



## Assessing Compliance: An Audit of the Medical Supplies Division's Storage Practices Against NMRA Good Storage Guidelines in Sri Lanka

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### Key Words:

Medical Supplies Division, National Medicines Regulatory Authority (NMRA), Good Storage Practices (GSP), Pharmaceutical supply chain, Quality assurance, public health, Digital transformation, international collaboration.

### Abstract

This article presents an audit of the storage practices at the Medical Supplies Division (MSD) in Sri Lanka, evaluating their compliance with the Good Storage Practices (GSP) guidelines set by the National Medicines Regulatory Authority (NMRA). The MSD plays a critical role in the national healthcare supply chain, responsible for the procurement, storage, and distribution of essential medical supplies to public health institutions across the country. Ensuring proper storage conditions is paramount to maintaining the quality, efficacy, and safety of these vital products. This audit assesses various aspects of MSD's storage facilities and procedures against the NMRA's comprehensive GSP guidelines, identifying areas of compliance and non-compliance. It also highlights the imperative for digital transformation and the role of international collaboration in addressing systemic challenges. The article proposes recommendations for continuous improvement to enhance the integrity of the medical supply chain in Sri Lanka.

### Introduction

The safe and effective storage of pharmaceuticals is a critical component of healthcare supply chain management globally. International bodies like the World Health Organization (WHO) extensively advocate for adherence to Good Storage Practices (GSP) to preserve the quality and integrity of medical products from manufacturer to patient [1]. Many national medical supply chains, from developed to developing nations, face similar challenges in maintaining GSP across diverse climatic conditions and logistical complexities.

The Medical Supplies Division (MSD), as the central forecasting, storage, and distribution arm of the Ministry of Health, plays a vital role in ensuring the availability and quality of medicines and medical devices across Sri Lanka. In this capacity, the MSD serves as the primary gatekeeper, as well as the central storekeeper tasked with safeguarding the quality and integrity of pharmaceutical products entering the public health system. The integrity and quality assurance of these products are essential for the safe and effective delivery of healthcare. This criticality is further underscored by findings from the Auditor General of Sri Lanka, whose recent reports [2]

have highlighted vulnerabilities in the medical supply chain, including issues related to stock management and the adherence to proper storage conditions.

The National Medicines Regulatory Authority (NMRA) of Sri Lanka is the regulatory body tasked with ensuring the quality, efficacy, and safety of all medicines, medical devices, and borderline products in the country. To achieve this, the NMRA has established various guidelines, including the "Guideline on Good Storage Practices for Pharmaceuticals (GSP)" [3], which aligns with international best practices.

This audit aims to evaluate the current storage practices of the MSD regarding the NMRA's GSP guidelines. Administrative Permission has been taken from the Director General of Health Services of the Ministry of Health, Sri Lanka, to evaluate and disseminate this vital information. This academic work has no external funding sources.

The assessment focuses on key areas including infrastructure, environmental conditions, inventory management, security, and documentation. By identifying existing strengths and areas requiring attention, this audit seeks to support the MSD in enhancing its quality

assurance systems related to pharmaceutical storage and to contribute to the safe and uninterrupted supply of medical products within the public health sector. This audit serves as a baseline assessment to inform future quality improvement initiatives, recognizing the evolving landscape that necessitates digital transformation for robust GSP adherence.

## Background

### *The NMRA's Good Storage Practices Guideline (GL-015)*

The NMRA's GSP guideline emphasizes key aspects of good storage practices, designed to preserve the quality and integrity of pharmaceutical products throughout their lifecycle in the supply chain. These guidelines, harmonized with international standards such as those from WHO, served as the benchmark against which MSD's practices were evaluated:

*Premises and Facilities:* Requires suitable location, design, construction, and maintenance; sufficient space, lighting, and ventilation; robust security; protection from pests; and separate, clearly defined areas for diverse types of products (e.g., hazardous, temperature-controlled, expired, recalled). International examples often highlight purpose-built, climate-controlled warehouses with advanced shelving systems (e.g., in Singapore or Scandinavia) [4].

*Storage Conditions:* Mandates defined instructions for specific products, continuous monitoring of temperature and humidity, and the use of calibrated monitoring equipment. Many advanced supply chains utilize automated environmental control systems and real-time alerts.

*Documentation:* Stipulates the necessity of comprehensive written instructions and accurate records for all storage operations, ensuring traceability and accountability. Digital documentation systems are increasingly becoming the norm internationally [5].

*Receipt and Dispatch:* Outlines proper procedures for handling incoming and outgoing materials, emphasizing protection from adverse weather conditions during these transitions.

*Stock Rotation and Control:* Requires the implementation of robust systems, such as First-Expiry; First-Out (FEFO), to prevent obsolescence, minimize waste, and ensure timely use of products. Automated inventory management systems enhance the efficiency of these practices.

*Control of Obsolete and Outdated Materials:* Demands segregated and clearly marked areas, along with documented procedures for the handling, management, and eventual disposition of expired, recalled, or damaged

products.

*Personnel:* Emphasizes the need for appropriately trained staff with adequate knowledge and experience in pharmaceutical storage practices. Continuous professional development is key in all high-performing supply chains.

*Quality Management System:* Requires the establishment of a comprehensive quality management system that includes regular self-inspections and proactive quality risk management.

## Methodology

This audit employed a dual-pronged approach to assess the storage practices at the Medical Supplies Division:

*Document Review:* A comprehensive examination was conducted of relevant MSD policies, Standard Operating Procedures (SOPs) related to storage, inventory records, temperature logs, pest control records, and facility maintenance schedules. The NMRA's GSP guideline (GL-015) served as the primary benchmark against which these documents and procedures were assessed.

*Physical Inspection:* On-site visits were conducted to MSD's central warehouses and MSD sub-stores. These inspections involved visual assessment of the physical infrastructure, verification of actual storage conditions (including organization of stock), review of security measures in practice, and assessment of general hygiene and cleanliness.

The audit aimed to provide a snapshot of compliance at the time of assessment, identifying both adherence to and deviations from the established GSP guidelines.

## Findings: Compliance with Good Storage Practices

The audit revealed several areas where the Medical Supplies Division demonstrates good compliance with NMRA's GSP guidelines, indicating a foundational commitment to quality storage, often aligning with basic international GSP requirements.

- **Temperature Control and Monitoring:** Regular temperature monitoring is consistently in place within cold rooms and designated temperature-controlled areas. Records are well-maintained, contributing to the quality assurance of temperature-sensitive pharmaceuticals. The MSD operates a 24/7 cold chain monitoring system with robust backup mechanisms, which is crucial for preventing deviations and minimizing quality failures related to temperature excursions. This mirrors fundamental requirements seen globally for cold chain integrity [1].

- **Segregation of Expired/Unserviceable Stock:** Clear segregation of expired and unserviceable goods from serviceable stock was observed, an essential practice for preventing inadvertent use and maintaining inventory integrity, a core GSP principle worldwide.
- **Pest Control:** Evidence of active and ongoing pest control programs was present across the storage facilities, contributing to the maintenance of hygienic storage environments.
- **Basic Security:** Access to the main storage facilities is generally restricted to authorized personnel, indicating a foundational level of security for valuable medical commodities.
- **Documentation:** All required documentation, including goods receiving records, issuing records, and stock records, were found to be properly maintained and immediately accessible within the MSD warehouses. This robust documentation system is fundamental for traceability, accountability, and regulatory compliance, although opportunities for digital enhancement exist.
- **Stock Rotation (FEFO):** The Medical Supplies Division (MSD) warehouses effectively maintain the First Expiry, First-Out (FEFO) system. This practice ensures that products with the earliest expiration dates are prioritized for distribution, actively preventing obsolescence and reducing the risk of expired goods reaching patients. This is a universally accepted inventory management principle for pharmaceuticals.
- **Hygiene and Cleanliness:** Storage areas are kept clean and dry, reflecting adherence to regular cleaning schedules. This contributes significantly to maintaining a contamination-free environment.
- **Personnel Practices:** While a detailed personnel audit was not the primary focus, observations indicated that personnel handling medical supplies were aware of proper handling techniques and the importance of storage conditions.

#### **Areas for Improvement and Ongoing Interventions**

Despite the observed areas of compliance, the audit also identified critical areas requiring significant improvement to achieve full adherence to GSP guidelines and further enhance the integrity of the medical supply chain, especially when benchmarked against more advanced international practices.

- **Space Utilization and Organization:** A primary challenge identified was limited storage capacity and suboptimal space utilization within existing MSD facilities. These findings

are consistent with observations in recent Auditor General's reports on the health sector, which have pointed to inefficiencies and shortages partly stemming from inadequate management of pharmaceutical stock (2). This directly impacts the ability to implement optimal GSP, potentially leading to overcrowding, reduced accessibility, and challenges in maintaining ideal environmental conditions and efficient stock segregation. The physical layout and age of some facilities also contribute to these limitations. This contrasts with modern pharmaceutical warehouses internationally which are designed with ample, flexible space and often multi-level storage systems.

- **Environmental Control in General Warehouses:** While cold chain monitoring is robust, maintaining consistent temperature and humidity within optimal ranges across general warehouse complexes remains a challenge, especially during peak seasons or periods of fluctuating ambient conditions. This highlights a need for upgraded infrastructure in non-cold chain areas. Advanced systems in other countries use integrated building management systems for precise climate control.
- **Digital Transformation in Operations:** While basic documentation is maintained, the audit noted that many processes remain manual. The integration of digital systems is crucial for enhancing traceability, improving inventory accuracy, streamlining stock rotation, and providing real-time data for decision-making. The need for such digital solutions has also been implicitly highlighted in past audits by the Auditor General, which noted that despite expectations for computerized management of the supply chain, issues like stock-outs persisted due indicating a gap in effective digital implementation (2). This is a significant area where international medical supply chains have made substantial advancements, utilizing Enterprise Resource Planning (ERP) systems, automated warehousing solutions, and advanced analytics (5).
- **Decentralized Clinical Audits:** Given that adherence to NMRA regulations is a statutory requirement, it is recommended that all central and provincial hospitals, as well as the Regional Medical Supply Divisions (RMSD), conduct regular self-audits against the GSP guidelines. This will ensure compliance is maintained at every level of the healthcare supply chain, from central storage to the point of use.

### Addressing Identified Gaps: Proactive Quality Improvement and International Collaboration

To address the long-standing issue of limited storage capacity and associated GSP compliance challenges, the Ministry of Health and MSD have initiated a significant new infrastructure development project. This proactive initiative involves:

- Renovation of existing storage facilities: Upgrading current warehouses to improve layout, environmental controls, and overall functionality.
- Construction of new store complexes: Establishing new, purpose-built storage facilities in key strategic locations, including Mahamodara, Anuradhapura, and Welisara.

Crucially, the Medical Supplies Division is now actively working in collaboration with international support secured by the Ministry of Health through the World Bank and the Asian Development Bank. This vital external support is focused on ensuring the required GSP standards are achieved, particularly in financing and technical expertise for the new infrastructure development and the overall modernization of the supply chain. This international partnership underscores the national commitment to elevating public health supply chain standards.

### Conclusion and Future Directions

This audit underscores the importance of adhering to Good Storage Practices in safeguarding the quality and integrity of medical supplies within Sri Lanka's public health system. While the Medical Supplies Division has demonstrated commendable efforts in implementing several key aspects of GSP, particularly in cold chain management, documentation, and FEFO practices, the identified areas for improvement, notably in overall storage infrastructure, environmental control in general warehouses, and the need for comprehensive digital transformation, highlight systemic challenges that require focused and sustained attention.

The initiation of the major infrastructure development project, significantly bolstered by international support from the World Bank and Asian Development Bank, is a highly commendable and necessary quality improvement intervention stemming directly from these identified needs. This proactive step, coupled with a concerted push towards digitalization of warehousing and inventory management processes, will move the MSD closer to international GSP benchmarks. By systematically completing these projects, enhancing technological adoption, and continuously striving for full compliance with NMRA's GSP guidelines, the MSD can significantly enhance the reliability and effectiveness of the national medical supply chain. This commitment to continuous

improvement will contribute to improved public health outcomes in Sri Lanka by ensuring patients receive safe, efficacious, and high-quality medical products. Future audits and re-assessments will be essential to measure the impact of these ongoing infrastructural and procedural advancements.

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