

Improving Access to Maternal Health Medicines through Optimization of Product Registration

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USAID MEDICINES, TECHNOLOGIES, AND
PHARMACEUTICAL SERVICES (MTaPS) PROGRAM
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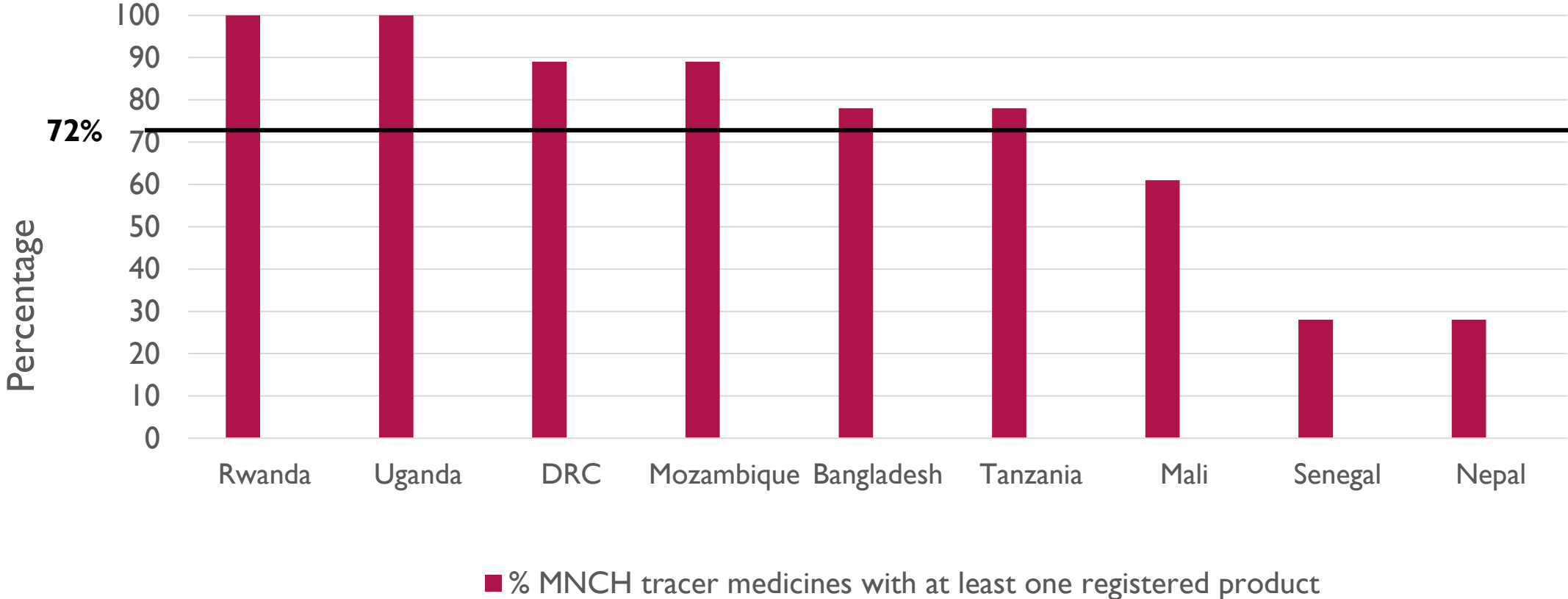
Medicine Registration & Maternal Health

- **Maternal mortality rates remain high** in many countries, despite global progress, but leading causes of mortality are treatable with **quality** medicines
- Most MH medicines are procured by governments using public sector funds rather than by donors.
- National regulatory authorities (NRAs) perform the fundamental role of ensuring the efficacy, safety, and quality of medical products, through registration or “marketing authorization”
- Challenges in the registration process can limit the availability of lifesaving, quality-assured MH medical products



Registration status of MNCH tracer medicines

MTaPS conducted a mapping of the registration of MNCH medical products in 9 countries to identify barriers and inefficiencies that affect the registration of MNCH medical 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
	Total	107	89	47	80	376	81	54	11	6

Number of registered products	0		1-2		3+	
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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

Other findings

- The registration process is long and inefficient :
 - The average timeline ranged from 6 months to 4 years due to NRA backlogs and complicated procedures.
- NRAs face inadequate funding and insufficient numbers of competent staff.
- Legal frameworks exist but do not include key provisions to support more efficient and effective regulation or to prioritize MNCH medicines as a public health priority
- The registration process often does not rely on other agencies for GMP inspection or recognition of registration status in other countries.
- Efficient regulation with the right incentives is even more important in a low-cost, low-profit context such as the market for MNCH medicines.

Prioritizing MH Medicine Registration

There are many opportunities to facilitate the product registration process that would motivate suppliers of quality-assured MNCH medicines to enter national markets for example :

Actions for national regulatory authorities (NRAs)	Actions for governments	Actions for donors and development partners
<ul style="list-style-type: none"> Establish policies, regulations, and guidelines to prioritize MNCH product registration that will ensure their access in the national health system Streamline registration processes and provide predictable approval timelines using reliance and regional networks and initiatives taking advantage of work sharing and joint review activities Simplify registration process by establishing electronic systems, also facilitating transparency 	<ul style="list-style-type: none"> Allocate sufficient budgets for the regulation of medical products, including those for MNCH Ensure that the budget allocated to ministry of health MNCH medical products procurements is enough to fulfill the country's public health priorities Develop and implement local manufacturing strategies to help satisfy public health needs by diversifying the sources of MNCH medical products 	<ul style="list-style-type: none"> Help NRAs to develop institutional development goals and appropriate financing mechanisms that would enhance registration of MNCH products Support NRAs to build capacity of assessors Support regional platforms to prioritize the registration of MNCH medicines Review and support the expansion of the list of MNCH items eligible for WHO PQP approval

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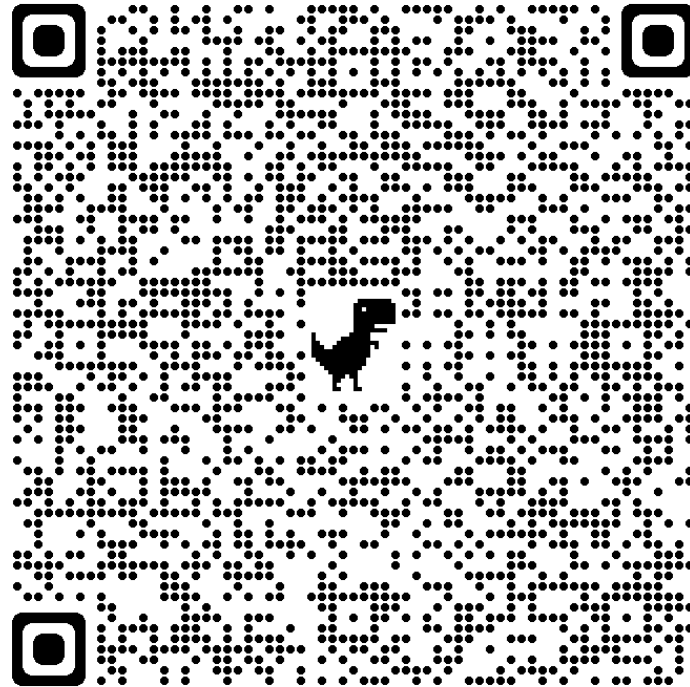
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Improving Access to Maternal, Newborn, and Child Health Products in Low- and Middle-Income Countries: Considerations for Effective Registration Systems

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Thank you

Questions



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