Supply of manufacturing of maternal health products in SSA

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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**.

**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

**Landscape Analysis**

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

**Products included:**
- Oxytocin
- Magnesium sulfate
- Heat-stable carbetocin
- Misoprostol
- Tranexamic acid
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
- 10 IU/ml (85%)
- 5 IU/ml (15%)

Supply of tranexamic acid
Supply of misoprostol

Supply of magnesium sulfate
Manufacturing of MH products in SSA

**Four MH products are manufacturered in SSA**

<table>
<thead>
<tr>
<th>Product</th>
<th>Number of manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium</td>
<td>4</td>
</tr>
<tr>
<td>Oxytocin</td>
<td>3</td>
</tr>
<tr>
<td>Tranexamic acid</td>
<td>2</td>
</tr>
<tr>
<td>Misoprostol</td>
<td>2</td>
</tr>
<tr>
<td>Heat stable carbetocin</td>
<td>None</td>
</tr>
</tbody>
</table>

**Ethiopia, Kenya, Nigeria, South Africa**

**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

**Most manufacturers developed products in-house**

<table>
<thead>
<tr>
<th>Tech transfer</th>
<th>In-house</th>
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</thead>
<tbody>
<tr>
<td>RMH product development</td>
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Thank You

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