

Improving Access to MNCH Medical Products in Low- and Middle-Income Countries

A Mapping of Registration of MNCH Medical Products
in Nine Countries

Jane Briggs
USAID MTaPS Program

Introduction



Leading causes of newborn and maternal mortality are **treatable with quality medicines**.



Most MNCH medicines are **procured by governments** using public sector funds rather than by donors.



A **strong regulatory system** is a critical public health priority—it ensures the safety, efficacy, and quality of medical products and improves outcomes for MNCH.



Registration or “marketing authorization”—often the most recognized regulatory function—evaluates the safety, efficacy, and quality of a product and the appropriateness of the product information before entering a market.



In many LMICs, challenges in the **registration process limit the availability** of lifesaving, quality-assured MNCH medical products.

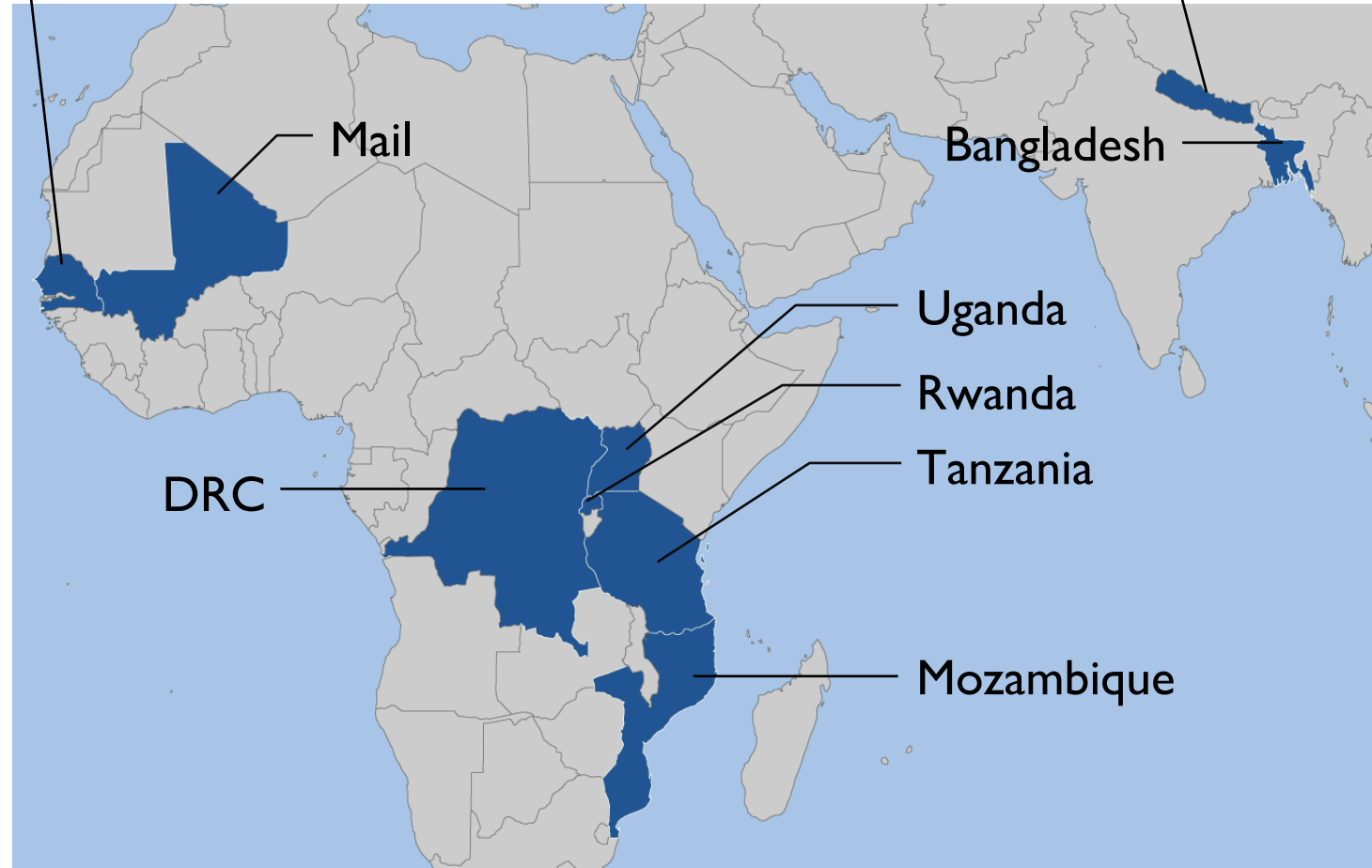
MTaPS conducted a nine-country study to assess the challenges in LMICs of registering MNCH and other essential medical products.

Methodology

- ✓ **Nine countries**
- ✓ The **registration status of 18 MNCH tracer medicines** was assessed through:
 - Interviews with regulators and pharmaceutical manufacturers
 - Policy and document review
 - Thematic analysis to identify major challenges

Senegal

Nepal



Mali

Bangladesh

Uganda

Rwanda

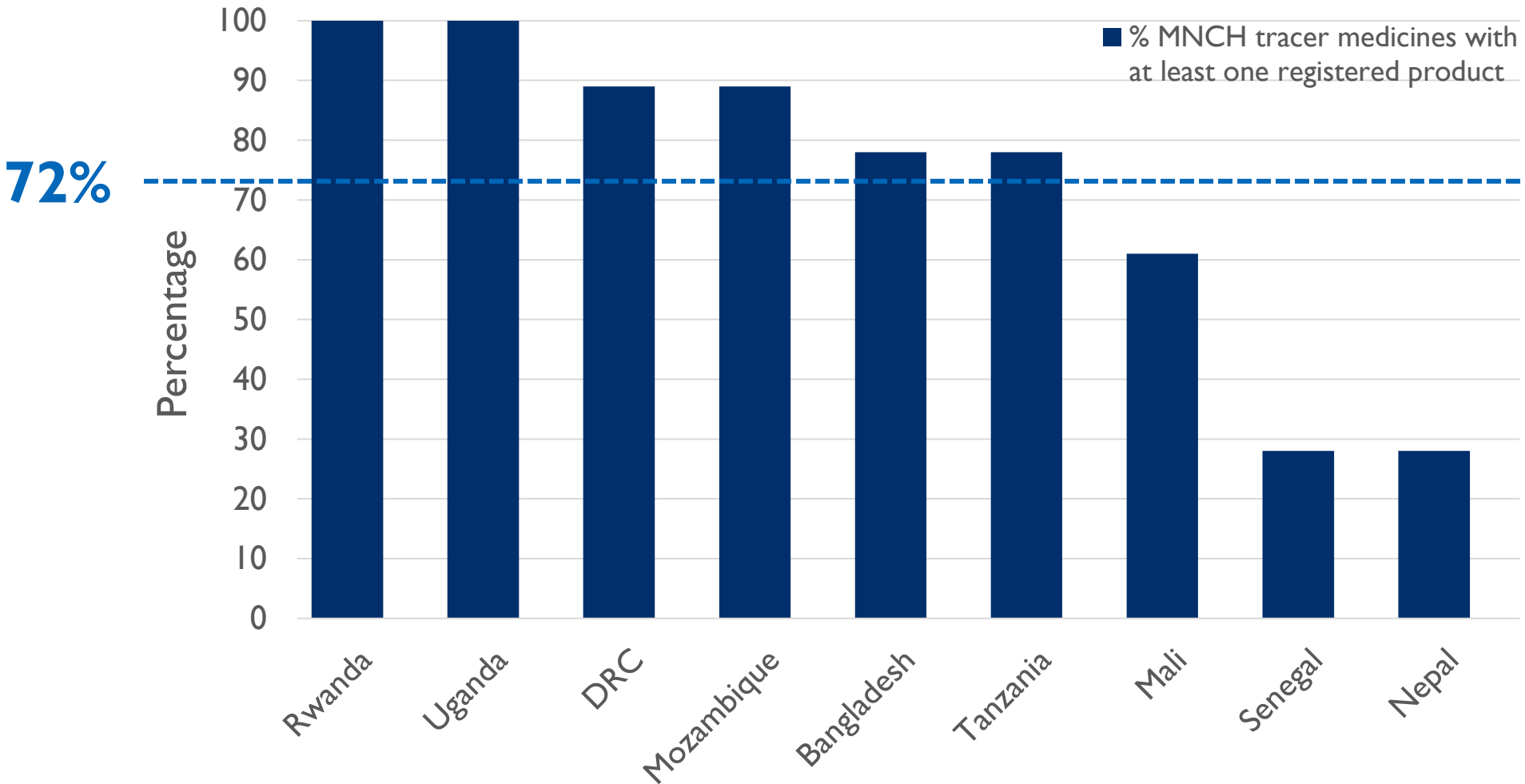
Tanzania

DRC

Mozambique



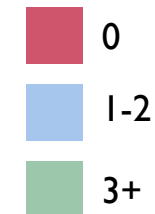
Registration status of MNCH tracer medicines



Registration status of MNCH tracer medicines

No.	Tracer Essential MNCH Medicines	Number of Registered Products								
		Rwanda	Uganda	DRC	Mozambique	Bangladesh	Tanzania	Mali	Senegal	Nepal
Maternal health medicines										
1	Hydralazine 20mg amp.				3					
2	Magnesium Sulphate 500mg/ml inj.	5				5				
3	Calcium Gluconate 1g/10ml inj.	3				9				
4	Tranexamic Acid 100mg inj. for IV	3	4			18	5			
5	Oxytocin 10IU/ml inj.	8	4			3	3	6		
6	Methyldopa 250mg tab.	12	4			10	5	4		
7	Misoprostol 200mcg tab.	6	5	3	8	20	4	3		
Newborn and child health medicines										
8	Procaine Benzylpenicillin 1g inj.	6	3							
9	Co-presentation of ORS/Zinc		3							
10	Amoxicillin 250mg dispersible tab.		8		6	10	4			
11	Amoxicillin 125mg dispersible tab.	3	3				3			
12	Benzylpenicillin 600mg inj.	4	3	4		3				
13	Zinc sulphate 20mg dispersible tablets	5	6		3	8	4			
14	Gentamicin 20mg inj or Gentamicin 80mg inj	7	4	5	8	27	5			
15	Chlorhexidine 7.1% solution or gel									
16	Amoxicillin 250mg/5ml syrup or suspension	10	3	5	23	4		12		
17	ORS low osmolarity 20.5g/1L sachets or ORS flavored 200ml sachets	3	4			4	7			
18	Ceftriaxone 250mg inj or Ceftriaxone 1g inj.	25	31	15	12	253	37	20	6	

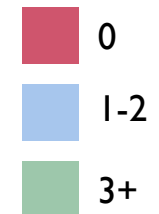
Number of registered products



Registration status of MNCH tracer medicines

No.	Tracer Essential MNCH Medicines	Number of Registered Products								
		Rwanda	Uganda	DRC	Mozambique	Bangladesh	Tanzania	Mali	Senegal	Nepal
Maternal health medicines										
1	Hydralazine 20mg amp.	2	1		3					
2	Magnesium Sulphate 500mg/ml inj.	5	1	1	2	5				
3	Calcium Gluconate 1g/10ml inj.	3	1	1	1	9		1		
4	Tranexamic Acid 100mg inj. for IV	3	4		2	18	5			1
5	Oxytocin 10IU/ml inj.	8	4	2	1	3	3	6		
6	Methyldopa 250mg tab.	12	4	1	6	10	5	4	2	
7	Misoprostol 200mcg tab.	6	5	3	8	20	4	3		1
Newborn and child health medicines										
8	Procaine Benzylpenicillin 1g inj.	6	3	1			1			
9	Co-presentation of ORS/Zinc	2	3	2			1	1		
10	Amoxicillin 250mg dispersible tab.	2	8	1	6	10	4			
11	Amoxicillin 125mg dispersible tab.	3	3	1	2		3			1
12	Benzylpenicillin 600mg inj.	4	3	4	2	3		2		
13	Zinc sulphate 20mg dispersible tablets	5	6	2	3	8	4			
14	Gentamicin 20mg inj or Gentamicin 80mg inj	7	4	5	8	27	5	2		
15	Chlorhexidine 7.1% solution or gel	1	1	1		2	1	1	1	1
16	Amoxicillin 250mg/5ml syrup or suspension	10	3	5	23	4	1	12	1	
17	ORS low osmolarity 20.5g/1L sachets or ORS flavored 200ml sachets	3	4	2	1	4	7	2	1	
18	Ceftriaxone 250mg inj or Ceftriaxone 1g inj.	25	31	15	12	253	37	20	6	2

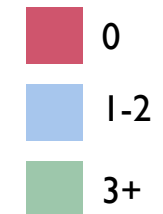
Number of registered products



Registration status of MNCH tracer medicines

No.	Tracer Essential MNCH Medicines	Number of Registered Products								
		Rwanda	Uganda	DRC	Mozambique	Bangladesh	Tanzania	Mali	Senegal	Nepal
Maternal health medicines										
1	Hydralazine 20mg amp.	2	1	0	3	0	0	0	0	0
2	Magnesium Sulphate 500mg/ml inj.	5	1	1	2	5	0	0	0	0
3	Calcium Gluconate 1g/10ml inj.	3	1	1	1	9	0	1	0	0
4	Tranexamic Acid 100mg inj. for IV	3	4	0	2	18	5	0	0	1
5	Oxytocin 10IU/ml inj.	8	4	2	1	3	3	6	0	0
6	Methyldopa 250mg tab.	12	4	1	6	10	5	4	2	0
7	Misoprostol 200mcg tab.	6	5	3	8	20	4	3	0	1
Newborn and child health medicines										
8	Procaine Benzylpenicillin 1g inj.	6	3	1	0	0	1	0	0	0
9	Co-presentation of ORS/Zinc	2	3	2	0	0	1	1	0	0
10	Amoxicillin 250mg dispersible tab.	2	8	1	6	10	4	0	0	0
11	Amoxicillin 125mg dispersible tab.	3	3	1	2	0	3	0	0	1
12	Benzylpenicillin 600mg inj.	4	3	4	2	3	0	2	0	0
13	Zinc sulphate 20mg dispersible tablets	5	6	2	3	8	4	0	0	0
14	Gentamicin 20mg inj or Gentamicin 80mg inj	7	4	5	8	27	5	2	0	0
15	Chlorhexidine 7.1% solution or gel	1	1	1	0	2	1	1	1	1
16	Amoxicillin 250mg/5ml syrup or suspension	10	3	5	23	4	1	12	1	0
17	ORS low osmolarity 20.5g/1L sachets or ORS flavored 200ml sachets	3	4	2	1	4	7	2	1	0
18	Ceftriaxone 250mg inj or Ceftriaxone 1g inj.	25	31	15	12	253	37	20	6	2

Number of registered products



Number of registered WHO-prequalified products for each MNCH tracer medicine by country

Tracer Essential MNCH Medicines	Rwanda	Uganda	DRC	Mozambique	Bangladesh	Tanzania	Mali	Senegal	Nepal
Oxytocin 10IU/ml inj.	0	0	0	0	0	1	0	0	0
Misoprostol 200mcg tab.	0	2	0	2	0	1	1	0	0
Magnesium sulphate 500mg/ml inj.	0	0	0	1	0	0	0	0	0
Zinc sulphate 20mg dispersible tab.	0	1	0	1	0	1	0	0	0

Number of registered products

- 0
- 1-2
- 3+

Note: Five countries had not registered any of the four World Health Organization-prequalified products.



Key observations

✓ Legal frameworks exist but **do not include key provisions** to support more efficient and effective regulation.

✓ NRAs face **inadequate funding** and **insufficient numbers of competent staff**.

✓ The average registration timeline ranged from **6 months to 4 years** due to NRA **backlogs and complicated procedures**.

✓ The registration process is **long and inefficient** and is not utilizing reliance on other agencies for GMP inspection or recognition of registration status in other countries.

✓ Efficacious and efficient regulation with the right incentives is even more important in a **low-cost, low-profit** context such as the market for MNCH medicines.

Considerations to facilitate the registration of MNCH medical products

STREAMLINING THE REGISTRATION PROCESS

- ① Amend legal provisions and regulations to:
 - Advance reliance and to enable the NRA to **formally recognize the registration decisions**, including GMP inspection outcomes of other reference NRAs and the WHO prequalification mechanism
 - Allow for **priority registration** of essential MNCH medical products as products of public health benefit
- ② The NRA and the health ministry could advocate for the government to include an adequate budget line in the national budget and for **greater financial autonomy**, as well as to increase fees that are deemed low.



Photo credit: Abimana Rwandenzi Eugene, MTaPS Rwanda

Considerations to facilitate the registration of MNCH medical products (2)

STREAMLINING THE REGISTRATION PROCESS



- 3 Align the medicine registration process with **international standards and best practices.**
- 4 **Improve communications with manufacturers** by making an updated list of registered medicines available and by creating transparency.
- 5 **Increase collaboration with regional/international bodies:**
 - Use regional platforms to enlist MNCH medicines as part of the priority medicines for joint assessments and subsequent registration in the member states.

Response to study findings

MTAPS IS SUPPORTING:

- ✓ **Capacity building of assessors** (e.g., in Mozambique, Rwanda, and Tanzania)
- ✓ Legal, organizational, and procedural **changes in registration** in Bangladesh, DRC, Nepal, Mozambique, and Rwanda
- ✓ Support to promoting convergence of medicine registration in SADC, with a focus on **MNCH medicines**
- ✓ Development of an **advocacy brief** to prioritize registration of MNCH medical products
- ✓ Collaboration with AMRH/AMDF on regulation of **MNCH medical devices**



Conclusions

Although most of the MNCH tracer medicines were registered in the nine countries studied, some countries have **few medicines registered** and for some medicines there are **few registered products**.



Streamlining the registration process will mitigate disincentives for market entry for manufacturers of quality-assured high volume–low cost/low profit MNCH medicines.



There is a need for legal, organizational, and procedural changes in **registration**.



Development partners have an important role to play in supporting countries in their initiatives to improve the quality and efficiency of regulation for better access to safe, effective, and good quality medical products.





USAID MEDICINES, TECHNOLOGIES, AND
PHARMACEUTICAL SERVICES (MTaPS) PROGRAM

Improved Access. Improved Services. Better Health Outcomes.



Thank you!

The USAID Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program enables low- and middle-income countries to strengthen their pharmaceutical systems, which is pivotal to better health outcomes and higher-performing health systems. The program is implemented by a consortium of global and local partners, led by Management Sciences for Health (MSH), a global health nonprofit.

This presentation is made possible by the generous support of the American people through the US Agency for International Development (USAID) contract no. 7200AA18C00074. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

