

Enabling regional manufacturing of maternal health products in SSA

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Assessment of supply of the MH products in sub-Saharan Africa

Efforts to strengthen the supply of the quality-assured products sources should be **strategic, market-based** and carried out with **cross-sectional support**.

Landscape Analysis

Goal: Understand the demand, supply, and local/regional manufacturing of maternal health (MH) products and interventions required to build a more reliable and sustainable supply in Sub-Saharan Africa










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

Products included:

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

1. Assess the supply of MH products in SSA.
2. Assess the demand from major procurers.
3. Identify all reproductive maternal health (RMH) manufacturers and product suppliers in SSA.
4. Assess manufacturer capacities, including production capacity, quality assurance systems, regulatory status, and existing customer base.
5. Identify the significant gaps and challenges to expanding manufacturing.
6. Determine the actions and resources to address gaps and challenges.

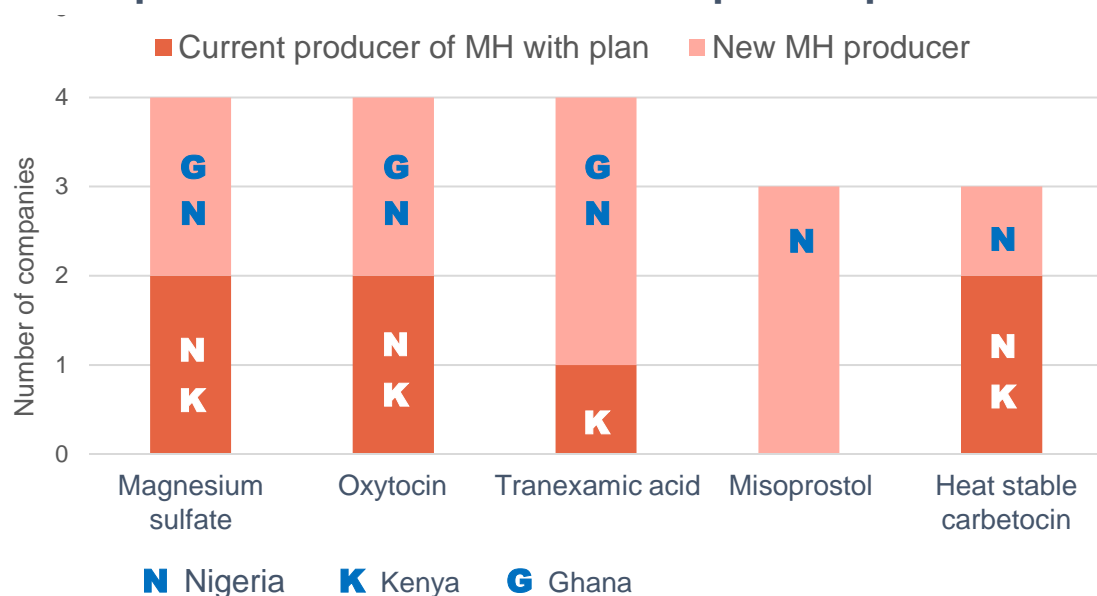
Current manufacturing of MH products in SSA

MH products and countries of production	Strength produced	Annual production capacity
Magnesium sulfate     NIGERIA KENYA ETHIOPIA SOUTH AFRICA	50% w/v	Approximately 150 million 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

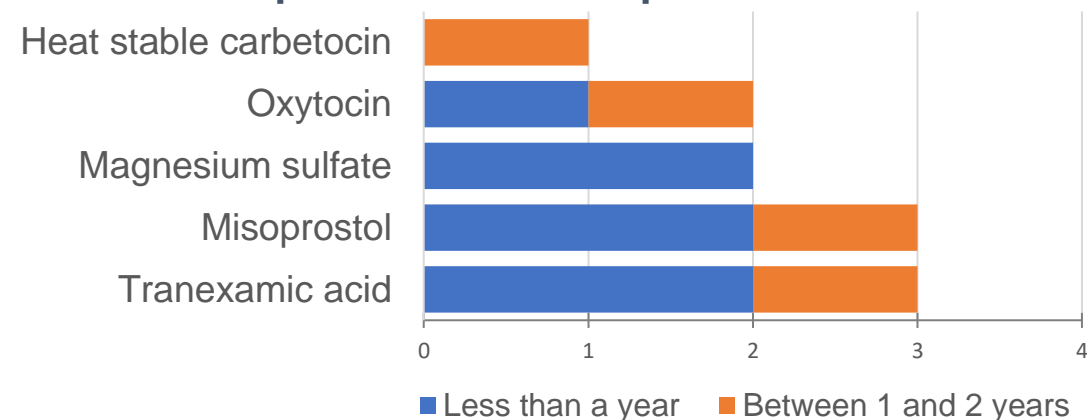
- Main buyers: **Public health systems (50% to 100%)**, pharmacies, and private hospital; No NGO or Donors
- Low utilization rates: from **10% to 60% (median 40%)**
- Most batches are produced based on **customer order (60% to 100%)** and stock inventory
- Two magnesium sulfate manufacturers are currently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

Future manufacturing plans in SSA

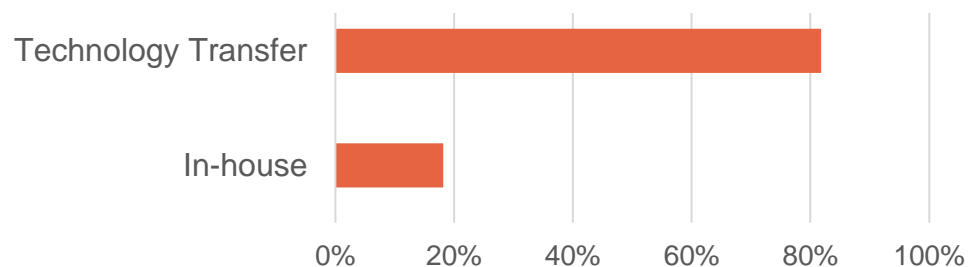
MH products the manufacturers plan to produce



Timeline for production of MH products



Future MH manufacturers responses



MH Products	Potential number of manufacturers
Heat stable carbetocin	3
Magnesium sulfate	8
Misoprostol	4
Oxytocin	5
Tranexamic acid	5

Challenges of MH manufacturers in SSA

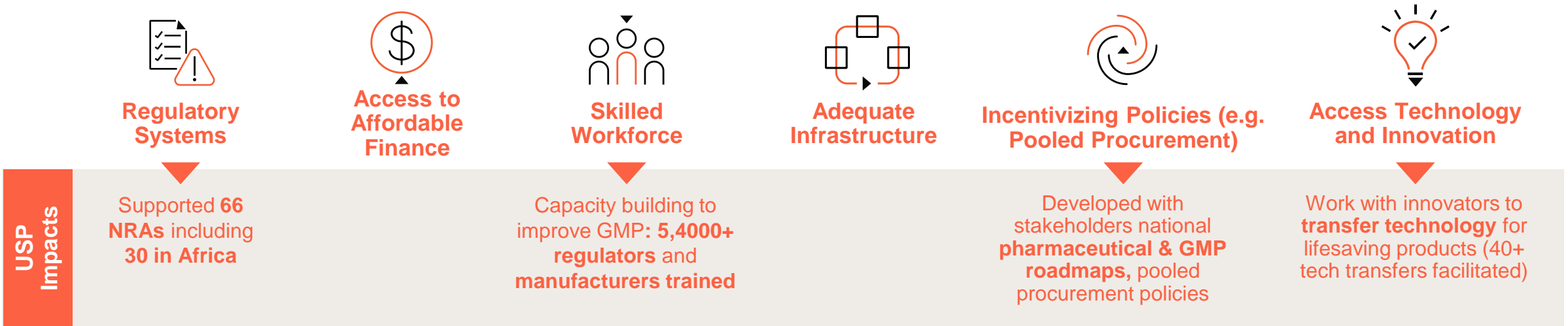
Challenges impacting manufacturers	Examples of needed intervention (manufacturers' responses)
Market factors	<ul style="list-style-type: none">• Supportive policies and local, regional, and international donors that increase procurements from local producers• Access to affordable financing• Improved conditions to access regional and continental markets• Local policies to support local manufacturers
Technical factors	<ul style="list-style-type: none">• Access to technology and know-how, including technology transfer opportunities• Technical assistance to improve technical capability including capacity for formulation and R&D• Technical support toward SRA approval and WHO prequalification
Regulatory factors	<ul style="list-style-type: none">• Efficient and timely dossier review and approval• Regional regulatory harmonization, including harmonization of registration and faster dossier evaluation

Our Recommendations

Regulatory	Maintain up-to-date NMRA registered products
	Improve the consistency of NMRA reporting of key indicators
	Foster information sharing and sustain efforts towards regional harmonization or convergence
Regional manufacturing	Diversify the manufacturing footprint across the region
	Support technical assistance to build capacity
	Create knowledge sharing platforms
Procurement	Establish comprehensive market sizing for MH products in SSA
	Guarantee volume through pooled procurement
	Prioritize procurement from local manufacturing

Framework for regional manufacturing of quality products

Regional manufacturing requires an **ecosystem**...



...and **partnerships** with various stakeholders to advance localize and sustainable regional manufacturing capacity



Thank You



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