Regulatory Barriers to Scale

Impact on Access to Maternal and Reproductive Health Supplies

i+solutions & Jhpiego

9 OCTOBER 2015

innovating to save lives

Jhpiego

an affiliate of Johns Hopkins University

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.

i+solutions
universal access to essential medicines

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.

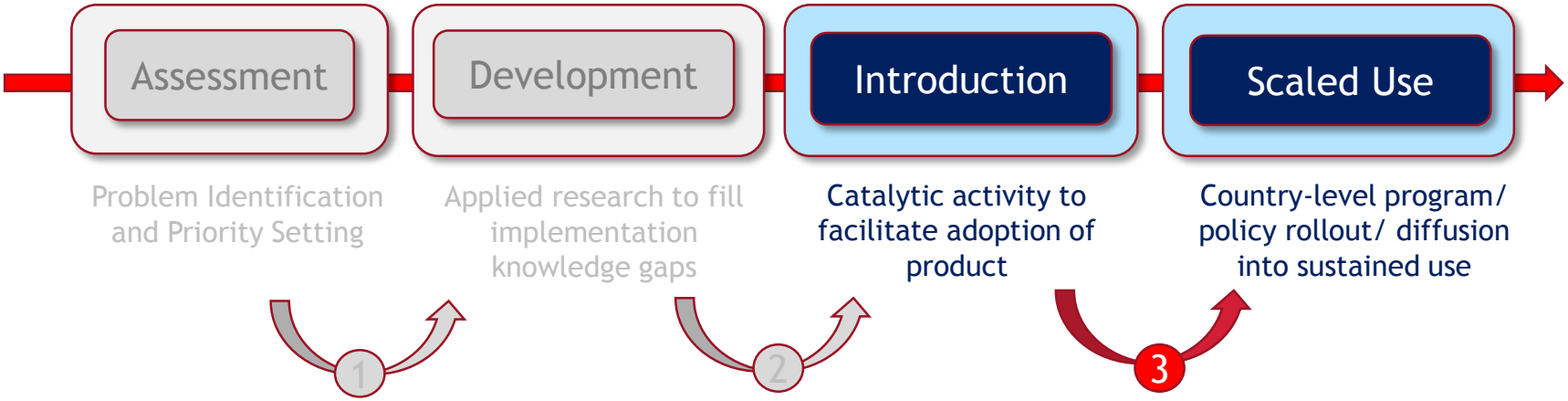
i+solutions is active in a number of projects that aim to solve bottlenecks in the access to medicines in developing countries. Not only do they procure essential medicines and health products, but they also conduct training and consultancy activities so that countries can improve their health systems 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

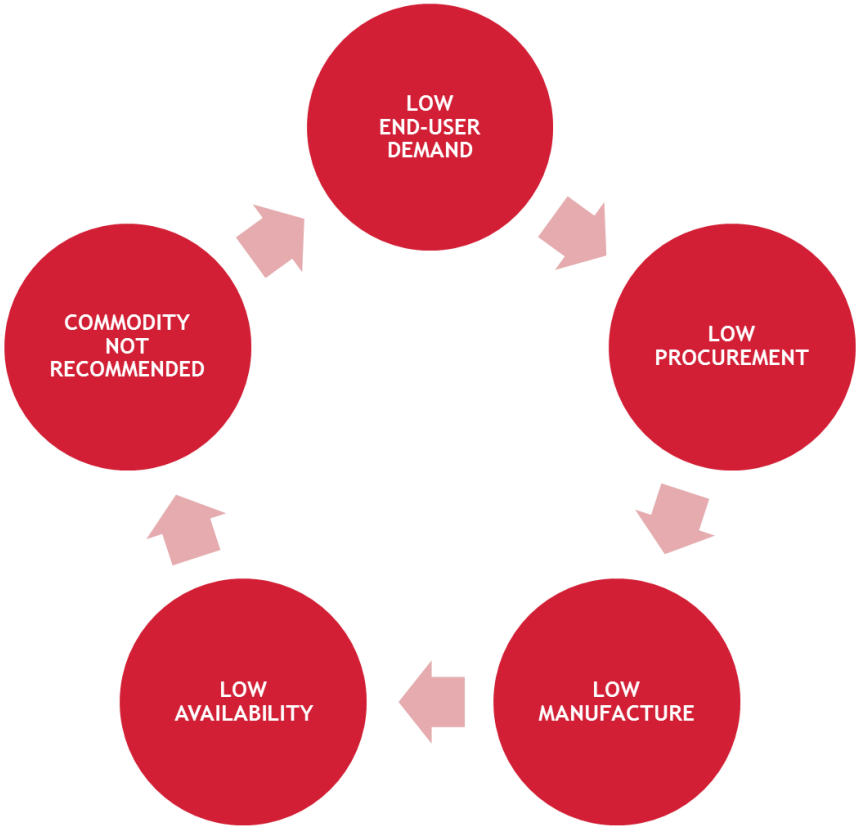
Source: USAID-Accelovate Program, 2014



From Introduction to Scale: The *Well-Regulated* Market Matters

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

Manufacture or authorized representative start the process

Dossier submission

MRA Received and evaluate the Dossier

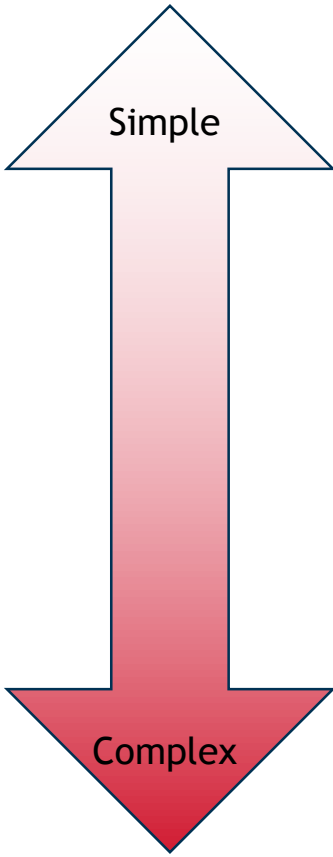
Request of clarification or additional information

Market Registration aproved

Approaches to Regulatory Intervention

Registration process

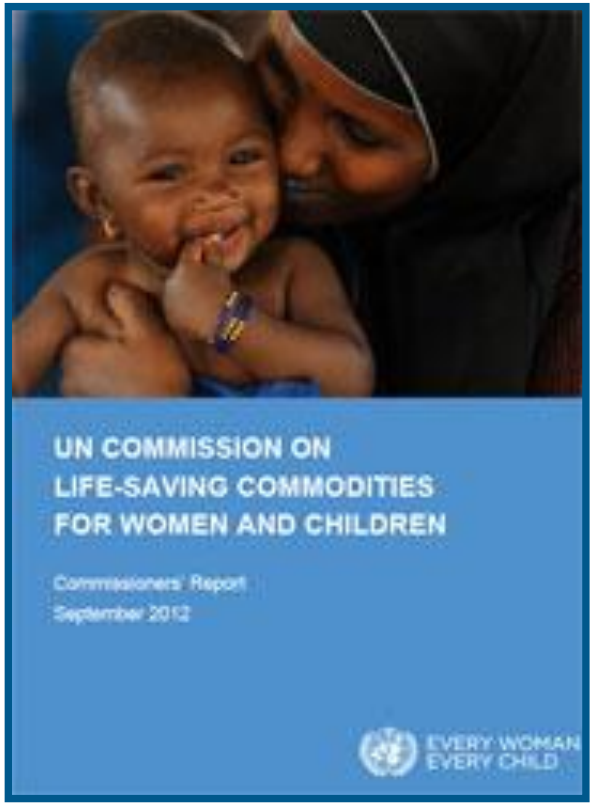
Medicines	Medical devices		Vaccines
Type 1 Bioequivalent (generic)	Class I	Class A	
Type 2 Existing regimen combination	Class II	Class B	
Type 3 Not existing regimen combination	Class III (II b)	Class C	
Type 4 New entity products	Class IV	Class D	vaccines
	Canada, USA EU, Australia, Ethiopia, Ghana	Tanzania, Kenia, 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

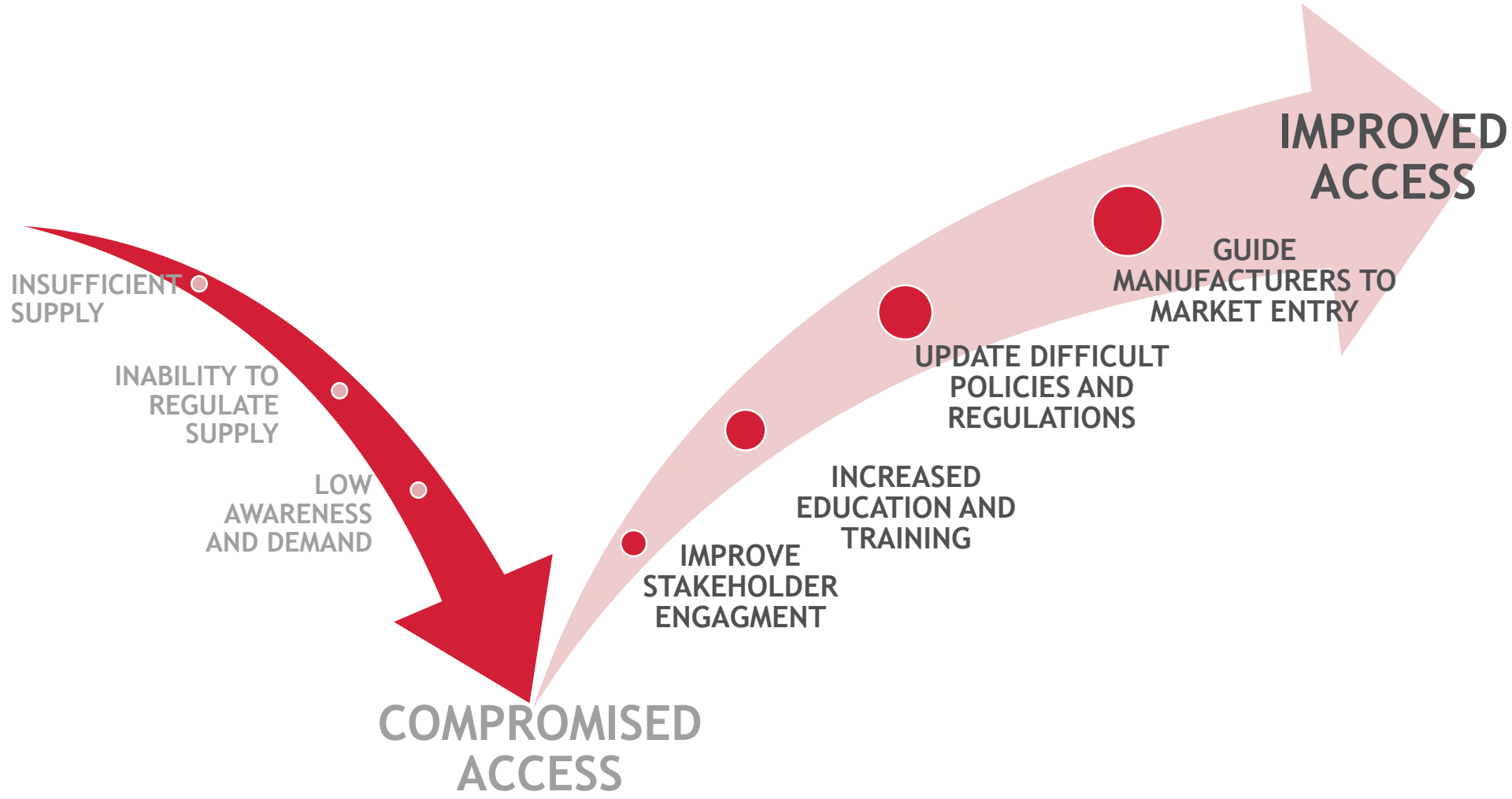
General Barriers to Commodity Access

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



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

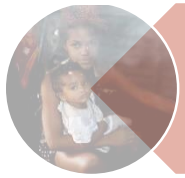
Foundational Steps

Clarify International Standards

Stakeholder Engagement and Education

Accelovate's Work

Modify Regulatory Environment



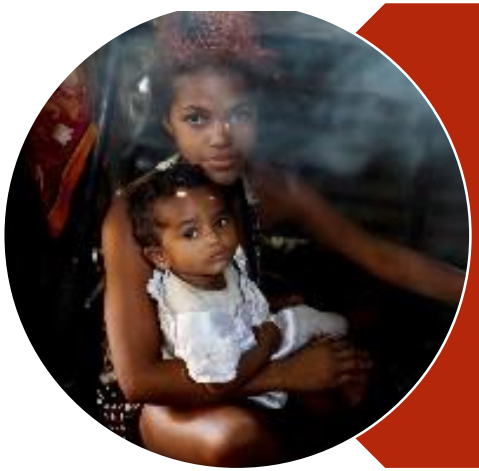
Guide Manufacturers to Market

Sustaining Steps

Regulate Commodity Quality

Accelovate's Work

Modify Regulatory Environment



Guide Manufacturers to Market

Path to Improved Access

Foundational Steps

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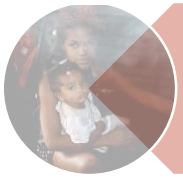
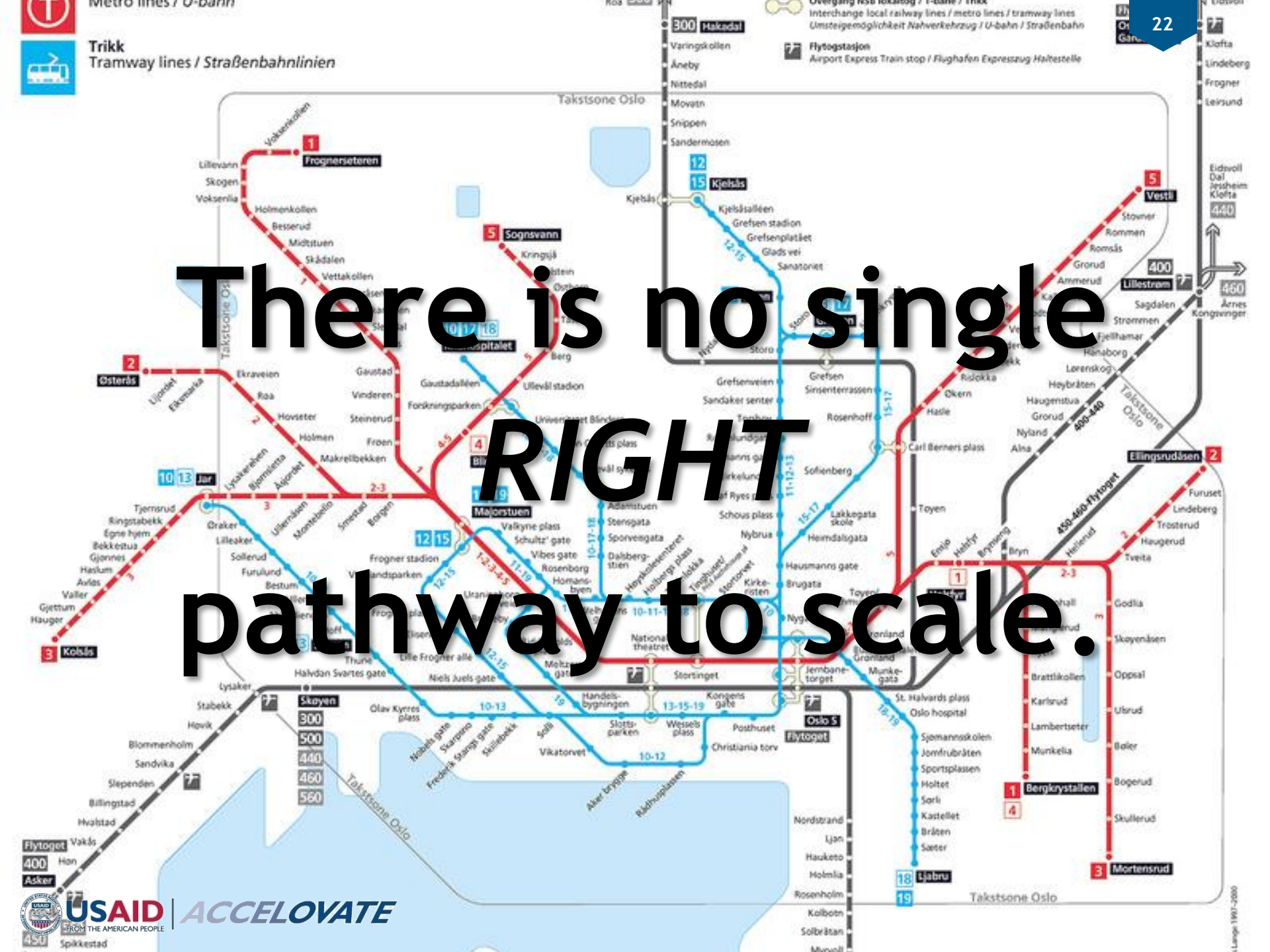
Modify Regulatory Environment



Guide Manufacturers to Market

Sustaining Steps

Regulate Commodity Quality


Metro lines / U-bahn
Trikk
Tramway lines / Straßenbahnlinien
Interchange local railway lines / metro lines / tramway lines
Umsteigemöglichkeit Nahverkehrzug / U-bahn / Straßenbahn
Flytogstasjon
Airport Express Train stop / Flughafen Expresszug Haltestelle
Takstsone Oslo
Frognerseteren
Kjelsås
Vestli
Sognsvann
Østerås
Majorstuen
Jar
Kolsås
Skøyen
Oslo S
Flytoget
Asker
Lillestrøm
Ellingsrudåsen
Bergkrystallen
Mortensrud
Ljabru
There is no single
RIGHT
pathway to scale.
USAID
FROM THE AMERICAN PEOPLE
ACCELOVATE

THANK YOU

Overcoming Regulatory Barriers to Promote Variety of Female Condoms

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female CONDOMS 4 All
UAFC
joint programme

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
- OPO3: To support global and local policy makers and donors.

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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

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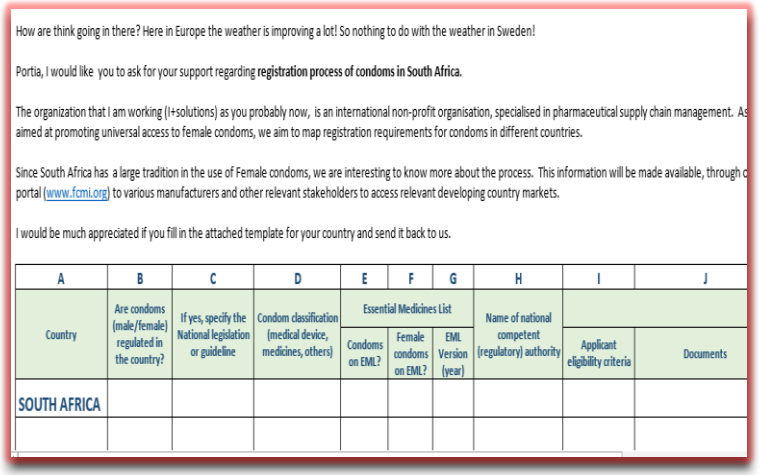
Female Condom Registration Requirements

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
- …



How are think going in there? Here in Europe the weather is improving a lot! So nothing to do with the weather in Sweden!

Portia, I would like you to ask for your support regarding **registration process of condoms in South Africa.**

The organization that I am working (I+solutions) as you probably now, is an international non-profit organisation, specialised in pharmaceutical supply chain management. As aimed at promoting universal access to female condoms, we aim to map registration requirements for condoms in different countries.

Since South Africa has a large tradition in the use of Female condoms, we are interesting to know more about the process. This information will be made available, through c portal (www.fcmi.org) to various manufacturers and other relevant stakeholders to access relevant developing country markets.

I would be much appreciated if you fill in the attached template for your country and send it back to us.

A	B	C	D	E	F	G	H	I	J
Country	Are condoms (male/female) regulated in the country?	If yes, specify the National legislation or guideline	Condom classification (medical device, medicines, others)	Essential Medicines List			Name of national competent (regulatory) authority		
				Condoms on EML?	Female condoms on EML?	EML Version (year)		Applicant eligibility criteria	Documents
SOUTH AFRICA									

(Email format used for data collection)

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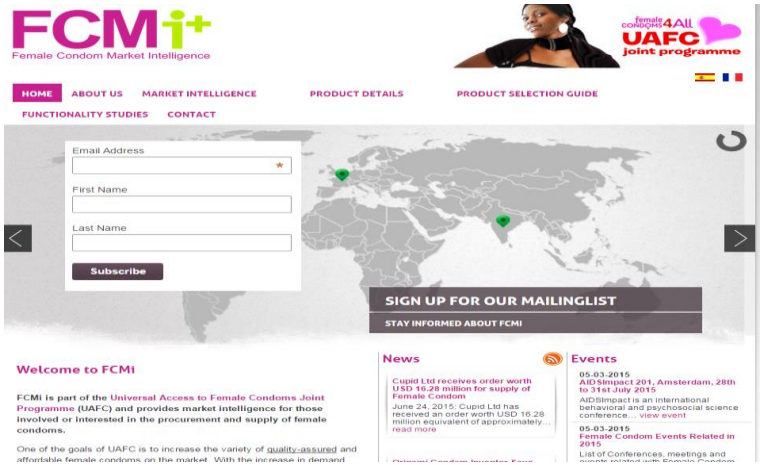
Female Condom Registration Requirements
Findings

Question	Outcomes
Are condoms (male/female) regulated in the country?	14 out of 15 countries condoms are regulated (no in Bangladesh)
If yes, describe the applicable regulation or directive	9 out of 15 regulation is secured with a local laws or acts
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

Question	Outcomes
Condoms on EML	13 out of 15 countries **include** condoms
Female Condom specified on EML	10 out of 15 countries do not include Female Condoms
Registration requirements	Applicant eligibility: Manufacture or Authorized rep.
	Administrative and technical documents
	Timeline: *2 (Nigeria) -9 month (Tanzania)*
	Registration: $365 (Peru) - $2,500 (India)
	Validation: 3 years (Ghana)- 5 years (Rwanda)

Data Outline: FMCI Portal



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Medicines Registration: International Initiatives

Region / Organization	Initiative
IMDRF	Regulatory Harmonization
WHO	Collaborative registration in PQ Process
US FDA	Accelerated approval Tentative approval
EU EMEA	Conditional Approval Article 58
AFRICA	EAC Medicines Registration Harmonization project Africa Medicine Regularly Harmonization Program
LATIN AMERICA	Red panamericana para la armonización de la regulación farmacéutica (red PARF)
ASIA	… ?

Questions and Discussion