



COMPASS INITIATIVE SERIES: REGIONALIZATION

Manufacturing MH supplies in Africa

Results from landscape assessment

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USP's enduring 200-year mission

“Increase the supply of safe, effective **medicines, vaccines, and trusted diagnostics**. USP strengthens health systems at local, regional, and global levels and delivers end-to-end pharmaceutical services that champion **equitable access to quality medical products**.”



Report overview

In sub-Saharan Africa, disruptions in health supply chains, limited regional pharmaceutical production, and reliance on foreign imports impede availability of essential maternal health (MH) products.

Manufacturing Landscape

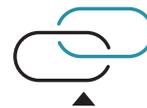
Products: Heat-stable carbetocin (HSC), magnesium sulfate, misoprostol, oxytocin, and tranexamic acid (TXA)

Countries: Ethiopia, Kenya, Uganda, Tanzania, Zimbabwe, Nigeria, Ghana, and South Africa



About the study

USP and RHSC conducted a landscape analysis to assess the demand for and manufacturing capacity of five essential MH commodities in eight countries across Africa.



Why it matters

In 2020, approximately 287,000 women died due to preventable causes related to pregnancy and childbirth. Most deaths were due to postpartum hemorrhage (PPH), and nearly 70 percent occurred in sub-Saharan Africa. Quality-assured MH products are crucial to reducing maternal mortality.



Key findings

Our analysis of the availability and sources of MH products, regional manufacturers, and strength and dosage of registered products across SSA found the following:

- **Overreliance on foreign imports**

- Based on supply data collected, the continent is highly dependent on foreign supply chains

- **More diverse, African-based producers needed**

- Only 6 manufacturers from 4 countries (Ethiopia, Kenya, Nigeria, and South Africa) are actively involved in the production of MH products.
- Only one product was manufactured by multiple African-based producers; however, those manufacturers are currently experiencing significant challenges with production capacity and distribution.



Key findings



4 OUT OF 5



essential MH products are either produced by a single African-based manufacturer or by none at all.



Key findings

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		

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

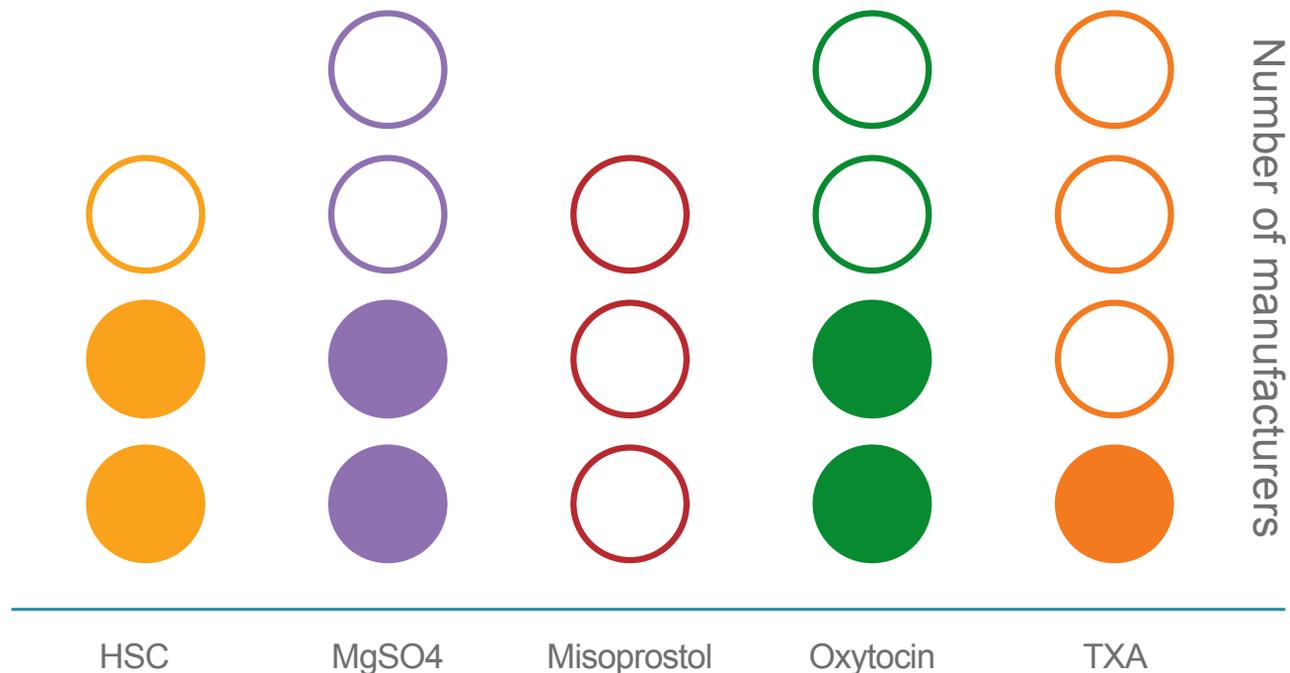


Key findings

Planned production expansion of MH products

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.



- Manufacturer not currently producing any MH products (prospective MH manufacturers)
- Manufacturer with ongoing production of other MH products



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.



Recommendations



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.



Recommendations



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.



Thank you!

