend on detection, reporting, and laboratory capacity. In Nepal's context, where comprehensive sampling and routine quality audits across geographic locations are limited, recalls may underrepresent the true risk of substandard and falsified medicines faced by patients.[1]

Moreover, recall data do not reveal where these products are most prevalent geographically, nor do they identify systemic weaknesses such as supply chain vulnerabilities, inadequate cold chain management, or inconsistent enforcement of good manufacturing practices (GMP).[1,6]

Policy and regulatory imperatives for Nepal

An estimated one out of every ten medicines used in low- and middle-income countries is substandard or falsified, underscoring the urgency of strengthening post-market drug surveillance systems.[8] Evidence from Nepal indicates that current recall-driven mechanisms remain insufficient to detect and prevent poor-quality medicines in a timely manner. The following policy imperatives outline key gaps in

Nepal's system and corresponding actions needed to strengthen post-market surveillance.

1. **Expand post-market surveillance infrastructure**
   Post-market surveillance in Nepal is largely centralized and reactive, with limited routine sampling across provinces. Quality testing is often triggered by complaints or adverse events rather than systematic risk-based surveillance, resulting in delayed detection of substandard medicines.[7,8-10] Nepal should expand routine, risk-based sampling across all provinces by decentralizing surveillance activities. Establishing regional sampling networks, deploying rapid field screening tools, and prioritizing high-risk medicines (e.g., antimicrobials, injectables) would enable earlier detection before widespread patient exposure.[8-10]

2. **Enhance laboratory capacity and regulatory enforcement**
   Limited laboratory capacity and prolonged testing turnaround times constrain the DDA's ability to take timely regulatory action. As a result, substandard medicines may remain in circulation for months before recalls are issued.[9] Upgrading the national quality control laboratory and establishing accredited regional laboratories are critical to reducing delays in confirmatory testing. Strengthened enforcement mechanisms-such as expedited recalls, penalties for repeat offenders, and suspension of manufacturing licenses-would further enhance regulatory deterrence.[6,7,10]

3. **Promote transparency and public access to recall information**
   Recall notices in Nepal are often fragmented, difficult to search, and provide limited batch-level or distribution details, reducing their usefulness for healthcare professionals and the public. The DDA should develop a centralized, publicly accessible, and searchable recall database that includes batch numbers, geographic distribution, reasons for recall, and corrective actions. Improved transparency would facilitate rapid identification of affected products by clinicians, pharmacists, and supply-chain stakeholders.[10, 11]

4. **Introduce traceability and authentication tools**
   Nepal currently lacks systematic track-and-trace or authentication mechanisms, making it difficult to detect falsified or unregistered medicines entering legitimate supply chains.[10,12] Implementing barcoding, serialization, and digital verification systems-particularly for high-risk medicines-would improve traceability from import or manufacture to dispensing points. Verification at pharmacies and hospitals could significantly reduce the circulation of falsified medicines.[10,12]

5. **Strengthen cross-border and regional cooperation**
   Nepal's heavy reliance on imported medicines, combined with porous borders and limited cross-border regulatory coordination, increases vulnerability to substandard and falsified products entering the market. Enhanced collaboration with neighboring regulatory authority (CDSCO) is essential. Recent initiatives by Nepal's drug regulator (DDA from 2024 April) to conduct on-site testing and inspections of medicines will demonstrate regional cooperation can help identify substandard products early.[9] Further, global risk-based post-marketing surveillance frameworks for low- and middle-income countries emphasize cross-border information sharing, joint inspections, and harmonized regulatory actions as effective strategies to control poor-quality medicines circulating through regional supply chains.[10] Such approaches could be adapted to Nepal's context through formal data-sharing agreements and coordinated inspections with neighboring countries**.**

6. **Advance continual research and national-level quality assessments**
   Nepal lacks regular, nationally representative data on medicine quality, limiting the ability to estimate the true prevalence of substandard and falsified medicines and to identify geographic or therapeutic risk patterns.[4,5] Institutionalizing periodic national medicine-quality surveys-incorporating random sampling from both public and private supply chains and focusing on high-risk formulations-would generate robust evidence to inform regulatory priorities and policy reforms.[10,13,14]

Conclusion

Repeated recall data highlight persistent drug quality issues in Nepal, reflecting regulatory, surveillance, and systemic challenges that cannot be addressed by recall notices alone. Linking Nepal's experience with global patterns emphasizes that medicine quality assurance requires proactive surveillance, regulatory capacity building, technology adoption, and continuous research investment. Strengthening Nepal's post-market surveillance ecosystem is not merely about issuing more recall notices - it is about building a resilient system where unsafe medicines are detected early, removed quickly, and prevented from reaching patients altogether.

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Conflict of Interests

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