Procurement and Supply Chain Management

Technical Brief

Grant Cycle 8

Core Guidance

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Adapting GC8 to new realities on the path to self-reliance

The result of the Global Fund Eighth Replenishment, while still partial, reflects the increasingly challenging global health landscape that the partnership must now navigate. Whereas the Global Fund's unique model remains strong, it is clear that **the approach to Grant Cycle 8 (GC8) must evolve**. With less funding, the partnership will need to work smarter and collaborate even more effectively.

In GC8, most countries will receive reduced allocations. Those with higher economic capacity and lower disease burden will see a more significant reduction. However, all countries will need to make difficult but necessary decisions to selectively target investments to protect HIV, TB and malaria outcomes and sustain momentum, **and more rigorously use Global Fund investments** in a catalytic manner, in complementarity with domestic budgets and other funding.

The Global Fund will introduce significant changes and strategic shifts in GC8, including revamping its approach to co-financing, sharpening the focus on transition planning, supporting public financial management, and other changes being discussed by its governance bodies. Country context will inform sustainability and transition pathways.

At the same time, the Global Fund will encourage faster introduction and scale up of innovative products that are becoming available and have the potential to transform responses to the three diseases, delivering better health outcomes and increasing cost-effectiveness. There is a need to maintain focus on providing rapid and equitable access to these new tools that could change the trajectory of the three diseases.

Introduction

This technical brief guides countries to include interventions related to health product procurement and supply management in Global Fund funding requests. It provides examples of investments to be prioritized and supported, and offers considerations for selecting the most impactful investments considering country context. It supports decision-makers to identify the right health product procurement, quality assurance and supply chain investments to strengthen supply chain performance and achieve key outcomes.

The brief also guides to support interventions related to advocacy at the highest levels of government to encourage effective health product and supply management investments, driven primarily through domestic financing and stronger oversight to enhance performance accountability and sustainability

Applicants, members of the Country Coordinating Mechanism (CCM), Principal Recipients (PRs) and partners, are encouraged to review this document in parallel with other GC8 core guidance documents, including the HIV, TB, malaria and resilient and sustainable systems for health (RSSH) information notes and other technical briefs.

The Global Fund's Guide to Global Fund Policies on the Procurement and Supply Management of Health Products provides descriptions of standards and principles for health product procurement, covering areas such as value for money, including efficiency and effectiveness, transparency and ethics.

Procurement and Supply Management (PSM) is foundational to Global Fund-supported health programs. It encompasses the entire lifecycle of health product management - from planning and procurement to delivery to the end user to product end of life management and beyond. Health product procurement is a strategic intervention that supports equitable access, accelerates disease control and strengthens health systems.

The Global Fund's approach to Procurement and Supply Management is designed to:

A. Ensure access to quality-assured, effective health products and innovations.
B. Maximize value for money through efficient product selection, procurement and strategic sourcing, aiming for the lowest sustainable prices.
C. Strengthen country-level capacity in planning, selection, sourcing, procurement, storage and delivery of health products.
D. Strengthen country-level capacity to design and implement health product management systems to reach people and communities through efficient, integrated and sustainable approaches.
E. Ensure compliance with regulatory and quality assurance standards.

Context and challenges

Despite countries' continued efforts in strengthening procurement and supply systems, challenges remain, which are further exacerbated by heightened global uncertainty and volatility, driven by geopolitical tensions and shifting trade dynamics.

Sustained and strategic efforts to maintain access to quality assured, affordable health products are essential to reinforce the effectiveness, cost-efficiency, equity, resilience and sustainability of HIV, TB and malaria response programs.

The following chapters outline priority investments, driven by impact, best practices and potential approaches to drive maturity improvement efforts across the six key thematic areas that the Global Fund encourages prioritizing, through country consultation efforts.

The identification of root causes of procurement and supply chain challenges, and the prioritization of what will work best to address them, will be specific to each unique context. These six thematic areas for consideration are:

1. Policy, Strategy, and Governance

Strengthen accountability, oversight, and monitoring systems, supported by growing political commitment. Investments can further enhance governance frameworks and build technical workforce capacity, ensuring sustainable and transparent procurement and supply chain operations.

2. Planning and Procurement

Ensuring that policies and regulatory frameworks for procurement and supply management are coherent and aligned with today's context is critical to enabling efficient access to quality-assured health products. This includes well-coordinated and integrated demand and distribution planning for health products. It should also include the flexibility to leverage collaborative procurement arrangements at regional or global levels when needed, thereby boosting access to high-quality products financed through domestic funds.

3. Storage and Distribution

Adequate warehousing capacity, equipment, and workforce development will strengthen storage and distribution systems. Enhanced stock management controls and adherence to good storage and distribution practices will improve order fill rates, delivery timelines, and overall operational performance.

4. Regulatory Systems and Quality Assurance

There is an opportunity to enhance national health product policies and harmonize regulations with regional and global standards. Leveraging regulatory convergence and reliance mechanisms will accelerate product approvals and ensure consistent quality assurance across the supply chain.

5. Information Systems

Strengthening compliance with data standards and improving interoperability will unlock the full potential of digital systems for track-and-trace, inventory visibility, and real-time decision-making. Enhanced information systems will support transparency and efficiency across the supply chain.

6. Waste Management and Climate Resilience

Adequate infrastructure, regulatory enforcement, and policy development will enable safe and sustainable waste disposal practices. Strengthening climate resilience measures will reduce environmental risks and ensure long-term sustainability of health supply chains.

Each focus area that follows includes priority investments and key considerations that propose potential approaches to alleviate challenges.

1. Policy, Strategy and Governance

Strong policy, strategy and governance are essential to building health product procurement and supply systems that are resilient, integrated and sustainable. The most effective national approaches are developed through inclusive and consultative planning processes that engage government institutions, development partners, communities, civil society and the private sector.

National health policies, strategies and plans (e.g., a national supply chain master plan) typically serve as a five- to ten-year roadmap for strengthening end-to-end systems to ensure health products are adequately financed and delivered, wherever relevant. They set a clear vision for ensuring the continuous availability of quality-assured health products and broader health services across public and private facilities, including for HIV, TB and malaria. They also provide a structured framework for prioritizing health product related investments, aligning partners and tracking progress toward national and global health goals.

In addition, effective policy implementation requires coherence across planning, costing and budgeting processes. This entails harmonization between national strategies, alignment with annual planning cycles, and the use of consistent, government-led planning tools. Robust costing and comprehensive budgeting that incorporate all sources of financing are also essential to ensure that health product management priorities are feasible, fully financed sustainably executed and monitored.

In the context of resilient and sustainable systems for health (RSSH), such strategies go beyond disease-specific approaches to promote integration, efficiency and long-term sustainability. They emphasize digital transformation, workforce development and data visibility, ensuring that decision-makers have the information and capacity to manage health product systems effectively, respond to emerging challenges and support the accelerated introduction of health product innovations.

1.1 Policy framework

An enabling policy environment is the cornerstone of an efficient, resilient and sustainable health product procurement and supply system. The Global Fund encourages national policies to reflect a whole-of-system vision—one that ensures the availability of quality-assured medicines, diagnostics and other health products across HIV, TB, malaria and broader health services. A coherent policy framework ensures that health product procurement and supply systems evolve from fragmented, disease-specific models toward integrated, resilient systems capable of supporting multi-program service delivery.

Key policy priorities include:

- Alignment of funding requests with **national health and development policies**, ensuring coherence with universal health coverage (UHC) and primary health care (PHC) agendas.
- **Clear definition of institutional roles and accountability,** including but not limited to Ministries of Health and Finance; central medical stores; supply chain agencies and regulatory authorities.
- Reviewing **national procurement laws and regulations** that may require updates to identify potential barriers and facilitate access to international suppliers, health product innovations and pooled procurement mechanisms to support access to quality assured health products, including specialized or low volume products.
- **Integration of vertical disease health product procurement and supply systems into one**, promoting shared infrastructure, integrated storage and distribution, and harmonized logistics systems.
- **Inclusion of private sector and community actors,** for example, in last-mile service delivery and data reporting, to extend reach and improve responsiveness.
- **Commitment to digital transformation**, fostering interoperable logistics management information systems (LMIS) that provide real-time visibility across all levels of the supply chain for performance insights and to drive a culture of transparency and continuous improvement.

1.2 Strategic direction

A comprehensive national health product strategy – often articulated through a supply chain master plan – translates policy intent into actionable, costed and measurable interventions. This strategy articulates a unified vision for strengthening end-to-end performance across procurement, quality assurance and supply chain functions, health products, programs and sectors. It covers all stages from the process for product selection and sourcing to last-mile delivery, including forecasting and supply planning, procurement, warehousing, storage and inventory management, transport and distribution, waste management, information systems, financing, workforce, and policy and regulations.

This strategy should cover all sources of funds (e.g., domestic resources, Global Fund grants, other resources) to ensure planning efficiency, reducing duplication and avoiding gaps, reduced transaction costs coordinating between plans and partners, opportunities for economies of scale in procurement and distribution, and greater efficiency. A well-defined strategy enables coordinated investments by the Global Fund and partners, contributing to long-term system sustainability and supporting equitable, reliable access to quality assured life-saving commodities across all health programs.

Priority strategic directions include:

- **Transition and sustainability planning.** Gradually reducing reliance on donor-funded systems by increasing domestic financing, ownership and policy coherence.
- **System integration and optimization.** Coordinating disease programs supply chains for HIV, TB, and malaria within a national health commodities platform.
- **Workforce and institutional strengthening.** Strengthening national leadership, professionalizing the procurement, quality assurance and supply chain workforce, and embedding principles of continuous learning and improvement.
- **Supply chain visibility and data use.** Expanding interoperable digital systems to improve demand forecasting, integrated supply chain planning (also known as Sales and Operations Planning (S&OP) or Integrated Business Planning (IBP)), inventory management, cost tracking and management, performance management and decision-making.
- **Resilience and risk management.** Establishing mechanisms for continuity during shocks such as pandemics or conflict.
- **Private sector and innovation partnerships.** Leveraging market actors for access points to health products, distribution and warehousing to improve efficiency and sustainability.

Key investment priorities include:

- **Creating a holistic, costed national strategic plan for HPM systems**. This includes quantification and forecasting, procurement, in-country supply chains, quality assurance, and waste management, supported by required governance and human resources and endorsed by relevant national authorities and stakeholders. Based on these plans, coordinating and leveraging other investments from the government, Gavi, the Global Financing Facility (GFF), multilateral/regional development banks and other bilateral donors and partners supporting the country. This can enable achieving consensus around tradeoffs in a limited resource landscape, actively inform budget-setting and serve as a tool for strategic advocacy.

- **Prioritizing development or revision of supply chain strategic plans**, including digital health strategies where needed. Using data from recent supply chain assessments, including supply chain maturity assessments, to inform strategic planning. Prioritizing aligned national supply chain strategies that accelerate and embed supply chain sustainability across core areas, such as financing, digitalization, governance, policies, recording and reporting, resource optimization, models for partnership with the private sector where appropriate, and reflect these within revised national strategic plans.
- **Investing in well-functioning central/decentralized medical stores or outsourced model governance, audits and information**, including financial reviews, business plans, key performance indicators, and financial dashboards to provide insights into current performance, future financial sustainability and evolving Value for Money principles.

1.3 Governance and coordination

Strong governance and coordination mechanisms ensure accountability, transparency and alignment among multiple stakeholders involved in national supply chain systems, and are essential to manage complexity, reduce duplication and sustain performance. Governance mechanisms should evolve into country-led, inclusive platforms that balance donor coordination with national ownership, ensuring that supply chain investments meet immediate program needs while strengthening the foundation of sustainable, integrated health systems.

Best practices include:

- Establishing national supply chain coordination platforms, led by the Ministry of Health, to oversee implementation, performance monitoring, and partner alignment.
- Institutionalized technical working groups, bringing together government, donors, civil society, and private sector representatives to drive harmonization.
- Data governance and accountability frameworks ensuring data quality, interoperability, and ethical use across digital platforms.
- Regular performance reviews linked to national health sector reviews and Global Fund grant performance monitoring cycles should include monitoring, tracking and mitigating supply chain inefficiencies, such as product expiries and product non-conformities.
- Transparency and risk oversight mechanisms to ensure compliance and fraud prevention, including of prohibited practices, such as product diversion and supply chain leakage.

Key investment priorities include:

- **Implementing better integrated supply chains** under the stewardship of countries and in coordination with core partners. This includes streamlining functions when disparate, consolidating and standardizing core processes to generate economies of scale where applicable, and minimizing duplication across procurement and supply chain functions along the value chain to the last mile. These efforts should yield efficiency gains, cost reductions and greater supply chain sustainability.

- **Supporting coordinated, comprehensive national procurement, supply chain management and regulatory governance** that provides accountability, stewardship, leadership and oversight across the entire health product management cycle and ensures effective performance management and execution of all policy, planning and implementation activities.

2. Planning and Procurement

Planning is critical to maximize the program outcomes through timely procurement, supply and distribution of health products, mitigating the risk of stock-outs and wastage as a result of product expires. There are a set of challenges that need to be addressed and potential strategic considerations should be taken for GC8 planning and implementation. Where appropriate, some may be considered for inclusion in a Funding Request.

2.1 Existing challenges and strategic considerations

2.1.1 Policy, regulation and legislation. Targeted to countries that face structural challenges that hinder the procurement of and access to health products.

Key challenges	Strategic considerations
1. Essential HIV/TB/malaria products may not be aligned with program needs, not prioritized for funding, and/or not included in national essential medicines and diagnostics lists delaying registration and procurement. 2. Regulatory systems: priorities may not be aligned with current program needs delaying review and approvals (see Regulatory and Quality Assurance Support section for more information). 3. Existing procurement laws, regulations, and administrative frameworks may be outdated, thereby restricting access to international markets and participation in regional or global pooled procurement mechanisms. In addition, overly protective provisions - such as mandatory reliance on intermediaries or agents - can result in inflated costs and reduced efficiency.	A. Use well recognized public health institutions, such as World Health Organization (WHO)'s, recommended optimal products in guidelines and national essential medicines and diagnostic lists, adapting dynamically as recommendations are updated. B. Engage with essential health product listing bodies and health product regulators to advise on any gaps and upcoming health product priorities. C. Map/analyze access issues, review past procurement outcomes and develop updated strategies to address past challenges. D. Leverage regional and global quality assurance mechanisms, such as the WHO collaborative registration procedure. E. Update national procurement laws and practices, including recognition of pooled procurement mechanisms as a potential option for procurement when using domestic health financing

2.1.2 Selection and rational use. The selection of health products must be evidence-based and aligned with global standards to ensure optimal outcomes and prevent resistance.

Key challenge	Strategic considerations
1. Outdated guidelines can lead to suboptimal product use and poor health outcomes.	A. Invest in systems and resources to develop transition plans, to enable the uptake and scale-up of optimal regimens/health products including early adoption of better products as soon as they are available. B. Regularly update clinical guidelines and diagnostic algorithms in line with WHO recommendations. C. Promote fixed-dose combinations (FDCs) and optimal regimens to improve adherence and reduce resistance. D. Monitoring and evaluation, training and capacity building for providers/users to ensure rational use of drugs and diagnostics for effective and rational use, drug safety, algorithm compliance, equipment utilization and management, etc. especially during the transition to new products to avoid wastage

2.1.3 Quantification and planning.

Key challenges	Strategic considerations
1. Despite investments in quantification exercises, they may not be effectively used or routinely integrated into procurement or supply scheduling 2. These gaps reduce forecast accuracy and responsiveness often resulting in late order placement, low on-shelf availability and higher risk of stockouts.	A. Foster collaboration between the program, procurement, and financing functions including across Ministries (e.g. with Ministry of Finance). B. Leverage planning and procurement software to enhance data accuracy, scenario planning, and real-time tracking. C. Ensure integrated planning across different funding sources and direct access of key decision makers to information to quantification, planning and inventory levels. D. Build flexibility into procurement strategies to adapt to demand shifts or supply disruptions.

2.1.4 Procurement and sourcing.

Key challenges	Strategic considerations
1. Absence of comprehensive procurement strategy and annual/multi-year plans, considering multiple sources of financing and procurement channels. 2. Procurement legislation is outdated, doesn't cater for health products and no longer fit for purpose. 3. High transaction / overhead costs and poor cost transparency resulting in higher total costs to access critical health commodities. 4. Procurement legislation doesn't include optionality to recognize global and regional procurement and quality assurance mechanisms to ensure continued access to quality products at low prices. 5. Restrictive tendering requirements (e.g., local agents, local currency bids) deter or exclude international suppliers that will very likely result in higher prices. 6. Misalignment of fiscal cycle and procurement timeline causing long procurement lead times and stock-out risks. 7. Limited market intelligence hampers strategic sourcing and price benchmarking.	A. Modernize procurement systems to enable the establishment of framework/long-term agreements prioritizing and encompassing quality, reliability, total cost of ownership, and past performance. B. Develop national procurement strategy and annual/multi-year plan across different financing sources, aligned to various fiscal cycles (domestic and donor). C. Update national legislation to allow purchasers access to international markets and pooled procurement mechanisms at the regional and global level as well as the provisions to allow for advance payments where necessary. D. Review procurement processes regularly, benchmark against global benchmark price/quality data, use market intelligence available from global and regional sources. E. Analyze local, regional and global markets to understand supplier landscapes, pricing trends to inform procurement strategies. F. Optimize efficiency by utilizing the Global Funds' Pooled Procurement Mechanism for both grant and domestic resources

2.2 Mitigating the impact of recent global uncertainty and volatility

Maintaining a healthy and viable market for health products is critical to the sustainability of HIV, TB and malaria responses. Priority services and products will differ by disease program, but as a general consideration, health products will continue to be a significant proportion of grant investments, and the following should be taken into account:

A. Focus Global Fund grant procurement on lifesaving HIV, TB, and malaria products, while considering financing essential medicines and routine laboratory supplies with non-Global Fund grant resources.

B. Reference pricing. For all procurement channels, Health Product Management Templates should budget using the Global Fund's Pooled Procurement Mechanism pricing for health products and associated services.

C. **Lead-times**. Principal Recipients should monitor updates to the Global Fund's guidance on lead times to enable that procurement orders are placed on time should lead times for some products be extended due to supply side challenges.

D. **Concentrate demand** on fewer variations of products, including pack sizes, to support efforts to maintain unit price efficiencies. Standardized specifications also help simplify global and national supply chains (e.g., storage, distribution, etc.). Advice will be published on Global Fund's website.

E. **Ending customization**. For example, on product labels and leaflets to increase flexibility to be more responsive to supply needs and help in controlling costs.

F. **Optimize procurement channels** for grants and domestic financing. The use of the Global Fund's Pooled Procurement Mechanism/wambo.org, or regional procurement platforms is recommended. This can enable countries to benefit from negotiated terms, prices and quality-assured products from a diversified and sustainable supply base by optimizing purchasing power to sustain access and pricing. It can also simplify orders and secure access, especially for lower volume products such as children's drugs, that may become scarce on the global market.

G. **Equipment.** Since purchase of general laboratory and other health product equipment is not prioritized, it is important to prioritize service, maintenance and warranty coverage of existing equipment to ensure precision of investments and maximize the useful life of the equipment.

3. Storage and Distribution Capacity, Design, Operations and Outsourcing

Efficient storage and distribution is critical to ensure program outcomes. Improvements can be considered through investments in supply chain design and operations and outsourcing logistics services.

3.1 Priorities for Global Fund investment

Countries are encouraged to undertake diagnoses such as supply chain maturity reviews, system design analyses, and operational assessments, including— supply chain maturity reviews, system design analyses, and operational assessments. Funding should therefore target the specific storage and distribution constraints revealed by these diagnostics to address bottlenecks.

Countries need to **first examine service levels, utilization, demand patterns and route performance**, before building or acquiring new assets. In many contexts, redesigning network tiers, optimizing routes and delivery cadence, revising inventory norms and segmenting product flows yield faster service gains and at a lower cost than new infrastructure. This approach

reduces stockouts and expiries, improves on-time-in-full performance, and helps quantify any residual capacity gap that truly merits investment.

Grants should continue to finance essential procurement and supply management operations for lifesaving products, provided these **activities deliver value for money and are monitored against clear service standards**. Where logistics service providers can reliably improve cost, reach, and quality, countries should use professional outsourcing. The Global Fund Logistics Outsourcing Guidance[1] sets out a lifecycle from assessing current operations and defining outcomes through market assessment, make/buy decisions, contracting, performance governance and eventual renewal/exit.

Operations improvement inside warehouses and transport fleets is a high-value for money use of grant funds. Priority interventions include warehousing layout optimization; temperature monitoring; cycle counting; safer material handling; and distribution controls including route adherence, proof-of-delivery, and fleet tracking. These measures typically reduce costs, losses and avoidable expiries, lift order accuracy and throughput without adding space, and lower total distribution cost by improving vehicle utilization rates and reducing emergency shipments.

Distribution models should be deliberately tuned to product characteristics and points of care. Increasing replenishment frequency shortens planning, aligns supply to demand, reduces cycle stock and storage pressure at lower tiers, accelerates product introduction, and strengthens pandemic readiness. Product segmentation (for example by cold-chain needs, value/volume profile, demand variability, or clinical criticality) allows countries to integrate flows where appropriate and differentiate where necessary. Purpose-built distribution alternatives—beyond the facility — to community health workers and private pharmacies— should also be prioritized to expand last-mile reach and equity in access.

Grants should also support **stewardship and governance of public supply chains,** particularly in medical stores and logistics management capacities. Visibility into actual warehousing costs, business plans, routine financial and performance reviews and KPI dashboards increase accountability and surface sustainability risks early. An empowered supply chain management leadership provides the backbone for supportive supervision, cross-program coordination, and rapid response to bottlenecks.

Finally, **resilience and climate considerations** should be taken into account for storage and distribution investment. Countries can consider interventions such as site and route stress-tests for heat, flooding, and access disruption, coupled with energy-efficient refrigeration/lighting and appropriate backup power, protect temperature-sensitive products and reduce outage risk and operating emissions.

[1] Document under finalization. Link will be made available post-publication.

3.2 Low priority and requiring strong justification if proposed

Proposals for siloed, disease-specific storage or distribution assets that duplicate existing capabilities, fragment workflows or resist integration should be considered low priority. Similarly, new warehouse construction and vehicle purchases warrant caution where design and operations improvements or contracted logistics providers can deliver at lower total cost of ownership the same or better outcomes. Any exception should quantify the service gap, compare total lifetime costs with alternatives, present a credible integration plan with milestones and specify measurable performance gains.

3.3 Optimization and efficiency considerations (including sustainability and integration)

Applicants should show that network, route and inventory design have been completed prior to capital requests, with explicit “what-if” scenarios and sensitivity to uncontrollable variables such as fuel prices and seasonality. They should also institutionalize contract governance for outsourced services: clear structures, obligation tracking, supplier scorecards, commercial governance, risk registers and periodic performance reviews tied to renewal decisions. Inside facilities, countries should measure and improve each step from receiving to dispatch, track utilization and dwell times and address avoidable damage, theft, and expiry. These disciplines, combined with integrated flows wherever product profiles allow, drive down cost-to-serve and raise on-shelf availability.

4. Regulatory and Quality Assurance Support

Investment decisions should be primarily based on existing and robust situation analyses of the quality assurance and regulatory systems, using recognized tools, such as the World Health Organization (WHO) Global Benchmarking Tool (GBT) for regulatory systems assessment or the Model Quality Assurance Systems for procurement agencies (MQAS) assessment tool.

Where situation analyses to strengthen quality assurance and regulatory systems have been completed, these should be used to inform planned activities and actions

CCMs are encouraged to engage with national regulatory authorities and findings from the Global Fund’s Office of the Inspector General reports where relevant.

4.1 Contributing to the national Health Product Quality Assurance Framework

Principal Recipients may be required to develop a **Quality Assurance Plan** during grant-making or ahead of grant implementation, subject to requirements in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products. This plan should outline different components under the quality assurance policy, specify approaches and activities, main actors involved, estimated budget and indicative implementation timeframes.[2]

4.2 Strengthening national regulatory systems

Should grant funds be requested to support initiatives for strengthening national regulatory systems, Principal Recipients may be required to develop a **Regulatory System Capacity Development Plan** during grant-making or ahead of grant implementation, subject to requirements in the Guide to Global Fund Policies on Procurement and Supply Management of Health Products.

Main priorities (for NRAs supported by the Global Fund)	Suggested optimization and efficiency considerations
1. Deliver and implement regulations that protect the public while enabling timely access to and innovation of quality products. 2. Strengthen the capacity of actors within the national regulatory and health product quality assurance systems through targeted training and technical assistance. 3. Support to Quality Management Systems (QMS) and Good Regulatory Practices implementation for NRAs at Maturity Level 3 and 4 (ML3 and 4).	A. Leverage existing regulatory tools and reliance mechanisms to avoid duplicative or lengthy reviews. A. Promote operational efficiency by adopting risk-based approaches and digital solutions. B. Leverage existing regional, continental and international capacity-building initiatives and partnerships to avoid duplication and enhance sustainability. C. Integrate the information management needs of national regulatory authorities into new or updated country systems. D. Leverage existing global and regional digital platforms and systems to improve efficiency, avoid duplication and ensure interoperability.
Low priority requiring justification if proposed	
Engaging in lengthy regulatory reviews should be avoided, except if justified, such as for alignment with regional or continental Model law. Instead, take best benefit of existing regulatory tools.	

[2] Additional guidance is provided in the Technical Brief: Support to Effective Regulatory Systems for Procurement and Supply Management of Health Products.

4.3 Supporting selected product life cycle steps

A. Product selection

Support the update of disease-related guidelines and essential health products lists to ensure alignment with the latest WHO recommendations, including rapid communications, and WHO Model Lists (for example, see https://www.who.int/publications/who-guidelines and https://www.who.int/publications/i/item/B09474).

Main priorities are to be defined based on country context and disease burden.

B. Registration and marketing authorization

Main priorities	Suggested optimization and efficiency considerations
1. Support national efforts to strengthen registration processes by facilitating the registration of innovative health products (e.g., Expert Review Panel (ERP) recommended products). 2. Prioritize the use of reliance mechanisms and collaborative registration procedures (e.g., WHO Collaborative Registration Procedure (CRP) or relevant regional initiatives).	A. Consider implementation of reliance principles in NRA day-to-day practices (legal framework, procedure). B. Leverage the WHO collaborative registration procedure for accelerated national registration. C. Take operational advantage of regional, continental, and international regulatory frameworks and initiatives to improve efficiency and harmonization.
Out of scope	
National standalone registration of SRA/WLA/WHO Pre-Qualification Programme-approved products without consideration for reliance mechanisms.	

C. Procurement and importation

Main priorities	Suggested optimization and efficiency considerations
Support auditing for procurement entities under the MQAS, following a risk-based approach that prioritizes products with less demonstrated quality.	Take benefit operationally of regional, continental and international procurement mechanisms, framework agreements, and relevant initiatives.
Low priority requiring justification if proposed	
Support to pre-qualification of SRA/WLA/WHO Pre-Qualification Programme-approved products, which are considered low-risk due to established regulatory oversight.	
Out of scope	
Support for ISO 9001 certification of procurement entities.	

D. Storage and Distribution

Main priorities	Suggested optimization and efficiency considerations
Support auditing for Good Distribution Practices (GDP) using a risk-based approach, prioritizing oversight where non-compliance would have the largest public health impact.	Support implementation of already existing associated corrective action plans based on external reviews and audits from reliable sources
Low priority requiring justification if proposed	
1. Support to facilities with well-established quality management systems or consistently demonstrating GDP performance/compliance. 2. Support to facilities handling health products which are not or are less sensitive to environmental conditions such as humidity, temperature, light, atmospheric pressure, vibrations (e.g., Personal Protective Equipment).	
Out of scope	
Support for ISO 9001 certification of storage and distribution entities.	

E. Dispensation and use

Main priorities	Suggested optimization and efficiency considerations
1. Support the implementation and supervision of Good Dispensing Practices (GDPs) and promote the rational use of health products, including antimicrobial stewardship. 2. Support efforts to strengthen policies, training and monitoring mechanisms that improve dispensing quality, ensure correct product use and enhance patient safety. 3. Reinforce linkages between dispensing sites, vigilance and sentinel centers and regulatory authorities.	A. Integrate dispensing and use interventions within existing national programs and digital reporting platforms. B. Promote harmonization with WHO guidance on Good Pharmacy Practice (GPP)[3] and rational use of medicines.[4] C. Support collaboration between regulatory authorities, professional associations, and public health programs to streamline supervision and feedback systems.
Low priority requiring justification if proposed	
Activities focused solely on awareness-raising or short-term training that are not embedded in a sustainable national strategy or supervision framework.	

[3] TRS 961 - Annex 8: Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services: https://www.who.int/publications/m/item/annex-8-trs-961

[4] https://www.who.int/activities/promoting-rational-use-of-medicines

Out of scope
1. Standalone training or awareness campaigns not linked to national strategies or regulatory follow-up mechanisms. 2. Support to private sector retail outlets outside national control frameworks, unless part of an approved national program.

F. Vigilance and market surveillance

Main priorities	Suggested optimization and efficiency considerations
1. Support the establishment and strengthening of national vigilance systems, focusing on NRAs at Maturity Levels 1 and 2 as per WHO's GBT. 2. Promote active monitoring and reporting to detect adverse events, substandard or falsified products and supply chain issues. 3. Support access to quality control services. 4. Support planning for a risk-based approach of market surveillance activities.	A. Benefit and contribute to global exchange of safety data such as the Uppsala Monitoring Centre. B. Apply reliance principles and act on trusted assessments.
Low priority requiring justification if proposed	
1. Support to siloed/disease-specific vigilance investments/programs. 2. Oversight of low-risk products or products with a long-standing safety record, unless flagged through a risk-based assessment. 3. Support to quality control testing laboratory infrastructure upgrades. 4. Support to testing product at registration or marketing authorization stage.	
Out of scope	
1. Support for NRAs at Maturity Level 3 or 4, where vigilance systems are already functional and well-established. 2. Establishing standalone reporting systems that are not linked to national or integrated regional vigilance mechanisms. 3. Routine post-shipment quality control testing activities of SRA/WLA/WHO Pre-Qualification Programme-approved products.	

5. Information Systems and Data Use

5.1 Priorities for Global Fund investment

Countries should accelerate implementation of interoperable, disease-agnostic supply chain information systems that enable end-to-end visibility and routine data-driven operations of the supply chain, including tracking the costs of relevant supply chain services/activities. This typically means deploying or scaling solutions, such as an electronic logistics management information system, a warehouse management system or an enterprise resource planning solution for digital transformation of the enterprise. These solutions provide capabilities such as transport management, automated requisitioning, fulfillment, lot/expiry tracking, cold-chain telemetry and electronic proof of delivery while integrating full traceability and verification. The objective is not technology itself, but reliable, timely data that supports integrated planning, early detection of supply gaps and continuous performance and risk management. End user focus must drive digitalization initiatives to allow for faster adoption and use.

Investments should be anchored in a national supply chain digitalization roadmap and enterprise architecture that fit within the broader health information strategy. This architecture clarifies business processes, information standards, applications and technology choices and ensures that master data, interoperability, security and support models are designed once and reused across programs. Investments should leverage resources such as TSS (Target Software Standards) to lower implementation costs while ensuring standards compliance. National master plans and digital strategies reduce duplication and improve coherence across platforms.

Master data management is a foundational element of enterprise architecture. For example, establishing a single, authoritative national product catalog and facility master—incorporating Global Standards One (GS1) identifiers for health products and standardized location codes—creates a “single source of truth” that simplifies integration, improves data quality and allows regulatory actions (for example, product status changes) to propagate consistently across all dependent systems. Where feasible, dedicated master data services should be maintained and synchronized with operational systems through application programming interfaces.

Interoperability should precede new bespoke modules and use industry standards such as HL7/FHIR (Fast Health Interoperability Resources) and GS1 EPCIS (Electronic Product Code Information Services) for data exchange. Countries can use interoperability layers to exchange data between supply chain systems and health management information systems such as DHIS2.

Priorities include standard interfaces for orders, shipments, inventory and service delivery data, disciplined retirement of duplicative, program-specific tools, and integrated analytics and dashboards that drive action during monthly supply reviews. GPS1 EPCIS-compliant

interoperability allows product identification and event data sharing downstream from manufacturers and ability to track and verify products end to end.

Integrated data analysis and visualization solutions that use data from all enterprise systems and provide comprehensive analysis are critical for tactical and strategic decision-making.

Total cost of ownership must be explicitly detailed. If Global Fund funding is requested, then funding should cover configuration, hosting, licensing, cybersecurity and maintenance alongside workforce development for system administrators, data managers and super-users, with a clear plan for operations and maintenance after rollout. Ownership models should weigh in-house versus outsourced support against service-level needs and budgets, with service levels and accountability specified either way.

5.2 Low priority and requiring strong justification if proposed

Single-disease supervision tools or stand-alone applications that replicate cross-cutting supervision or that do not integrate into national platforms. Custom builds are also low priority when configurable open-source or commercial off-the-shelf solutions can meet requirements. Any exception should present a gap analysis against the national roadmap, an interoperability and migration plan (including retirement of duplicative tools) and a quantified benefit that exceeds integration costs and risks.

5.3 Optimization and efficiency considerations (including sustainability and integration)

Proposals should show how data will routinely drive decision-making: exception alerts for stockouts/overstocks, root-cause analysis, action logs with accountable owners and KPI tracking for on-shelf availability, on-time-in-full, expiry losses and cost-to-serve. Interoperability with DHIS2, finance and insurance systems allow triangulation of logistics and service data to spot leakage and validate consumption. Comprehensive business continuity plans, enterprise security and audit trails are essential to maintain trust, resilience and stability. Where upfront digital investments are higher, applicants should make the savings case via long term return on investment, fewer emergencies, lower expiries, improved load factors and reduced supervision costs over time.

6. Waste Management, and Climate Resilient and Environmentally Sustainable Health Facility Systems

6.1 Priorities for Global Fund investment

The immediate investment priority is to sustain and safely operate existing healthcare waste management assets. Domestic financing should cover warranties, preventive maintenance, essential operating costs, and operator training. Where domestic financing is not yet feasible, grant funding can be considered with a co-financing path defined, noting grant limitations for covering warranty/maintenance agreements that span beyond a single grant cycle. Sustaining what is already installed typically delivers faster risk reduction and better compliance than intermittent cycles of equipment purchase without operations and maintenance funding.

Countries are encouraged to use national assessments to prioritize improvements across the full waste lifecycle: segregation at source, safe collection and internal transport, decontamination, recycling and diversion where compliant markets exist, and final treatment and disposal for the residual risk fraction. Improvements across the full waste lifecycle should be prioritized in line with a national Health Care Waste Management plan or strategy. Where no such plan or strategy exists, developing one should be a key priority.

The emphasis should be on prevention and resource efficiency first—clear bin systems, labeling, and point-of-use standard operating procedures—because this drive the largest reductions in hazardous volumes, handling risk and treatment costs per dollar spent. Mapping and optimizing waste management networks, including options for regional treatment with compliant transport, helps right-size capacity and avoid stranded assets.

Standards, workforce capability and performance monitoring are integral. Grants should support national standards and SOPs, training and coaching of staff and routine monitoring of occupational safety and emissions, where applicable, with actionable key performance indicators. Where waste services are outsourced, contracts should specify outcomes for safe handling, manifests, emissions performance and diversion/recycling rates, verified through spot checks and independent audits.

Where technology upgrades are needed, choices should reflect waste characterization and facility infrastructure. Alternatives to high-temperature incineration can manage most waste streams safely when segregation is effective. Where high-risk or pathological waste requires high-temperature treatment, proposals must include emissions controls, wastewater treatment, operator safety measures and routine compliance monitoring. Integrating reverse logistics into distribution routes can lower costs and improve compliance for backhauling segregated waste to regional facilities.

Investments in making facilities and warehouses climate-smart should accompany waste improvements. Climate risk assessments of sites and inventories should inform measures such as ensuring safe and reliable transport of hazardous health care waste during and after extreme weather events, clean or renewable energy (for example, solar photovoltaics), efficient refrigeration and ventilation, insulation, water efficiency and temperature monitoring.

6.2 Optimization and efficiency considerations (including sustainability and integration)

The most cost-effective first steps are rigorous segregation and minimization at point of generation, backed by coaching and compliance audits. Treatment capacity should be sized from measured volumes (for example, kilograms per bed per day or per facility per month) to avoid both idle assets and overload. Where outsourcing is used, outcome-based contracts with enforceable service levels and transparent reporting minimize risk. Pairing solar power with efficient cold-chain and ventilation upgrades often yields dual benefits: improved product protection and lower operating costs and emissions.

6.3 Low priority and requiring strong justification if proposed

Proposals centered on new waste equipment purchases should be deprioritized where site readiness risks—power, housing, siting, utilities, staffing, or operations and maintenance financing—are unresolved. Expansion of high-temperature incineration capacity is also low priority where waste audits show that safer, lower-emission alternatives can handle most volumes or where emissions controls and monitoring cannot be assured. Any exception should provide waste characterization, a readiness checklist, a financed operations and maintenance plan, and a comparative environmental and health risk analysis.

Annex: List of Abbreviations

CCM	Country Coordinating Mechanism
DHIS2	District Health Information System/Software 2
EPCIS	Electronic Product Code Information Services
ERP	Expert Review Panel
FDC	Fixed dose combination
FHIR	Fast Healthcare Interoperability Resources
GBT	Global Benchmarking Tool
GDP	Good Distribution Practices
GPP	Good Pharmacy Practices
GS1	Global Standards One
HL7	Health Level 7
ISO	International Standards Organization
KPI	Key Performance Indicator
LMIS	Logistics Management Information System
ML	Maturity Level
MQAS	Model Quality Assurance System
NRA	National Regulatory Authority
PHC	Primary Health Care
PPM	Pooled Procurement Mechanism
PR	Principal Recipient
PSM	Procurement and Supply Chain Management
QMS	Quality management system
RSSH	Resilient and Sustainable Systems for Health
SOP	Standard operating procedures
SRA	Stringent Regulatory Authority
TRIPS	Trade-related Aspects of Intellectual Property Rights
TSS	Target Software Specifications
UHC	Universal Health Coverage
WHO	World Health Organization
WLA	WHO Listed Authority