

Introduction

Sub-Saharan Africa (SSA) faces critical challenges in ensuring the availability of maternal health (MH) supplies, a situation exacerbated by the COVID-19 pandemic. This landscape assessment addresses the urgent need for a resilient health supply chain that ensures the continuous availability of essential MH products, specifically focusing on heat-stable carbetocin (HSC), magnesium sulfate, misoprostol, oxytocin, and tranexamic acid (TXA). The reliance on imports and limited local manufacturing capabilities underline the vulnerability of MH supplies in SSA, impacting maternal mortality rates.

Overall, the analysis provides a comprehensive understanding of the MH product landscape in SSA, highlighting potential vulnerabilities and opportunities for intervention to strengthen regional manufacturing capacities and ensure a more resilient and diversified supply chain. Additionally, the report highlights the challenges associated with estimating the demand of these MH products in SSA.

Purpose and Objectives of the Study

The purpose of this study was to conduct a landscape assessment of RMH products to:

- Determine the current demand for RMH products
- Assess resources, capacity, and needs of manufacturers of RMH products in SSA
- Identifying and assessing current and future manufacturers and their capability to meet market demands.

The assessment included the following products:

- Oxytocin
- Misoprostol
- Magnesium sulfate
- Tranexamic acid
- Heat-stable carbetocin

Methodology

Employing a mixed-methods approach, the assessment involved an extensive review of regulatory databases, interviews with manufacturers, and analysis of procurement data across eight selected SSA countries.

The study focused on understanding the production capacity, regulatory compliance, market authorization, and the challenges and opportunities faced by manufacturers in the region.

Supply assessment:

- Countries with a diverse range of pharmaceutical companies producing a wide array of products.
- Countries whose national regulatory agencies are listed by the World Health Organization (WHO) as Maturity Level 3 (ML3).
- Countries where there is at least one manufacturer with at least one product prequalified by the WHO.

Demand assessment:

- Desktop reviews on medicine stockouts and quantification and demand forecasting challenges in public health systems in SSA.
- A search for tender award information from 2017/2018 to 2022/2023 from procurement portals and websites of ministries of health (MoHs), public procurement authorities, and central procuring entities. Data were assessed and captured into excel spreadsheets.

Results

MH products and countries of production	Strength produced	Annual production capacity
Magnesium sulfate	50 % w/v	Approximately 150 millions ampules
Misoprostol	200 mcg	800 kg or 4 million tablets
Oxytocin	10 IU/2mL	600 kg
Tranexamic acid	500 mg/2 mL	800 kg or 1,600,000 ampules

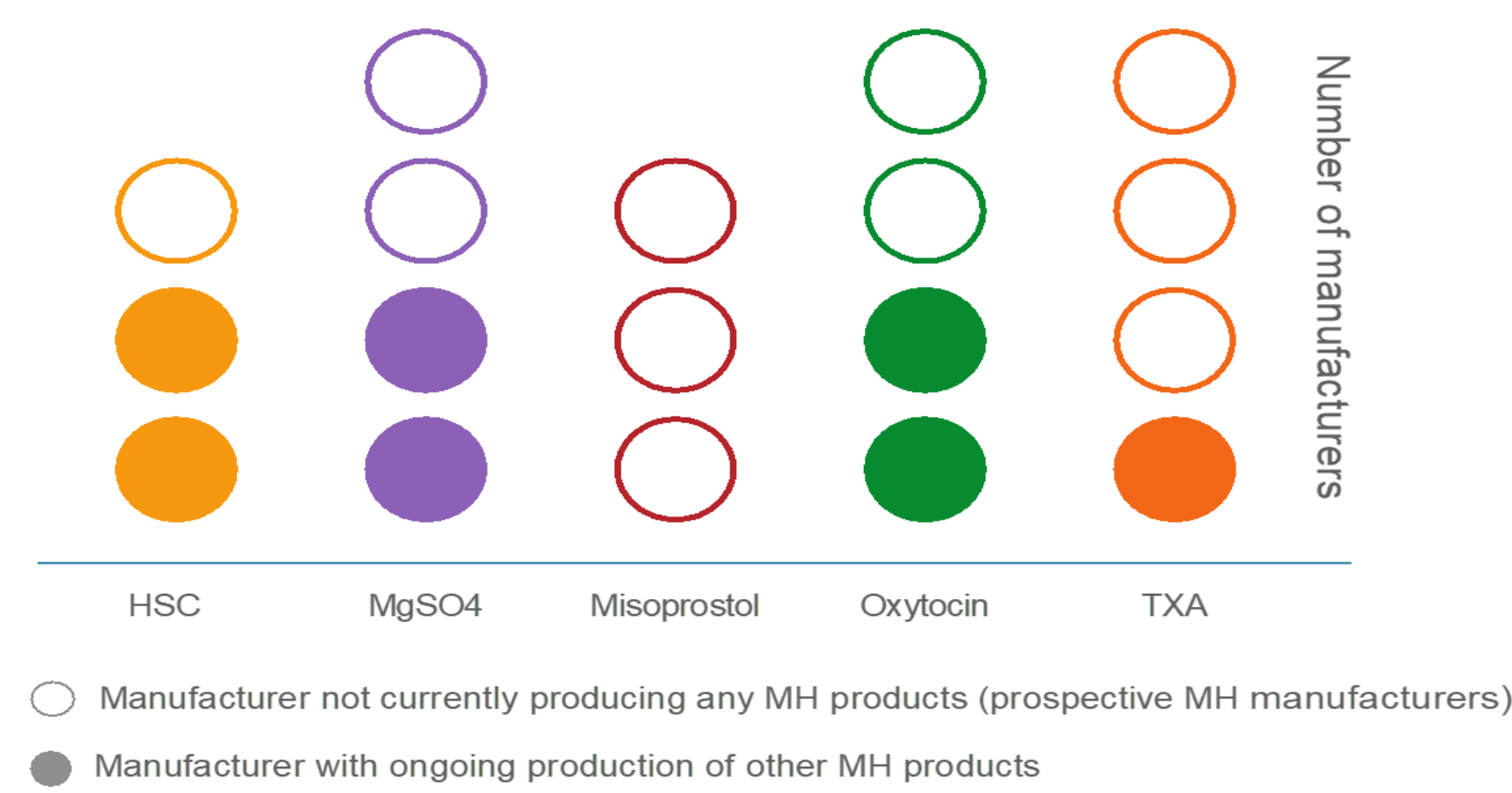
- Low utilization rates: from 10% to 60% (median 40%)
- Main buyers: Public health systems (50% to 100%), pharmacies, and private hospital; No NGO or Donors
- Most batches are produced based on customer order (60% to 100%) and stock inventory
- Two magnesium sulfate manufacturers are currently pursuing WHO-PQ

Results



Snapshot of MH products	Countries	Strength	Annual production capacity
Magnesium sulfate	4 producers in Ethiopia, Kenya, Nigeria, South Africa	50% w/v	~150 million ampules
Oxytocin	1 producer in Nigeria	200 mcg	800 kg or 4 million tablets
Misoprostol	1 producer in Nigeria	10 IU/2mL	600 kg
Tranexamic acid	1 producer in Kenya	500 mg/2 mL	800 kg or 1.6 million ampules
Heat-stable carbetocin	0 producers		

Planned production expansion of MH products



Current manufacturing of MH products in Africa

- Main buyers: Public health systems (50% to 100%), pharmacies, and private hospitals; **No NGO/Donors**
- Low utilization rates: 10% to 60% (median 40%)
- Most batches are produced based on customer order (60% to 100%) and stock inventory
- 2 magnesium sulfate manufacturers are currently pursuing WHO-PQ

Planned manufacturing of MH products in Africa

- Prospective MH manufacturers plan to rely on technology transfer to produce ~85% of their MH products and develop 15% in-house.
- Most prospective MH manufacturers plan to begin production of one or more products in 1-2 years.

Recommendations

- Maintain an up-to-date national medicines regulatory authority (NMRA) registration database and foster information sharing among national regulatory bodies.
- Increase harmonization and convergence among NMRAs and regional regulatory authorities to streamline product registration and align fees, approvals, and processes.
- Strategically diversify the manufacturing footprint of MH commodities across the region, while ensuring that new production lines don't exceed regional demand or dilute the market.
- Build capacity for regional manufacturers to more efficiently navigate regulatory processes, improve good manufacturing practices (GMP), and absorb new technologies and skills.
- Support manufacturers through technical assistance in achieving WHO prequalification and stringent regulatory authority approvals.
- Create knowledge-sharing platforms among manufacturers to exchange best practices, regulatory insights, and market information.
- Prioritize procurement from regional manufacturers and track procurement volumes of regionally manufactured products as a supply chain disruption mitigation strategy.
- Establish comprehensive market sizing for MH products to facilitate accurate demand estimates and increase transparency of market data.
- Consider market shaping interventions such as guaranteed procurement volumes and pooled procurement mechanisms.

Conclusion

Strengthening the manufacturing capacity is crucial for enhancing maternal health outcomes. There is need for targeted policy interventions, investment in manufacturing infrastructure, and collaborative efforts to build a more self-sufficient and resilient health supply chain in the region. Enhancing local production capabilities can contribute to the availability of essential MH products, ultimately reducing maternal mortality in SSA.

