Combating Falsified Medicines at the Gate: A Reflexive Auto-Ethnography of Administrative Resilience at the Medical Supplies Division in Sri Lanka (2023–2025)

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***Abstract*- Introduction**: The economic crisis of 2022–2023 significantly impacted Sri Lanka's medical supply chain, creating vulnerabilities that allowed substandard and falsified (SF) medicines to infiltrate the public health system. With the National Medicines Quality Assurance Laboratory (NMQAL) facing severe resource constraints, the Medical Supplies Division (MSD) was compelled to strengthen its gatekeeping mechanisms.
Objectives: To describe the operational challenges faced by the MSD administration during the post-crisis period and to analyse the strategic, non-laboratory-based interventions deployed by the leadership team to secure the supply chain against falsified documentation and substandard products.
Methods: This study employs a Collaborative Reflexive Auto-Ethnography following the SRQR framework, utilizing thematic analysis of administrative records and the authors' lived experiences. The authors, comprising the MSD Directorate and senior pharmacists, analysed administrative records, sentinel events of 2023, and decision-making protocols from November 2023 to January 2025. The core intervention analysed is the "Triple-Layer Gatekeeping Protocol."
Results: The analysis reveals a shift from "good faith" reception to "high vigilance" scrutiny. The implementation of mandatory manual verification of Customs Declarations (Cus-Dec), direct email-based cross-verification of waivers with the National Medicines Regulatory Authority (NMRA), and "collective decision-making" protocols for technical discrepancies significantly increased the detection of irregular consignments. These measures successfully intercepted multiple instances of documentary error at the entry point, though they created initial logistical delays that required process re-engineering.
Conclusions: In resource-limited settings where laboratory capacity is compromised, rigorous administrative gatekeeping serves as a critical, interim proxy for pharmacovigilance. The study demonstrates that empowering frontline staff to interrogate procurement documents is an essential defence against SF medicines.

Index Terms- Medical Supplies Division, Substandard and Falsified Medicines, SRQR, Medical Supply Chain Security, Pharmacovigilance

I. Introduction

Substandard and falsified (SF) medical products pose a serious and growing threat to public health worldwide. These products can cause direct harm to patients by delivering ineffective or dangerous treatment, wasting public resources, and undermining health system effectiveness. According to a World Health Organization (WHO) report, at least 1 in 10 medical products in low- and middle-income countries (LMICs) are substandard or falsified, with an estimated global economic burden of USD 30.5 billion annually due to their circulation [1].

The Medical Supplies Division (MSD) of the Ministry of Health is the central entity responsible for ensuring the uninterrupted and equitable provision of vital medical supplies to all government healthcare institutions across Sri Lanka. In this capacity, the MSD serves as a primary gatekeeper, tasked with safeguarding the quality and integrity of pharmaceutical products entering the public health system. The integrity and quality assurance of these

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products are essential for the safe and effective delivery of healthcare [2].

In Sri Lanka, the period spanning 2023–2024 brought major vulnerabilities in the gatekeeping process into sharp focus. Several alarming incidents, notably the distribution of contaminated eye drops and the supply of substandard batches of human immunoglobulin, served as critical "sentinel events" for the national healthcare system [3, 4]. These events highlighted that while the National Medicines Regulatory Authority (NMRA) holds the mandate for regulation, the practical burden of "stopping the fakes" often falls on the logistical arm when regulatory enforcement is strained by resource deficits.

It is important to understand that developing robust systems is an evolutionary process. Critical incidents, rather than pointing solely to individual blame, serve as catalysts for identifying and rectifying systemic frailties. This qualitative analysis, developed using the collaborative reflexive autoethnography methodology, drawing upon the operational experiences of the authors, aims to detail the specific quality assurance interventions proactively implemented by the MSD in response to these profound challenges.

At the outset, it is important to understand the differences between substandard and falsified products, as shown below. Both categories are of major concern, though the Falsified category must be dealt with through litigation as well.

Aspect	Substandard Products	Falsified Products
Intent	Unintentional; poor manufacturing or storage	Deliberate fraud to deceive for profit
Origin	Authorized, legitimate manufacturers failing quality specs (e.g., low potency)	Criminal networks may mimic genuine packaging
Composition	Correct but sub-quality ingredients or specs	Wrong/no active ingredients, toxins, or fakes
Legal Status	Licensed but "out of specification"	Illicit; misrepresent identity/source

Understanding the Landscape of Substandard and Falsified Medicines (2023–2024)

Definitions and Prevalence:
The World Health Organization defines Substandard medical products as "authorized medical products that fail to meet either their quality standards or specifications," and Falsified medical products as "medical products that deliberately or fraudulently misrepresent their identity, composition or source" [5]. In Sri Lanka, the presence of SF medicines became acutely evident through several incidents in 2023, which were exacerbated by the prevailing economic crisis [6].

The prevalence of SF medical products in LMICs statistics

Substandard and falsified (SF) medical products are significantly prevalent in low- and middle-income countries (LMICs), where weak regulations and complex supply chains exacerbate the issue. WHO estimates at least 1 in 10 medicines are affected globally, with higher rates in LMICs driving treatment failures and deaths [7].

Key Prevalence Statistics

When looking at a systematic review of 96 studies (67,839 samples) we found an average SF prevalence of 13.6% across LMICs (95% CI: 11.0%-16.3%), with Africa at 18.7%. Antimalarials showed 19.1% poor quality, antibiotics 12.4%; smaller studies reported up to 28.5% median in 25 LMICs [7, 8].
In the Sri Lankan Context by 2023, while this was always a concern among the officials and academia, data was limited. Quality Failures of Supplies were known as a factor; as such, substandard products remained a matter of concern, but falsified products were not well documented. When analyzing the safety alerts for defective medicines published by Sri Lanka's National Medicines Regulatory Authority (NMRA) between June 2018 and August 2021, a study identified 143 defective medicines, with contamination (36.2%) and stability defects (25.2%) being the most common issues. Anti-infectives and parenteral (injectable) preparations were the most frequently defective products [3].

Contributing Factors to Vulnerabilities of the Sri Lankan Medical Supplies Chain:

Several systemic factors contributed to the vulnerability of the supply chain during this period:

- •Regulatory Resource Constraints: The NMRA has historically faced staffing shortages, particularly in its Law Enforcement Division, hindering effective post-market surveillance [9, 10].

- •Inadequate Testing Capacity: A significant vulnerability was the limited testing capacity of the National Medicines Quality Assurance Laboratory (NMQAL). As noted in the Auditor General's report and subsequent media analysis, the NMQAL faced challenges including inadequate facilities and a critical shortage of technical staff (approximately 30 vacancies as of early 2024), limiting its ability to perform comprehensive pre-release quality checks [10, 11].

- •Economic Crisis Impact: The severe national economic crisis (2022–2023) necessitated emergency procurement pathways. These expedited channels, while essential to prevent stockouts, inadvertently reduced the time available for rigorous due diligence, potentially allowing bad actors to exploit the urgency [12, 13].

II. Objective of the Study

To describe the operational challenges faced by the MSD administration during the post-crisis period and to analyse the strategic, non-laboratory-based interventions deployed by the leadership team to secure the supply chain against falsified documentation and substandard products.

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III. METHODOLOGY

This study utilizes a qualitative Collaborative Reflexive Auto-Ethnography design. Unlike traditional observational research, this method acknowledges the authors as "active research instruments" who were embedded in the decision-making hierarchy during the crisis.

Study Design and Framework

The research adheres to the Standards for Reporting Qualitative Research (SRQR). We frame the study as a "Root Cause and Corrective Action Analysis," covering the intervention period from November 2023 to January 2025.

Setting and Participants:

The study was conducted at the Medical Supplies Division (MSD), the central hub responsible for the inventory and distribution of pharmaceuticals to all government hospitals in Sri Lanka. The primary participants and data sources are the administrative and technical leadership team responsible for gatekeeping decisions. The core author group served as active participants in the intervention, comprising:

1. The Directorate (Director & Deputy Director): Responsible for strategic oversight, legal compliance, and authorization of new protocols.

2. Senior Pharmacists (Stock Control & Quality Assurance): Responsible for the operational execution of verification checks and the coordination of frontline technical staff.

Data Collection:

Data were derived from three primary sources:

1. Retrospective Review of Sentinel Events: A forensic examination of the procurement pathways utilized in the confirmed SF cases of 2023 to identify the specific failure points in the previous reception mechanism.

2. Administrative Records: Analysis of internal circulars, Standard Operating Procedures (SOPs), and minutes from "Internal Review" meetings.

3. Lived Experience: The authors documented the operational challenges, legal pressures, and real-time decision-making processes required to implement stricter gatekeeping without disrupting the essential supply of life-saving drugs.

Positionality and Reflexivity:

The author group comprises the MSD Directorate (Director and Deputy Director) and Senior Pharmacists (Stock Control and Quality Assurance). We acknowledge our dual roles: we are both the architects of the "Triple-Layer Protocol" and its primary analysts. To mitigate "self-serving bias," we utilized Analytic Triangulation, cross-referencing our narratives against:

- Retrospective Review of Sentinel Events: Forensic examination of the 2023 failure points.

- Administrative Records: Internal circulars, SOPs, and Internal Review meeting minutes.

- Archival Data: Verified Customs Declarations (Cus-Dec) and NMRA email correspondence.

Ethical Considerations:

Permission for analysis of the intervention and the dissemination of this administrative data was granted by the Director General of Health Services (DGHS) OF Sri Lanka. All sensitive legal particulars regarding ongoing litigation have been excluded to focus solely on the system-strengthening aspects of the cases. This study is a self-study of professional administrative practice. As the research involves the analysis of existing administrative processes and reflexive self-narration by the authors, no third-party human subjects were involved.

Conflict of Interest: None declared.

Funding: None.

IV. RESULTS
V.

The analysis of the MSD's response reveals a distinct evolution in gatekeeping philosophy, progressing from a reliance on "paper compliance" to a doctrine of "investigative verification and from trust-based reception to verified acceptance."

Phase 1: The Crisis Trigger (The Sentinel Events)

The retrospective review of the 2023 incidents identified that falsified products had bypassed entry points not due to a lack of regulation, but due to a "trust-based" reception culture. The leadership noted that in the absence of routine pre-registration testing—caused by the NMQAL's reported inability to check quality prior to issuance—the administrative check at the MSD reception was the *only* remaining barrier. The vulnerability was clear: if a supplier provided a forged Waiver of Registration (WOR) that matched the invoice, the goods were accepted under the previous assumption of upstream validity.
Lived Experience:
"Detection of falsified documents, which we have indeed seen and experienced multiple times, is terrifying and sends a shock wave through the system. The agitation and anxiety that is felt of the possibility of missing such a matter and the repercussions that can follow echoes in the thought processes of all involved. It is paralyzing in a way that it slows down day-to-day activity and brings officers to the sheer breaking point. Constant reporting on

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the Media and bombardment of questions by the public remained a constant reminder of the grave risks the system had."

Phase 2: Operational Mobilization (The Intervention)

To close this gap, the MSD deployed enhanced verification protocols starting in November 2023. This involved a granular restructuring of the reception workflow. This was a triple–layer gatekeeping protocol that transitioned the MSD to Investigative Verification Practice.

1. *The Document Firewall*

The Stock Control Unit was instructed to refuse any consignment that did not possess verifiable original or certified copies of the complete regulatory dossier. The specific checklist for imported products was expanded to include:

- Customs Declaration (Cus-Dec): Previously treated as a financial document, this was re-purposed to verify that the *quantity* declared to Customs matched the *quantity* delivered to MSD, preventing the "leakage" of unauthorized extra stocks into the system.
- Custom Assessment Notice (CAN): Verified to ensure fiscal compliance and origin tracking.
- Import License: Cross-verification of the Import Controller's license against the NMRA's authorization.
- NMRA Registration Certificate or Waiver of Registration (WOR) Registration from NMRA/WOR/ Exemption for registration
- Certificate of Analysis (CoA) or Certificate of Conformity (CoC) or Performance Report (PR): Scrutinized for consistency with batch numbers on the physical product.

Enhanced Verification for Locally Manufactured Supplies**:** For medical supplies sourced from local manufacturers, the MSD mandated the submission and verification of:

- Certified Copy of NMRA Registration from NMRA/WOR/ Exemption for registration
- Certificate of Analysis (CoA) or Certificate of Conformity (CoC) or Performance Report (PR)

Lived Experience:

"The sudden introduction of a barrage of documents at the point of supply was a shock to the supplier community as well as the frontline staff. The Stock Control Officers and their supervising officers, as well as the Medical Supplies Assistants at the Stores Level, were confused and disoriented as this was a new move that was rolled out rapidly due to the sentinel event of initiation of a large-scale litigation process that highlighted the need for protective steps to be taken by the MSD Management. While there was a major resistance that was felt from many parties at the beginning, all parties slowly accommodated, recognizing the safety net it was creating. The Strong Backing from the hierarchy of the Ministry of Health in this regard to ensure verified acceptance was a key factor for success."

2. *The Email Verification Loop*

The physical document regarding the NMRA documents alone was deemed insufficient. A mandatory "Email Verification Loop" was established. Stock Control officers were required to hold the Goods Received Note (GRN) until the NMRA explicitly confirmed the authenticity of the Registration/WOR via an official institutional email.

Lived Experience:

"The Verification via Email was not an easy task to establish. When we started going beyond trust based reception process, there was a backlash. Suppliers as well as NMRA officers were a bit reluctant and saw this as more red tape leading to delays. Whether this is a passive resistance generated by the unhappiness that was building up with the ongoing litigation was being questioned. Yet the NMRA senior management responded very positively to establish this loop and also created WhatsApp® groups to communicate and iron out initial barriers to ensure the email loop was a success."

3. *The Quality Assurance Firewall*

For the Quality Assurance Unit, the "Zero Trust" policy was applied. Beyond document verification, all checking processes at each level of the MSD's supply chain, from procurement to reception and initial warehousing, were further strengthened. This included an intensified focus on visual inspections, quantity verification, and adherence to storage conditions. Further feasibility is being considered, as part of its standard procurement conditions, "to immediately after delivery at MSD, the consignments to be subjected to testing appropriately drawn, one random batch sample (Post-delivery sample) of the consignment at a government/semi-government/accredited laboratory" at least for the most critical items. Robust post-delivery testing, coupled with clauses for recovery of costs from suppliers for batch/product withdrawals due to quality failure, reinforces MSD's commitment to quality at the point of entry. MSD also intensified the attempts to establish a Sample Room at MSD and started looking for funding and support to enhance the quality assurance in the storage practices.

Phase 3: Overcoming Resistance via Collective Decision-Making

The "lived experience" of the authors highlighted significant friction during the initial rollout. Suppliers accustomed to rapid clearance protested the delays caused by the "Email Verification Loop," which initially added 24–48 hours to the reception process. Frontline pharmacists faced intimidation and pressure to "Expedite and push through."

The Directorate had to invest a significant amount of time and resources for staff training and staff motivation to ensure that the intensified verification methodologies are accepted and normalised within the day-to-day practice.

To mitigate the pressures on individual officers as well as to overcome individual officer lapses and delays, the Directorate introduced a "Collective Decision-Making Model." Technical discrepancies were no longer the responsibility of a single receiving officer. Instead, ambiguous cases—such as a CoA with a slightly deviant test method—were referred to a panel consisting of the Assistant Director and Senior Pharmacists. This de-personalized the rejection process, shielding frontline staff from coercion and ensuring that rejections were legally defensible.

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Phase 4: Observed Outcomes

While quantitative compilation is ongoing, preliminary administrative data indicate a comparative decline in quality failure reports for stocks received in the 2024–2025 period compared to the height of the crisis in 2023. The intervention successfully detected anomalies such as:

- Discrepancies between the batch numbers on the physical vials and the submitted Certificates of Analysis.
- Erroneous Regulatory documents that failed the email verification step with the NMRA.
- Temperature excursions identified through mandatory data logger inspections, which were previously performed only randomly.

The Technical Teams were able to collaborate within the MSD as well as with the NMRA to clarify and clear the issues that were detected, resulting in the verified acceptance process becoming more streamlined. The Suppliers themselves slowly adjusted to the new process, accommodating the requirements stipulated by the MSD, and the Directorate ensured an open-door policy for the suppliers to raise any grievance or disagreement they felt against the collective decision of the acceptance committee. Where the MSD felt necessary, we also had the practice to take up such disagreements that needed a larger consensus taken up for discussion at the Medical Supplies Review Meetings of the Ministry of Health, chaired by senior officials of the Ministry.

VI. DISCUSSION

Administrative Rigor as a Proxy for Pharmacovigilance.

This study highlights a paradigm shift in the role of the medical storekeeper. In an ideal health system, quality is assured by the laboratory (NMQAL) and the regulator (NMRA). However, when the "Swiss Cheese" model of safety fails—due to laboratory vacancies or emergency procurement waivers—the warehouse reception desk becomes the final line of defence. Our experience suggests that rigorous administrative triangulation (comparing Customs data with Regulatory data) can serve as an effective, low-cost proxy for safety when chemical testing is unavailable. It creates a "hostile environment" for falsified documents.

The Human Element of Resilience:

Literature on supply chain security often focuses on technologies like blockchain [14, 15]. However, our findings suggest that human factors are equally critical. The "Collective Decision-Making" model addressed the psychological reality of corruption and negligence. By diffusing the responsibility of rejection across a panel, the MSD neutralized the power dynamics that often facilitate the entry of SF medicines. This supports the organizational theory that system resilience relies on "psychological safety" for staff and staff training as much as it does on technical protocols [16, 17].

Limitations of the Manual Firewall

While effective against documentary fraud, the current "Triple-Layer Protocol" has limitations. It cannot detect chemical substandardness (e.g., insufficient Active Pharmaceutical Ingredient) if the documentation is perfect. Therefore, the administrative interventions described here must be viewed as a complement to, not a substitute for, the revitalization of the NMQAL. The reliance on manual email verification is also resource-intensive and not scalable indefinitely without digital automation.

VII. RECOMMENDATIONS

Building upon the lessons learned from the MSD's ongoing quality improvement journey, the following strategic recommendations are proposed for enduring resilience against SF pharmaceuticals:

Comprehensive Digital Transformation for Verification:

While manual checks have proven effective, their long-term efficiency and scalability are limited. A strategic shift towards integrated digital systems is imperative. This includes:

Interconnected Databases: Developing seamless, real-time digital linkages between MSD, NMRA, Customs, and the State Pharmaceuticals Corporation (SPC) databases to automate the verification of registration, import licenses, and consignment details.

- Digital Certificates of Analysis/Conformity: Implementing a secure platform for suppliers to upload digital CoAs/CoCs, with cryptographic verification to prevent tampering.

- Blockchain Technology: Exploring blockchain for immutable records of drug origins, manufacturing processes, and distribution pathways to provide unparalleled traceability and combat counterfeiting, aligning with global best practices [14, 15].

Strengthening National Medicines Quality Assurance Laboratory (NMQAL) Services:

A critical long-term investment must be made in developing and strengthening the NMQAL to ensure robust, independent quality assurance. This requires:

- Infrastructure Upgrade and Equipment: Modernizing laboratory facilities and acquiring state-of-the-art equipment to enable comprehensive chemical, physical, and microbiological testing, including advanced capabilities like bioequivalence studies.

- Staff Recruitment and Capacity Building: Addressing the significant technical staff shortages and providing continuous, specialized training to ensure the NMQAL

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has the expert human resources required for its vital mandate.

- International Accreditation: Pursuing international accreditation for the NMQAL to enhance the credibility and acceptability of its test results globally. The NMRA does seem to be actively seeking WHO support for refurbishment, indicating a positive step in this direction.

Robust and Continuous Staff Training:

Sustained investment in human resource development is critical. Training should evolve beyond initial procedural changes to include:

- Digital Proficiency: Mandatory, continuous training on new digital platforms and data literacy for all staff involved in the supply chain.

- Advanced Detection Techniques: Training on identifying increasingly sophisticated falsification methods and utilizing new detection technologies as they become available.

- Risk Management: Developing expertise in proactive risk assessment and mitigation within the supply chain.

Strengthening NMRA's Overall Regulatory Capacity:

While MSD's internal checks are vital, the foundational strength of the NMRA in drug registration, post-market surveillance, and enforcement remains paramount. Continued support for NMRA's overall staffing and digital infrastructure is crucial.

Formalized Inter-Agency Coordination:

Establish formal, regular inter-agency working groups involving MSD, NMRA, Customs, and law enforcement to facilitate intelligence sharing, joint investigations, and harmonized policies against SF products.

Supplier Performance Management:

Develop a robust system for continuous monitoring and evaluation of supplier performance, including adherence to quality standards and timely provision of required documentation, with clear punitive measures for non-compliance.

Further research:

Further analysis in this regard is recommended as collaborative interdisciplinary research between Medical Administrators, Clinical Pharmacologists, Academics in Pharmacy, and Health System Researchers.

VIII. CONCLUSION

The presence of substandard and falsified medicinal products in Sri Lanka poses a persistent public health challenge. The incidents of 2023 catalyzed the Medical Supplies Division to undertake significant quality improvement initiatives in its gatekeeping processes, characterized by strengthened manual verification, inter-agency digital collaboration, and dedicated human resource development. While initial implementation presented challenges, these were systematically addressed, demonstrating the MSD's adaptability and commitment. This study underscores that continuous vigilance, coupled with strategic digital transformation and robust staff training, and the essential strengthening of national testing capacities, is indispensable for building a resilient, transparent, and trustworthy national medical supply chain. These ongoing efforts are paramount to ensuring uninterrupted access to safe and efficacious life-saving medical supplies, thereby safeguarding the health and well-being of the Sri Lankan population and contributing to the overall quality improvement of the national healthcare system.

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