Regulatory Barriers to Scale
Impact on Access to Maternal and Reproductive Health Supplies

i+solutions & Jhpiego
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Jhpiego is an international, non-profit health organization affiliated with The Johns Hopkins University. For 40 years and in over 155 countries, Jhpiego has worked to prevent the needless deaths of women and their families.

Jhpiego works with health experts, governments and community leaders to provide high-quality health care for their people. Jhpiego develops strategies to help countries care for themselves by training competent health care workers, strengthening health systems and improving delivery of care.

Jhpiego designs innovative, effective and low-cost health care solutions to ensure a level of care for women and their families. These practical, evidence-based interventions are breaking down barriers to high-quality health care for the world’s most vulnerable populations.
Over the last 10 years, i+solutions has provided services that support the procurement and distribution of essential medicines, supporting governments and organizations in their quest for creating sustainable access to medicines and health products. During this history, their portfolio has been continuously expanded and their services, adapted to local and contemporary needs.

i+solutions is active in a number of projects that aim to solve bottlenecks in the access to medicines in developing countries. Not only do they procure essential medicines and health products, but they also conduct training and consultancy activities so that countries can improve their health systems and eventually take full control of their pharmaceutical supply chain management.
Introduction to Regulatory Barriers to Scale
From Introduction to Scale: The Market Matters

Fig 1: Accelerating the Path to Introduction and Use

Source: USAID-Accelovate Program, 2014
Conclusion #1: RMNCH product availability and access is essential to the uptake of essential clinical interventions

Fig 2: Poor Drug Quality Reinforces Low Demand and Use
WHO’s Model Essential Medicines List provides an internationally recognizable set of selected medicines to help countries choose how to treat their priority needs.

- WHO, Behind the Essential Medicines List
Regulatory barriers negatively impact access to essential RMNCH health supplies

Conclusion #2: Barriers that threaten a strong regulatory environment ultimately threaten access to essential RMNCH supplies

Conclusion #3: Addressing regulatory barriers begins translating global standards into national policies

Regulatory Barriers
- Lack of clear legislative framework
- Unclear standards
- Inconsistent enforcement of regulatory standards
- Dispersion of regulatory responsibilities
- Lack of experience and qualified staff
- Lack of political support

Impact on access to RMNCH supplies
- Delayed access
- Inability to provide clear guidance
- Lack of sufficient safety and efficacy data
- Inappropriate risk-benefit assessment for wider use
Approaches to Regulatory Intervention

Registration of Medicines
(Also known as Market Authorization or Product Licensing)
An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality” [...].

World Health Organization, 1999
Approaches to Regulatory Intervention
Overcoming Medical Device Registration

1. Manufacture or authorized representative start the process
2. Dossier submission
3. MRA Received and evaluate the Dossier
4. Request of clarification or additional information
5. Market Registration approved
Approaches to Regulatory Intervention
Registration process

**Medicines**
- Type 1: Bioequivalent (generic)
- Type 2: Existing regimen combination
- Type 3: Not existing regimen combination
- Type 4: New entity products

**Medical devices**
- Class I
- Class II
- Class III (II b)
- Class IV

**Vaccines**
- Class A
- Class B
- Class C
- Class D

Canada, USA EU, Australia, Ethiopia, Ghana
Tanzania, Kenya, South Africa
UN Commission on Life-Saving Commodities

UNCoLSC Goals

- Define a list of overlooked life-saving commodities for women and children
- Identify key barriers preventing access to and use of these commodities
- Recommend innovative action to rapidly increase both access and use
Magnesium Sulfate
General Barriers to Commodity Access

- Insufficient Supply
- Inability to Regulate Supply
- Low Awareness and Demand

Compromised Access
Specific Barriers to Magnesium Sulfate Access

1. Lack of demand among health workers
2. Very small profit margins
3. Cumbersome market authorization processes
4. No WHO prequalified product
5. Not included in national essential medicine lists

Compromised Access
Combatting Barriers to Commodity Access

- Insufficient supply
- Inability to regulate supply
- Low awareness and demand

Compromised access

- Improve stakeholder engagement
- Increased education and training
- Update difficult policies and regulations
- Guide manufacturers to market entry

Improved access
Path to Improved Access

- Clarify International Standards
- Stakeholder Engagement and Education
- Modify Regulatory Environment
- Guide Manufacturers to Market
- Regulate Commodity Quality
Path to Improved Access

Foundational Steps

- Clarify International Standards
- Stakeholder Engagement and Education
- Modify Regulatory Environment
- Guide Manufacturers to Market
- Regulate Commodity Quality
Accelovate’s Work

Modify Regulatory Environment

Guide Manufacturers to Market
Path to Improved Access

- Clarify International Standards
- Stakeholder Engagement and Education
- Modify Regulatory Environment
- Guide Manufacturers to Market
- Regulate Commodity Quality
There is no single RIGHT pathway to scale.
THANK YOU
Overcoming Regulatory Barriers to Promote Variety of Female Condoms
Introduction to the UAFC Program

Universal access to Female Condom

• OPO 1: To increase availability and affordability of Quality assured Female Condoms

• OPO 2: To increase a sustained demand of Female Condoms at local level

• OPO 3: To support global and local policy makers and donors.
Introduction to the UAFC Program

OPO1: To increase availability and affordability of Quality assured Female Condoms

Activities:
- To assist in-country programs in SCM related activities (pool procurement, LMIS software, distribution)
- To support FC manufactures in the WHO prequalification process
- To support FC manufactures in-country registration process
Female Condom Registration Requirements

Methodology

Data collection methodology
Mixed Questionnaire (open and closed questions)

Source of information
MRA (medicines regulatory agencies)
Official MRA’s website or its direct personnel.
FC manufactures
International organization’s Reports (complementary)

Sample
26 countries were identified
Inclusion criteria: Countries with FC consumption level
Countries with FC manufacturing capacities
Countries with Stringent Regulatory authorities

15 completed the questionnaires
Africa: RD Congo Ethiopia Tanzania Zimbabwe Nigeria Rwanda Kenya Ghana South Africa South Africa
South America: Peru, Brazil
Asia: Bangladesh India Indonesia Malaysia
Female Condom Registration Requirements
Overview of FC Registration Pathway

Mixed Questionnaire (open and closed questions)
- Are condoms (male/female) regulated in the country?
- If yes, describe the applicable regulation or directive
- Condom classification (medical device, medicines, others)
- Essential medicine list:
  - Condoms on EML
  - Female Condom specified on EML
- National competence authority
- Registration requirements
  - Applicant eligibility
  - Administrative and technical documents
  - Sample
  - Label Requirements
  - Timeline

(Email format used for data collection)
# Female Condom Registration Requirements

## Findings

<table>
<thead>
<tr>
<th>Question</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are condoms (male/female) regulated in the country?</td>
<td>14 out of 15 countries condoms are regulated (no in Bangladesh)</td>
</tr>
<tr>
<td>If yes, describe the applicable regulation or directive</td>
<td>9 out of 15 regulation is secured with a local laws or acts</td>
</tr>
</tbody>
</table>
| Condom classification (medical device, medicines, others) | 15 out of 15 NRAs classified as a medical device  
9 out of 15 NRAs specified the type (class II or Class C)                                                        |
| National competence authority                 | 6 out of 15 National Authorities has a separate entity for Registration process                                                           |
## Data Outline: EMCI Portal

<table>
<thead>
<tr>
<th>Question</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condoms on EML</td>
<td>13 out of 15 countries include condoms</td>
</tr>
<tr>
<td>Female Condom specified on EML</td>
<td>10 out of 15 countries do not include Female Condoms</td>
</tr>
<tr>
<td>Registration requirements</td>
<td>Applicant eligibility: Manufacture or Authorized rep.</td>
</tr>
<tr>
<td></td>
<td>Administrative and technical documents</td>
</tr>
<tr>
<td></td>
<td>Timeline: 2 (Nigeria) - 9 month (Tanzania)</td>
</tr>
<tr>
<td></td>
<td>Registration: $365 (Peru) - $2,500 (India)</td>
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<tr>
<td></td>
<td>Validation: 3 years (Ghana) - 5 years (Rwanda)</td>
</tr>
</tbody>
</table>
Data Outline: FMCI Portal
## Medicines Registration: International Initiatives

<table>
<thead>
<tr>
<th>Region / Organization</th>
<th>Initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMDRF</td>
<td>Regulatory Harmonization</td>
</tr>
<tr>
<td>WHO</td>
<td>Collaborative registration in PQ Process</td>
</tr>
<tr>
<td>US FDA</td>
<td>Accelerated approval, Tentative approval</td>
</tr>
<tr>
<td>EU EMEA</td>
<td>Conditional Approval, Article 58</td>
</tr>
<tr>
<td>AFRICA</td>
<td>EAC Medicines Registration Harmonization project, Africa Medicine Regularly Harmonization Program</td>
</tr>
<tr>
<td>LATIN AMERICA</td>
<td>Red panamericana para la armonización de la regulación farmacéutica (red PARF)</td>
</tr>
<tr>
<td>ASIA</td>
<td>... ?</td>
</tr>
</tbody>
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Questions and Discussion