

Supply of manufacturing of maternal health products in SSA

Dr. Perrerr Tosso, United States Pharmacopeia

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About United States Pharmacopeia

- A global scientific, independent, nonprofit organization that has been expanding access to quality medical products for more than 200 years
- Our mission: To improve global health through standards and programs that ensure the quality, safety, and benefit of medicines and foods
- Our standards: Used in 140 countries
 - *More than 2 billion people have access to quality medicines, dietary supplements, and food as a result of USP standards, advocacy, and education*
- Managing global programs for more than 65 years
 - *Implemented global health programs in <50 low- and middle-income countries (LMICs)*
 - *3 state-of-the-art laboratories and training facilities in the USA, Ghana, and India*

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

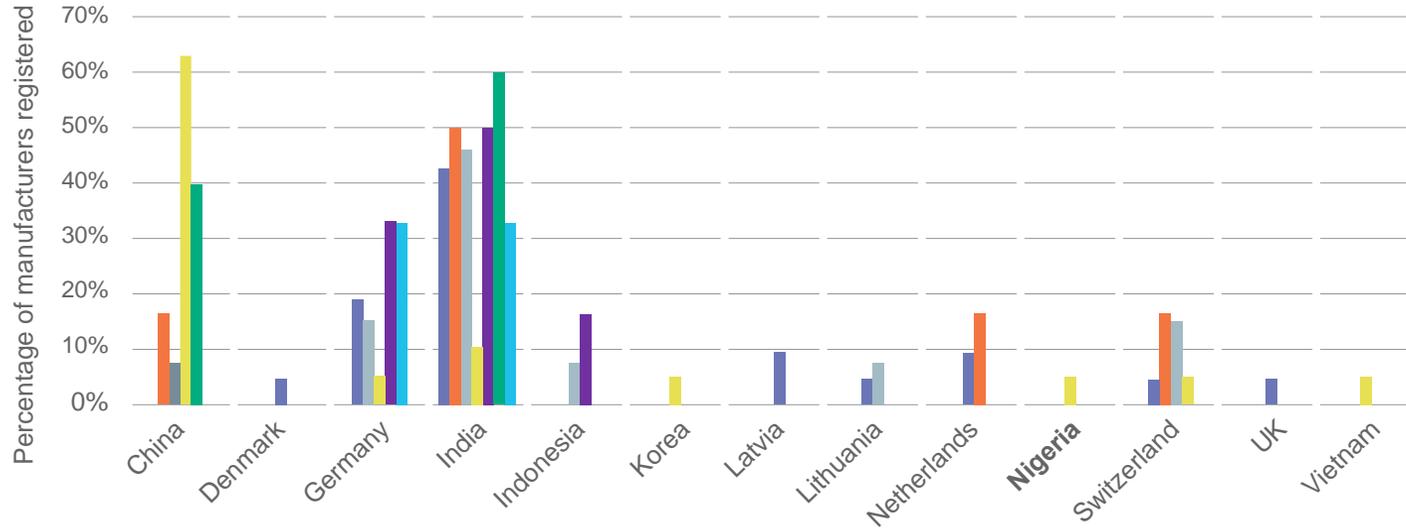
Focus Countries: Ethiopia, Kenya, Uganda, Tanzania, Zimbabwe, Nigeria, Ghana, and South Africa

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.

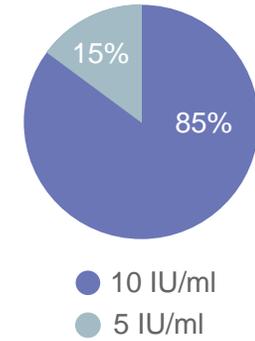
Supply of oxytocin



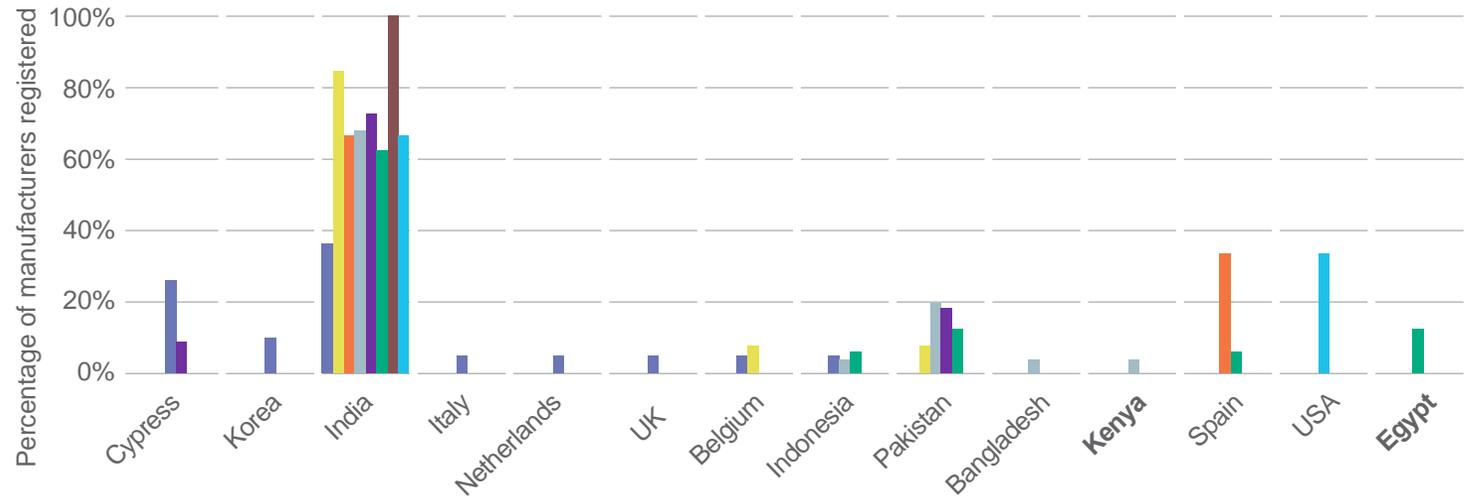
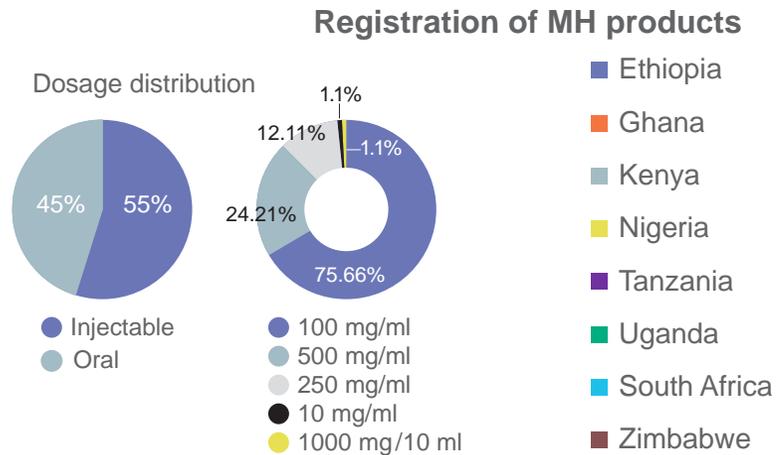
Registration of MH products

- Ethiopia (n=21)
- Ghana (n=6)
- Kenya (n=13)
- Nigeria (n=19)
- Tanzania (n=6)
- Uganda (n=5)
- South Africa (n=3)

Dosage distribution



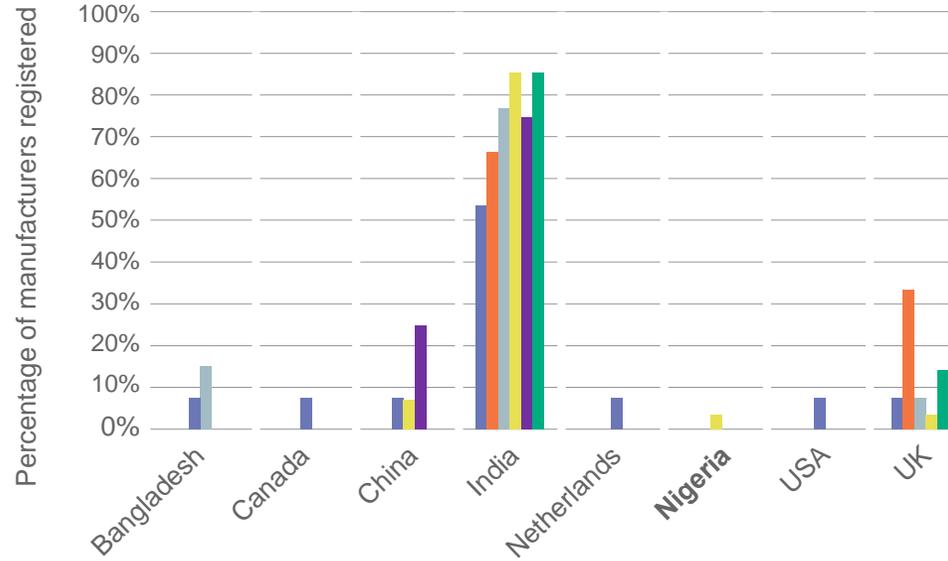
Supply of tranexamic acid



Supply of misoprostol

Registration of MH products

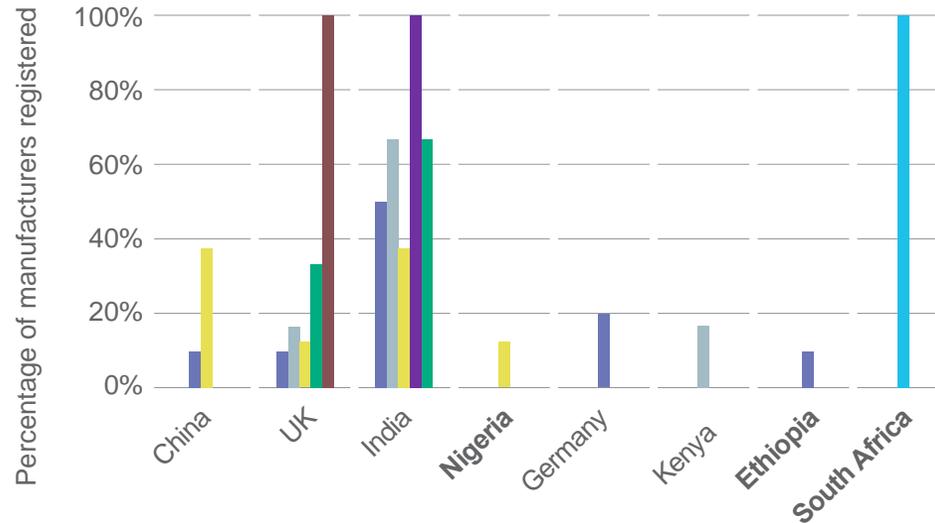
- Ethiopia
- Ghana
- Kenya
- Nigeria
- Tanzania
- Uganda



Supply of magnesium sulfate

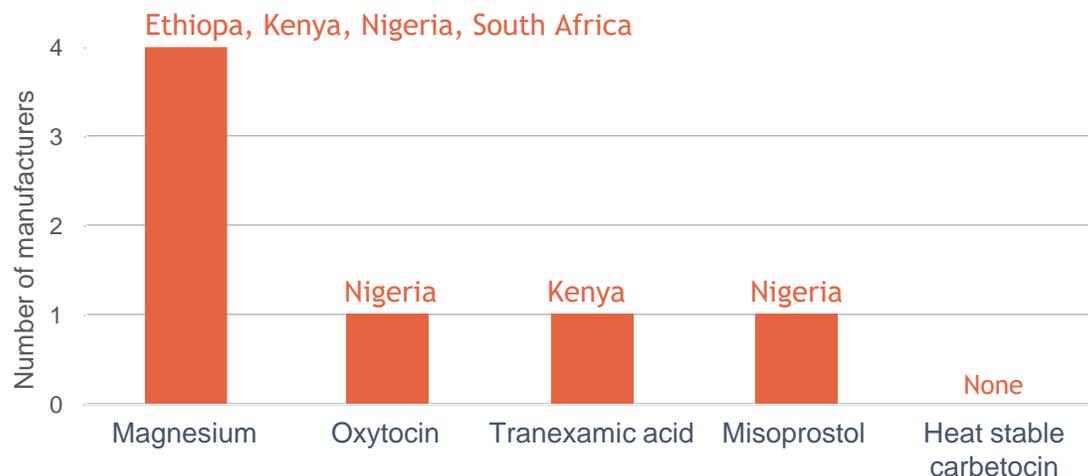
Registration of MH products

- Ethiopia (n=10)
- Kenya (n=6)
- Nigeria (n=8)
- Tanzania (n=1)
- Uganda (n=3)
- South Africa (n=1)
- Zimbabwe (n=1)

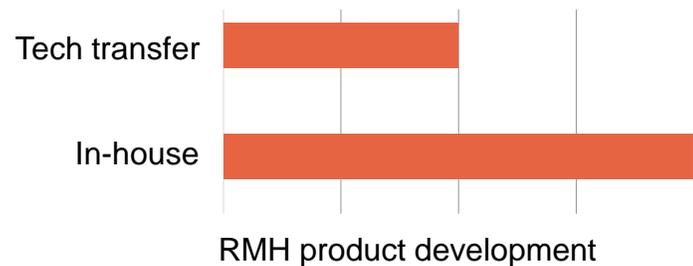


Manufacturing of MH products in SSA

Four MH products are manufactured in SSA



Most manufacturers developed products in-house



Challenges

- Competition from import
- Shortage of skilled labor for R&D, formulation, and engineering
- Limited timely access to equipment and spares
- lack of regulatory harmonization & slow and opaque national regulatory systems
- lack of market data & transparency around demand adversely impact local production

Interventions

- Regulatory harmonization & improving regulatory processes and approvals
- Providing support to manufacturers to build capacity in technical areas where gaps exists
- Implement policies that guarantees offtake of products from SSA manufacturers

Thank You



Perrer Tosso, Ph.D.

Director, Pharmaceutical Manufacturing Programs

Email: perrer.tosso@usp.org