A PATHWAY TO IMPROVING ACCESS TO QUALITY MATERNAL NEWBORN HEALTH PRODUCTS

Introduction

The Maternal and Newborn Health (MNH) product ecosystem is an interconnected set of technical and institutional domains that determine whether essential products reach women and newborns. As illustrated in Figure 1, domains such as manufacturing, regulation, financing, procurement, service delivery, and data systems are highly interdependent; weaknesses in any one area can disrupt the entire value chain and limit access to quality-assured products. Ensuring access to quality MNH products is the responsibility of government, healthcare professionals, and civil society, acting together.

Unlike products supported by various financing mechanisms, the availability of MNH products is largely shaped by national dynamics. This pathway therefore focuses on strengthening national systems to support the right of every woman and newborn to equitable access to safe, timely, quality-assured MNH products, helping reduce mortality and improve the health and wellbeing of mothers and newborns everywhere.

Figure 1: Key domains influencing access to quality-assured MNH products

Stakeholders in the MNH Product Value Chain

Achieving reliable access at national and sub-national levels requires coordinated action among diverse stakeholders across service delivery, financing, supply chains, regulation, and civil society (Figure 2). Together, these actors and domains form the foundation of a resilient MNH product ecosystem necessary to consistently and equitably deliver high-quality, life-saving products for every woman and every newborn.

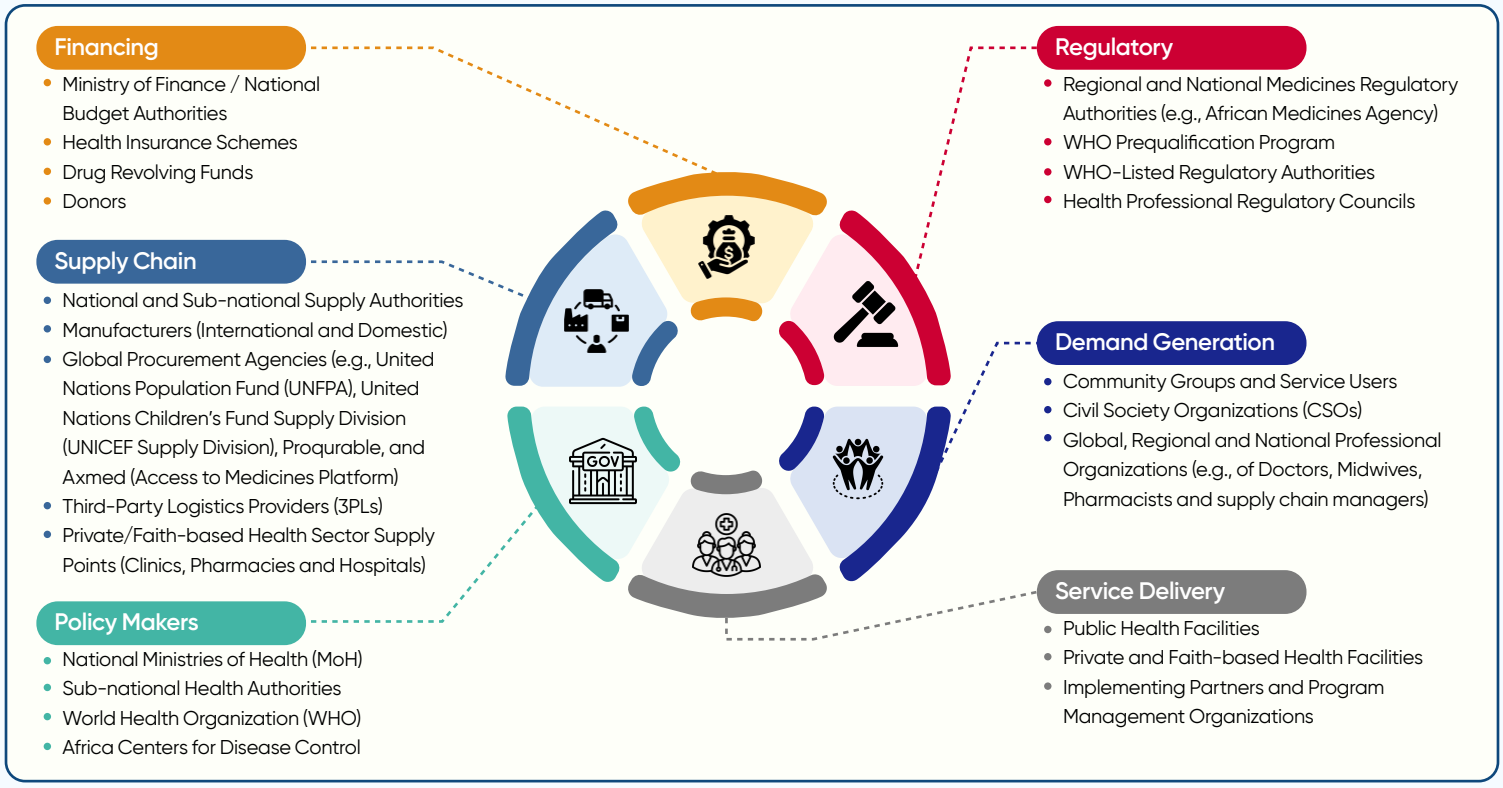


Figure 2: Integrated stakeholder mapping across the MNH product value chain

To increase access to quality MNH products, this document helps you:

Clarify the Vision

Understand what optimal MNH product access looks like in the context of a national product access system

Map Key Actors

Identify the key stakeholders and institutional counterparts responsible for decision-making and implementation across domains

Identify Targeted Improvements

Objectively assess potential actions across value-chain domains, to drive improvements in MNH product access

Identify Dependencies

Understand how domains are interrelated and know which domains require information and action within other domains

Strengthen Collaboration

Increase partnerships toward improved MNH product access and work to overcome fragmentation of efforts in the national product access ecosystem

Value Chain Domains & Challenges Limiting Equitable Access to Quality MNH Products

Description	Challenges in LMICs
Manufacturing develops products in anticipation of projected clinical uptake and sale through various procurement channels. Good manufacturing helps ensure consistent supply of quality, safe and efficacious products, demonstrated through: • Evidence of quality-assured Good Manufacturing Practice (GMP)-compliant manufacturing sites • Reliable quality testing and assurance systems • Market authorizations in targeted countries of relevant products • Manufacturers and suppliers that respond to tenders with competitive prices for quality-assured products	• Small, fragmented markets limit economies of scale and deter investment in manufacturing of MNH products • Proliferation of products of unknown quality • Vulnerability to currency fluctuations, lower purchasing power, and limited regulatory capacity to ensure and monitor quality
Market Shaping improves market viability by addressing pricing, competition, and incentives for suppliers to invest in quality-assured MNH product lines. Good performance is reflected in: • Existence of strategies that expand, or reinforce the reliability of an existing, supplier base, improving access to affordable quality-assured MNH products • Deployment of effective tools such as Long-term agreements (LTAs) and pooled procurement (where feasible) to lower prices and improve access	• Fragmented procurement reduces bargaining power and creates price inconsistency • Financing for collective negotiation or pooled procurement is often not available for MNH products, limiting such solutions • Unpredictable demand volumes discourage supplier investment • Unpredictable funding undermines long-term agreements (LTAs), pooled procurement and volume guarantees
Regulatory and Quality Systems ensure MNH products meet quality standards of safety and efficacy from the point of approval through to post-market surveillance. Good performance is demonstrated through: • A National Regulatory Authority that is effective, timely and able to coordinate relevant stakeholders • Quality monitoring mechanisms – pharmacovigilance and post-market surveillance	• Limited regulatory capacity, including for MNH products • Regulatory reliance mechanisms (e.g. collaborative registrations, joint reviews) exist, but are not leveraged consistently for MNH products
Normative Policy and Guidance determine service delivery standards and thus define which MNH products are adopted and how they should be used. Good performance is evident when: • MNH policies/guidelines exist with regular updates • Relevant in-country stakeholders are informed about the importance and benefits of quality-assured products • MNH products are included in NEMLs • Availability of accountability mechanisms	• Delayed translation of WHO guidelines into national policy, including National Essential Medicines Lists (NEMLS) and formularies • Budget for products face pressure from competing priorities, which may reduce available funding for MNH products • Monitoring systems rarely track adherence to MNH product guidelines

Description	Challenges in LMICs
Forecasting and Quantification predict needs to guide procurement and contract terms, and enable a system where fluctuations can be managed without stockouts or overstocking. Good performance is demonstrated through: • Availability of consumption data that are regularly analyzed and used for inventory optimization, including data to distinguish registered from unregistered products • Forecasting is integrated into national supply planning cycles • Regular reporting and monitoring, with corrective action when needed	• Limited Logistics Information Management Systems (LMIS), where data is unreliable, limiting quality and accuracy of forecasts. • Limitation on expansion of LMIS tools and systems to lower-level facilities, impacting ability to use data for regular oversight, course correction, and contract updates
Financing provides sustainable and timely funding to support uninterrupted procurement of MNH products. Good performance is demonstrated through: • Predictable MNH products' budgets, achieved either through budget monitoring or dedicated and adequate allocations for MNH products • Timely and predictable fund disbursement • Use of available financial incentive mechanisms (e.g. match funds, etc.) as bridges to increased domestic financing • Financial protection mechanisms (e.g., insurance) to lower out-of-pocket costs	• Fragmented financing schemes which create parallel pipelines and duplication • Competition for financial resources from other program areas • Small volume purchasing leading to products that are unnecessarily costly • Complexity of funding mechanisms and cost recovery models which reduces efficiency • High out-of-pocket costs limit maternal newborn health services and products access
Demand Generation includes practitioner knowledge and skills as well as health seeking behavior from women and families. Appropriate demand creation builds awareness, trust, and timely care-seeking among women and communities to support appropriate MNH product uptake. Good performance is demonstrated through: • The existence of active coordination structures and community engagement mechanisms • Engagement of professional bodies that reinforce demand for MNH services and appropriate use of MNH products	• Misinformation or low confidence in services limits women's autonomy and trust in MNH services and use of MNH products • Poor alignment between demand creation and product availability leads to unmet or underused demand • Limited engagement of community influencers reduces uptake and weakens sustainability • Inconsistent provider knowledge or confidence in new MNH products and guidelines that can weaken appropriate use and provider driven demand
Procurement and Distribution systems ensure timely product orders and efficient delivery of products to service delivery points. Good performance is demonstrated through: • Availability of quality-assured MNH products • Last mile distribution • Monitoring systems which allow insight into stock status or on-shelf availability • Supplier scorecards or other monitoring that shows performance per contractual obligations	• Limited procurement and supply chain capacity leads to poor performance in delivering MNH products to points of care • Inadequate warehousing and cold-chain infrastructure and systems compromise product quality • Weak last-mile distribution and facility management for managing product inventory
Service Delivery enables health workers to use MNH products safely and effectively through adequate skills, tools, and systems. Good performance is evident with: • Facility readiness to provide MNH services • The availability of Emergency Obstetric and Newborn Care ready facilities • Presence of supervisory/quality systems	• Poor training of providers leads to underuse or incorrect use of products and negatively impacts demand and forecasting • Weak clinical documentation prevents tracking of MNH products use • Limited facility readiness, including capacity for stock management impacts correct product use and can result in workforce misalignment
Data Systems generate timely, accurate data on availability, use, and outcomes to strengthen decision-making, forecasting, financing and accountability. Good performance is demonstrated through: • Functional and monitored digital platforms that provide visibility across the supply chain • Existence of monitoring and evaluation frameworks and data use for evidence-based decision-making	• Limited financing for digitals systems prevents scale-up and sustainability • Private sector facilities whose systems are not part of national reporting structures distort understanding of overall product use and needs • Fragmented, non-interoperable digital systems reduce capacity for integration and system efficiencies • Poor quality data limits the use of data for decision-making and forecasting

The Current Landscape

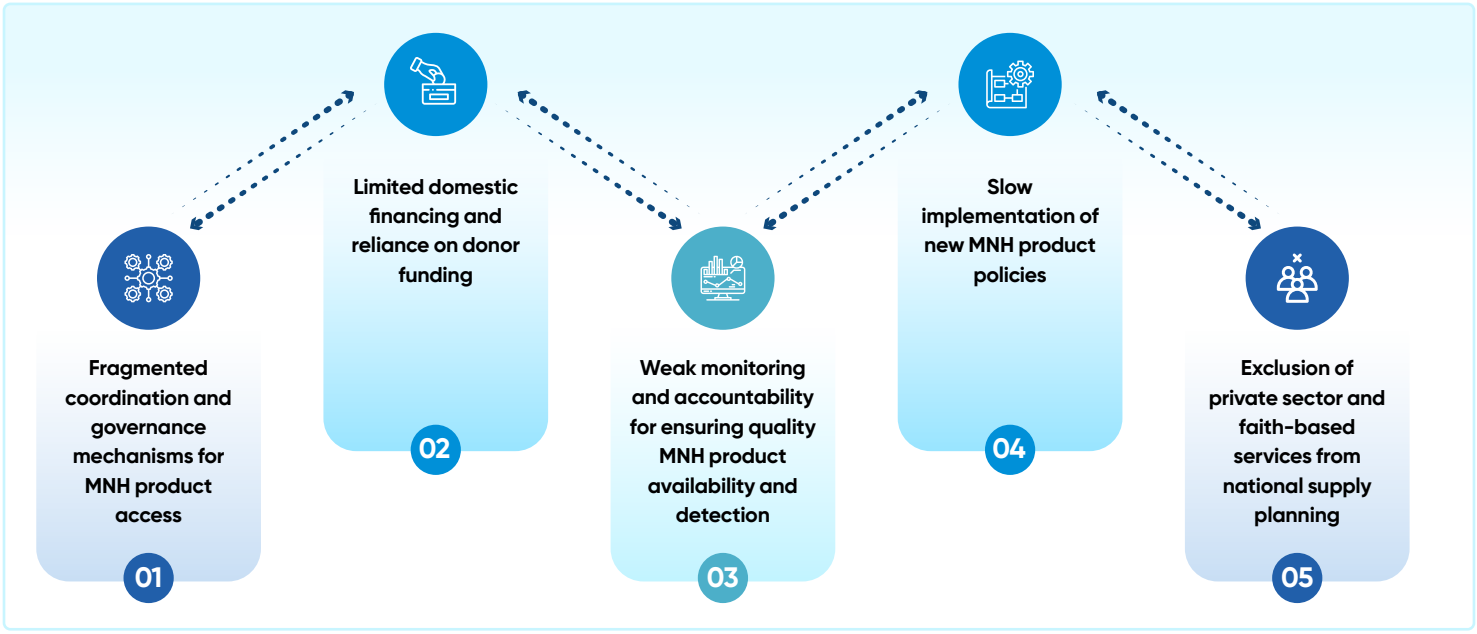
In 2023, an estimated 260,000 women died from preventable complications of pregnancy and childbirth, 2.4 million newborns died in the first month of life, and 1.9 million babies were born stillborn. More than 90% of these deaths occur in low and middle income countries. Access to care has improved, and now the task is to improve quality of care. Although the tools to prevent these deaths exist, insufficient funding, stockouts, poor-quality products, and limited coordination among product access actors continue to undermine provision of quality maternal and newborn care.

MNH products – including diagnostics, medicines, devices and consumables – are essential for safe, high-quality care. Yet well-documented supply gaps spanning manufacturing, financing, regulation, and last-mile distribution continue to disrupt the consistent availability and use of quality-assured products.

To understand the root causes of these challenges, the EWENE (Every Woman, Every Newborn, Everywhere) Health Products Working Group conducted:

- A comprehensive review of academic, peer-reviewed, and grey literature, drawing on global, regional, and country-level evidence
- Targeted interviews with key global and country stakeholders, drawing on their implementation experience, to understand what a well-functioning system should look like.

This revealed a set of five (5) interconnected systemic gaps that constrain access, deepen inequities, and compromise quality of care across the MNH product ecosystem.



These challenges have multiple further causal impacts across an inherently interconnected MNH product access ecosystem. The illustration below highlights the interdependence of the ten value-chain domains, using relationships to the data system domain as an example.

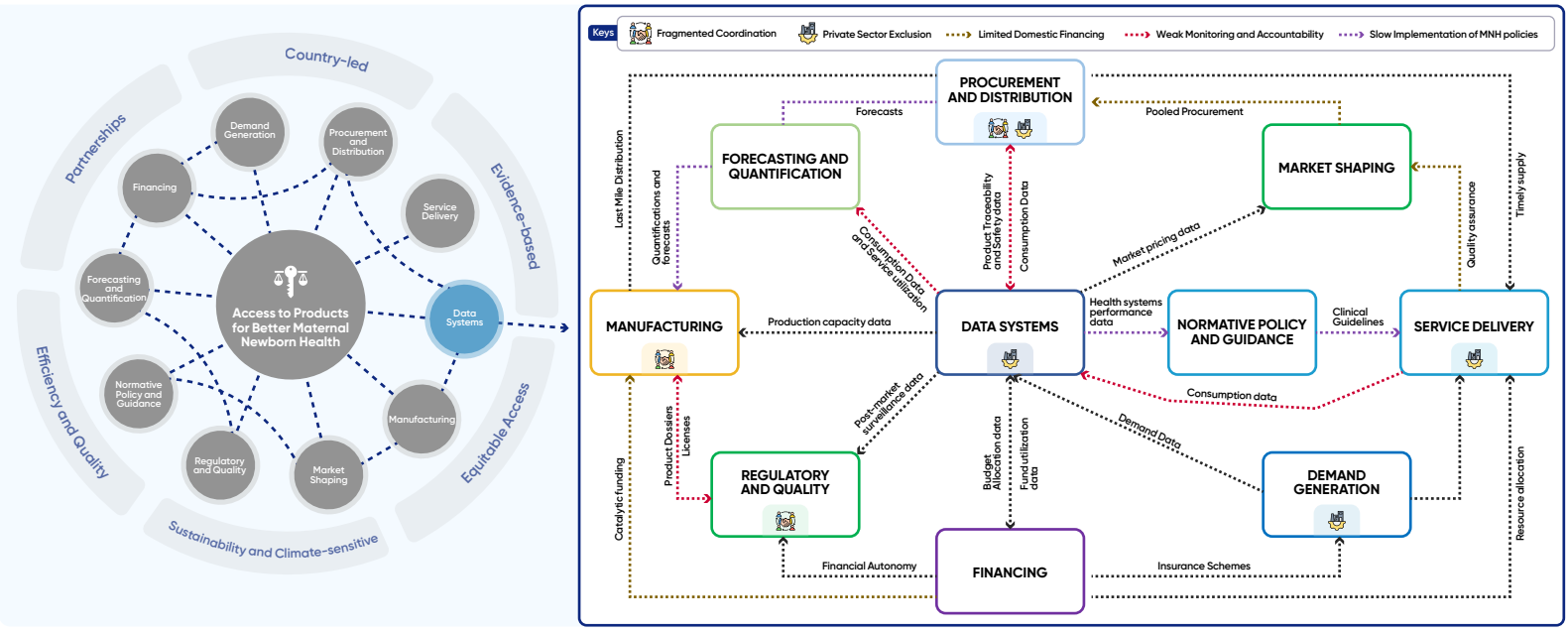


Figure 3: Key interdependencies within the data systems domain

The journey to MNH products access is shaped and often delayed by these cross-cutting challenges

Needed stakeholders

- Financing
- Supply Chain
- Government
- Service Delivery
- Professional, Community and Civil Society
- Regulatory

Fragmented coordination and governance mechanisms for MNH product access

- **Manufacturing:** Fragmented procurement and "price above all" signals across countries create demand uncertainty and opportunism, discouraging manufacturers from investing in quality-assured MNH products production for LMICs
- **Market Shaping:** Uncoordinated procurement weakens collective bargaining, leading to higher prices
- **Regulatory and Quality:** Parallel processes lead to slow, inconsistent approval timelines across agencies
- **Normative Policy and Guidance:** Policies are inconsistent across ministries, partners, and donor programs
- **Procurement and Distribution:** Overlapping systems cause duplicated orders, inefficiency, and misaligned distribution. Uncoordinated decisions allow poor quality products to enter national/sub-national inventory

Limited domestic financing and reliance on donor funding

- **Financing:** Co-funding of MNH product access exposes system to funding gaps, increases risk of instability in product access, and masks true cost of quality healthcare delivery
- **Market Shaping:** Fragmentation of markets and limited financing creates unpredictable demand and reduces supplier incentives to enter or remain in the market
- **Norms, Policy and Service Delivery:** Insufficient funding hinders alignment of policy and practice, and delays capacity building that aligns with evolving global standards
- **Procurement and Distribution:** Constrained budgets lead to delayed and/or inadequate procurement volumes, to purchasing that is not value-based, and to client mistrust in quality, respectful service delivery

Weak monitoring and accountability for ensuring quality MNH product availability and detection

- **Regulatory and Quality:** Insufficient oversight results in poor-quality products slipping through regulatory gaps
- **Procurement and Distribution:** Lack of accountability enables waste, leakage, and uncorrected supply-chain failures
- **Service Delivery:** Dysfunctional and inadequate pharmacovigilance mechanisms lead to inappropriate use and wastage
- **Data Systems:** Incomplete reporting obscures stockouts and outcomes, and distorts supply-chain decision-making
- **Forecasting and Quantification:** Widespread data gaps lead to chronic under- or over-estimation of product needs

Slow implementation of new MNH product policies

- **Normative Policy and Guidance:** Delayed rollout of new guidelines means long reliance on outdated policies
- **Forecasting and Quantification:** Outdated policies drive incorrect quantification for new priority products
- **Data Systems:** Without timely updates, reporting tools fail to track emerging MNH interventions
- **Financing:** Delayed policy costing stalls budget alignment and prevents implementation
- **Service Delivery:** Delayed implementation of new policies by providers results in outdated practices and poorer-quality of care for patients

Exclusion of private sector and faith-based services from national supply planning

- **Service Delivery:** Exclusion of private and faith-based services leaves large portions of MNH users outside national planning
- **Demand Generation:** Private and faith-based-sector users are left out of coordinated MNH communication and outreach
- **Procurement and Distribution:** Private and faith-based facilities cannot access pooled procurement, or procure through separate channels, contributing to market fragmentation and inefficiencies such as higher prices
- **Data Systems:** National systems lack full visibility of MNH product flows in private and faith-based networks

Cross Cutting Recommendations to Strengthen MNH Product Access

A resilient MNH product ecosystem rests on strong governance, intentional coordination, and a strengthened commitment to deliver quality-assured, life-saving products without delay. The system should foster unified, government-guided, data-driven coordination. Below are five core recommendations built on consensus, and some potential solutions, that can strengthen the pathway to consistent, affordable and equitable access for every woman, every newborn, everywhere.

Strengthen coordination across all levels of the MNH ecosystem

- Anchor MNH product governance in a single, government-led coordination mechanism that aligns stakeholders, with routine multi-sector performance reviews to enforce accountability.
- Use regional platforms to lower costs, strengthen supply security, align regulatory standards, and coordinate responses to MNH product risks.
- Align donor financing, technical assistance, and product pipelines to national MNH priorities to prevent parallel systems, reduce market distortions, and shorten the timeline from evidence to access.

Increase domestic financing and foster donor alignment

- Shift MNH product financing to predictable domestic funding through expanded government budgets and co-financing mechanisms.
- Rigorously align donor funding to national supply plans to eliminate duplication and stabilize access when external funding fluctuates.
- When conditions are favorable, increase access to complementary funding pathways, with clear transition criteria.
- Where donor funding is applied, ensure country resilience and sustainability mechanisms are in place.

Strengthen data quality, use, and intelligence across the MNH value chain

- Use integrated MNH product data to drive leadership decisions, prioritize investments, and trigger rapid corrective action across the value chain.
- Apply market and performance data to enable volume guarantees, long-term contracting, demand stabilization, and performance-linked financing for affordability, quality, cost-effectiveness and supply security.
- Use routine quality, safety, and pharmacovigilance data to rapidly detect, track, and remove substandard and falsified MNH products.

Fast-track introduction and scale-up of new MNH products

- Coordinate regulatory, adoption, procurement, and service delivery efforts that can stall MNH innovation uptake.
- Rapidly include approved products in essential medicine lists and clinical guidelines.
- Pre-position financing and deploy in-service provider training (both knowledge and skills) in parallel with procurement to accelerate scale-up from policy to practice.
- Integrate new MNH products into pre-service curricula.

Fully integrate private and faith-based services into national systems

- Integrate private and faith-based services into national procurement, distribution, training, and reporting systems to close access, affordability and data gaps.
- Position private and faith-based providers as full system partners across financing, logistics, data, and service delivery.
- Use public–private coordination to expand reach, strengthen last-mile access, improve market efficiency, and scale innovation under common quality standards.

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