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

Improved Access. Improved Services. Better Health Outcomes.

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

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FROM THE AMERICAN PEOPLE

INTRODUCTION

National regulatory authorities (NRAs) perform the critical role of ensuring the efficacy, safety, and quality of medical products that circulate in national markets. One key function of an NRA is to provide marketing authorization, or registration, for a medical product after evaluating data and information submitted by the manufacturer. This process ensures the product's safety, efficacy, and quality and is specific to the manufacturer, the product presentation, and the manufacturing site.

In many low- and middle-income countries (LMICs), challenges in the registration process limit the availability of lifesaving, quality-assured maternal, newborn, and child health (MNCH) medical products, including medicines;[1] medical devices like oxygen concentrators, pulse oximeters, and female condoms; and medical gases such as oxygen. As a result, innovator medical products are slow to enter the markets where they are most needed, and quality-assured products of generic medicines, including those prequalified by the World Health Organization (WHO), are not registered or their registration status expires without renewal, leaving a vacuum that may be filled by products that are substandard or falsified, especially in countries where enforcement is weak.

In 2020, the US Agency for International Development (USAID) Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program conducted a nine-country study that included interviews with regulators and selected pharmaceutical manufacturers to better understand the challenges of registering MNCH medical products. This technical brief synthesizes key findings of the registration status for 18 tracer essential MNCH medicines (table 1) in seven African countries and two Asian countries and the key challenges to registration from the perspective of regulators and selected MNCH medicine manufacturers. It also summarizes options to consider for facilitating the registration of MNCH and other essential medical products across the nine countries, which are also applicable to other LMICs.

[1] Briggs J, Embrey M, Maliqi B, Hedman L, Requejo J. How to assure access of essential RMNCH medicines by looking at policy and systems factors: an analysis of countdown to 2015 countries. BMC Health Serv Res. 2018 Dec 7;18(1):952

METHODOLOGY

MTaPS used a two-phased approach to conduct the study. First, the MTaPS team performed a review of key documents, including policies, laws, regulations, guidelines, procedures, reports, and lists of registered products. Interviews were conducted primarily with key informants from the NRA to validate the information gathered; ascertain the registration process and fee structure; determine the registration status of 18 essential tracer medicines used to manage conditions in women, newborns, and children; and identify key challenges (table 1). The second phase involved interviews with 11 MNCH medicine manufacturers, including six that produce a WHO prequalified tracer list medicine and one regional manufacturers association, to understand the challenges manufacturers face in registering their products in LMICs.

TABLE 1: Tracer Essential MNCH Medicines

Maternal Health Medicines	
Oxytocin 10IU/ml inj.*	Postpartum hemorrhage
Misoprostol 200mcg tab.*	Postpartum hemorrhage
Tranexamic acid 100mg inj. for IV	Postpartum hemorrhage
Hydralazine 20mg amp.	Severe hypertension in pregnancy
Methyldopa 250mg tab.	Severe hypertension in pregnancy
Magnesium sulphate 500mg/ml inj.*	Eclampsia and pre-eclampsia
Calcium gluconate 1g/10ml inj.	Eclampsia and pre-eclampsia (treatment of magnesium toxicity)
Newborn Health Medicines	
Chlorhexidine 7.1% solution or gel	Newborn cord care
Benzylpenicillin 600mg inj.	Possible serious bacterial infection
Ceftriaxone 250mg inj. or ceftriaxone 1g inj.	Possible serious bacterial infection
Gentamicin 20mg inj. or gentamicin 80mg inj.	Possible serious bacterial infection
Procaine benzylpenicillin 1g inj.	Possible serious bacterial infection
Child Health Medicines	
Amoxicillin 125mg dispersible tab.	Pneumonia
Amoxicillin 250 mg dispersible tab.	Pneumonia
Amoxicillin 250mg/5ml syrup or suspension	Pneumonia
ORS low osmolarity 20.5g/1L sachets or ORS flavored 200ml sachets	Diarrhea
Zinc sulphate 20mg dispersible tab.*	Diarrhea
Co-presentation of ORS/zinc	Diarrhea

*WHO prequalified product exists

The nine countries were purposively selected from the countries where MTaPS is providing pharmaceutical systems strengthening support and included two in Asia (Bangladesh and Nepal) and seven in West (Mali and Senegal); East (Rwanda, Tanzania, and Uganda); Central (the Democratic Republic of Congo [DRC]); and Southern (Mozambique) Africa. All 18 tracer medicines are available as generics on the global market, and a WHO-prequalified generic product exists for four of the tracer medicines (oxytocin 10IU/ml injection, misoprostol 200mcg tablets, magnesium sulphate 500mg/ml injection, and zinc sulphate 20mg dispersible tablets).[2] MTaPS conducted a thematic analysis based on the data and information gathered to identify the major challenges in the medical products registration system and provide options for consideration for governments, regulators, and development partners to improve access to MNCH medical products.

[2] WHO prequalification involves a transparent, scientifically sound assessment that includes dossier review, consistency testing or performance evaluation, and site visits to manufacturers to ensure that products for high-burden diseases meet global standards of quality, safety, and efficacy. Information on WHO prequalification of medicines is available at https://extranet.who.int/pqweb/.

KEY FINDINGS

PHARMACEUTICAL MARKET

The nine NRAs operate in widely different markets with different capacities for local manufacture. The value of the pharmaceutical market ranges from USD 2.4 billion (2018) in Bangladesh[3] to USD 135 million (2011) in Mali[4] (table 2). Imported products account for a large share of the market in all seven African countries; the percentage of locally manufactured products ranges from around 15% in Mozambique to 1% in Rwanda and is minimal in Mali. Several have introduced or are in the process of introducing initiatives to increase incentives for local companies, such as tax breaks, preference in public tenders, and taxes/higher fees on imported products as part of a government strategy to increase local manufacturing.

The market share of locally manufactured products in the two Asian countries is about 90% in Bangladesh and 45% in Nepal. In Bangladesh, the government encourages local pharmaceutical manufacturers to produce generic drugs and discourages importation when a medicine is produced by four or more local firms.

POLICY AND REGULATORY FRAMEWORK FOR MEDICINES REGISTRATION

All nine countries have in place the legal framework that provides legal provisions for the NRA to perform its registration activities and mandates that all medicines are registered before they enter the market (table 2). However, it is not uncommon for registration to be waived or bypassed for medicines (e.g., by applying for a special request for importation or a one-time registration waiver).

Reliance on the regulatory decisions made by WHO, regional bodies, and other reference NRAs on prequalification or registration of medical products and outcomes of Good Manufacturing Practices (GMP)[5] inspections can enable LMICs to expedite registration (box 1). Although all countries surveyed belong to regional economic communities, the countries lack clear national legal provisions for recognition of regulatory decisions and/or reliance, and some have no mechanism for the application of good reliance practices.

BOX 1: WHO Definitions of Regulatory Reliance and Recognition

Reliance: "The act whereby the National Regulatory Authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others."

Recognition: "The acceptance of the regulatory decision of another regulator or other trusted institution. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority is sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement."

For more information on principles and good reliance practices in regulatory decision making, see this WHO 2020 working paper at https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS20_851_good_reliance_practices.pdf?ua=1.

[3] https://www.thefinancialexpress.com.bd/views/pharmaceutical-sector-flourishing-1574867109

[4] McCabea et al. HNP Discussion paper 2011. Private Sector Pharmaceutical Supply and Distribution Channels in Africa: A Focus on Ghana, Malawi and Mali. Available at: http://documents1.worldbank.org/curated/en/756351468194341354/pdf/656010WP00PUBL00PvtSectorPharma0811.pdf

[5] According to WHO, Good Manufacturing Practices (GMP, also referred to as "cGMP" or "current Good Manufacturing Practice") is the aspect of quality assurance that ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification. For more information on WHO GMP certification, see https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/gmp.

TABLE 2: NRA Organization and Funding; Pharmaceutical Market; and Regulatory Framework for Medicines, Medical Devices, and Medical Gases

REGION	Asia		Africa						
COUNTRY	**Bangladesh**	**Nepal**	**DRC**	**Mali**	**Mozambique**	**Rwanda**	**Senegal**	**Tanzania**	**Uganda**
NRA organization and resources									
NRA organization	Directorate under health ministry	Department under health ministry (proposal for transition to autonomous agency)	Directorate under health ministry (transitioning to autonomous agency)	Directorate under health ministry	Directorate under health ministry (transitioning to autonomous agency)	Semi-autonomous agency[6] answerable to health ministry	Directorate under health ministry	Semi-autonomous agency under health ministry	Autonomous agency under health ministry
NRA retains service fees	No	No	No	No	Partially (60% retained)	No	No	Yes	Yes
Number of staff for registration activities (as of 2020)	30 (not dedicated)	5 dedicated	43 (30 dedicated and 13 not dedicated)	13 dedicated	15 dedicated	32 dedicated	11 dedicated	17 dedicated	30 dedicated
Number of medicines registration applications received/year	5,000	244 (average) (787 in 2019)	1,200	1,353 (2017)	391 (average 2017–2019)	800–1,000 (2018)	500	600–700	500–800
Ratio of application received per year to staff	167 (not dedicated)	49 (average) 157 (for 2019)	28	104 (2017)	26 (2017–2019)	25–31(2018)	45	35–41	17–27
Pharmaceutical market									
Market value (USD) (imported and domestic manufacture)[7,8]	2.4 billion (2018)	400 million (2018)	457 million (2015)	135 million (2011)	140 million (2012)	155 million (2019)	225–244 million (2020)	400 million (2014)	414 million (2017)
Local manufacturing (% of market)	97%	45%	10%	Minimal	15%	1%	5–10%	10%	5%
Regulatory framework for registration									
Legal mandate requiring registration of medicines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Legal mandate requiring registration of medical devices	Yes, and registration under way	Yes, but none registered yet	Yes (several registered)	No	No	Yes, but none registered yet	No	Yes, and registration under way	Yes, but none registered yet
Legal mandate requiring registration of medical gases	Yes, and registration under way	No	No	No	No	Yes, but none registered yet	No	Yes, and registration under way	Yes (regulated as per medicines), but none registered yet

[6] Ndomondo et al. 2020 National medicines regulatory authorities financial sustainability in the East African Community PLoS ONE 15(7): e0236332.https://doi.org/10.1371/journal.pone.0236332

[7] Market value for medicines, except for DRC and Mozambique where market value includes medical devices

[8] Source: ***Bangladesh***: https://www.thefinancialexpress.com.bd/views/pharmaceutical-sector-flourishing-1574867109; ***Nepal***; https://appon.org.np/events/nepal-pharma-expo; ***DRC***: Plan National de Développement Sanitaire 2016–2020: Vers la Couverture Sanitaire Universelle. Kinshasa, Democratic Republic of Congo: Ministère de la Santé Publique (MSP) de la République Démocratique du Congo; ***Mali***: McCabea et al HNP Discussion paper 2011. Private Sector Pharmaceutical Supply and Distribution Channels in Africa: A Focus on Ghana, Malawi, and Mali http://documents1.worldbank.org/curated/en/756351468194341354/pdf/656010WP00PUBL00PvtSectorPharma0811.pdf; ***Mozambique:*** COWI. 2012. *Finalização Do Plano de Negócios Da SMM: Situação Dos Mercados Farmacêuticos Em Moçambique E Na Região Da SADC.* Maputo: COWI Consulting; ***Rwanda***: Economic Development and Health Insurance will support demand for medicines in Rwanda, by Fitch Solutions/Healthcare &Pharma/Rwanda/Rwanda/Thu 17 Oct, 2019; ***Senegal*** communication with director of DPM (pending report); ***Tanzania***: East African Community. 2nd EAC Regional Pharmaceutical Manufacturing Plan of Action 2017 – 2027. 2017;1–33; ***Uganda*****:** https://pharmexcil.com/uploads/countryreports/uganda.pdf

NRA ORGANIZATION AND RESOURCES

The nine NRAs are notably diverse in terms of their organization, autonomy, staffing levels, and the number of marketing authorization applications processed each year (table 2). One NRA is fully autonomous (Uganda), and two (Rwanda and Tanzania) are semi-autonomous. Six (Bangladesh, Nepal, DRC, Mali, Mozambique, and Senegal,) are directorates or departments in their respective health ministries. Many LMICs, including DRC, Mozambique, and Nepal, are moving toward establishing an autonomous medical products regulatory body with administrative, financial, and technical autonomy. Both Mozambique and DRC have the enabling legal framework in place, and Mozambique has just approved and DRC is in the process of enacting statutes to transition to fully autonomous agencies. The government has proposed a similar change in Nepal.

BOX 2: WHO Global Benchmarking Tool

WHO has developed the Global Benchmarking Tool (GBT) as the global standard for objectively assessing regulatory capacity for medicines and vaccines. It provides countries with a systematic process for strengthening their regulatory systems. The methodology incorporates the development of an institutional development plan to advance performance and maturity of the NRA. The maturity levels are level 1 (existence of some elements of regulatory system); level 2 (evolving national regulatory system that partially performs essential regulatory functions); level 3 (stable, well-functioning, and integrated regulatory system); and level 4 (regulatory system operating at advanced level of performance and continuous improvement).

The GBT uses 268 sub-indicators disaggregated into nine indicator categories to measure capacity across an overarching framework (national regulatory system) and eight regulatory functions: registration and marketing authorization, pharmacovigilance, market surveillance and control, licensing of establishments, regulatory inspections, laboratory testing, clinical trials oversight and lot release of vaccines.

Information on the WHO GBT is available at https://www.who.int/medicines/regulation/benchmarking_tool/en/.

All the NRAs are engaged in using WHO's Global Benchmarking Tool (GBT) (box 2) for objectively assessing and strengthening national regulatory authorities. DRC, Mali, Nepal, and Senegal have self-benchmarked their strengths and areas of weakness. Bangladesh, Mozambique, Rwanda, Tanzania, and Uganda have also completed the formal benchmarking process with WHO and international experts and have developed an institutional development plan that sets out actionable steps for improving their system's functionality and maturity.

The nine NRA registration activities are challenged by insufficient numbers of competent staff and inadequate funding. Some NRAs are also dealing with high staff turnover and expanding responsibilities, including a wider and more complex range of medical products to regulate. Staffing levels assigned to registration activities vary widely across the nine countries, as do the number of applications received per year (table 2). While noting that the number of assigned personnel may not necessarily reflect the number of full-time competent assessors available, a comparison of applications received per year to staff assigned to registration activities across the nine countries indicates that the registration activities in Bangladesh, Mali, and Nepal may be particularly under-resourced (table 2).

The WHO GBT[9] level 4 indicator (RS07.04) recommends that "the NRA has authority to manage the funds allocated and/or generated internally." In all countries except Uganda, the functioning of the NRA relies to a great degree on funding allocated by the state budget (table 2); Uganda is dependent on fees. All countries collect fees for registration and other regulatory services. With the exception of Mozambique, Tanzania, and Uganda, all revenue generated from fees reverts to the treasury. In Mozambique, the NRA retains 60% of the fees generated, and the rest reverts to the Treasury. In Senegal specifically, although fees are earmarked for use by the NRA, delays in reallocating monies generated from fees back to the NRA have led to the deferral of meetings of its

[9] The WHO GBT is available at https://www.who.int/medicines/regulation/benchmarking_tool/en/.

registration advisory and decision making bodies because the NRA is unable to pay committee members their allowances. All NRAs also receive technical and financial support from donors and/or development partners and in some countries, most planned activities rely on donor funding.

MEDICINES REGISTRATION PROCESS

The registration processes, including compliance with international standards and best practices, such as those specified by WHO, are summarized below and in table 3.

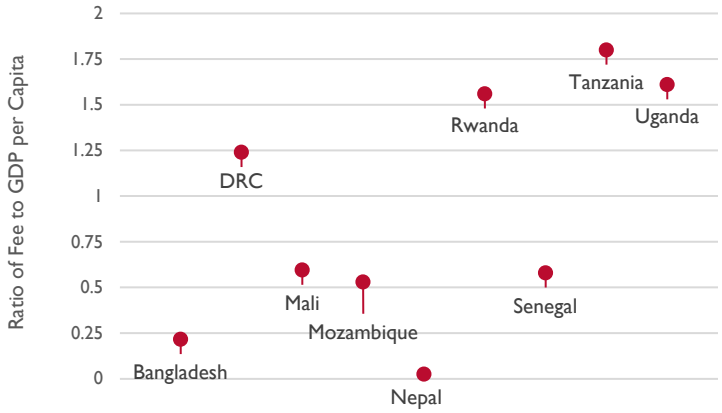
Product Application Requirements

- COMMON TECHNICAL DOCUMENT (CTD). All countries except Bangladesh and Nepal require the use of the CTD format[10] for dossier submission. The CTD format is only partially implemented in Nepal and applied only for biological products in Bangladesh.

- GMP CERTIFICATION AND/OR INSPECTION REPORT. GMP certification is required in all countries prior to product registration, but it is not fully enforced in Nepal, where non-GMP-certified local manufacturers can get a two-year market authorization on the basis of a commercial batch testing report, after which they must obtain GMP certification. Most of the nine countries conduct GMP inspections themselves, and few fully rely on GMP certification and inspections by other NRAs or the WHO prequalification program, primarily because their legal frameworks do not allow them to rely on other inspections. Only Mali and Senegal officially recognize and rely fully on the GMP certificate from the country of manufacture. Mozambique, Nepal, and Tanzania consider WHO inspection reports or GMP inspection certificates issued by reference members states within regional bodies (e.g., South African Development Community [SADC], East African Community [EAC]) without full recognition, meaning that the NRA performs a review of the GMP certificate and/or a report before making a determination on the GMP compliance status of the manufacturing facility for the product to be registered.

- REGISTRATION FEES. Fees vary across countries and product origin, ranging from USD 27 in Nepal to USD 2,000 in Tanzania for imported medicines and from USD 3 in Nepal to USD 675 in DRC for locally manufactured products. In all but DRC and Mali, the fees to register locally manufactured products are lower than for imported products. Only Nepal offers a preferential fee for the import of essential, lifesaving, and emergency medicines, which presumably includes MNCH medicines (the already low fees are halved), but there is an even

FIGURE 1: Ratio of Registration Fee for Imported Products to GDP per Capita



[10] CTD is an internationally agreed on set of specifications for organizing applications for the registration of medicines for human use to regional and national regulatory authorities. Its use enables the systematic organization of product information for in depth evaluation by regulators and is in compliance with WHO recommendations for national medicines regulatory authorities to adopt the format. The format also facilitates convergence and harmonization at the regional and global levels and reduces documentation burden for manufacturers. For more information, see https://www.ich.org/page/ctd.

greater discount for locally manufactured medicines as mentioned above. Figure 1 shows the ratio of the registration fee for an imported product to GDP per capita. The data indicate that the fees charged in Bangladesh, Mali, Mozambique, Nepal, and Senegal may be low relative to the income level of the country as indicated by GDP per capita.

TABLE 3: NRA Medicines Registration Process: Compliance with International Standards and Best Practices[11]

REGION	Asia		Africa						
COUNTRY	**Bangladesh**	**Nepal**	**DRC**	**Mali**	**Mozambique**	**Rwanda**	**Senegal**	**Tanzania**	**Uganda**
Product application requirements									
Dossier submitted in CTD format	No	Partially	Yes	Yes	Yes	Yes	Yes	Yes	Yes
GMP certificate and/or inspection report	Partially	Partially	Partially	Yes	Partially	Partially	Yes	Partially	Partially
Fee for registration of imported medicines (USD)	400	27	675	Branded generics and specialties: 530 Generics: 358	259	1,250	862	2,000	1,250
Fee for registration of locally manufactured medicines (USD)	120	3			195	400	431	500	200
Product assessment process									
Priority processes based on public health benefit	Partially	Partially	Partially	Partially	Partially	Partially	Partially	Partially	Partially
Abridged registration procedures based on good reliance practices	Partially	No	Partially	Partially	Yes	Yes	Yes	Yes	Partially
Procedures for assessment of the dossier and per class of medicines	Partially	Partially	Partially	Partially	Yes	Yes	Yes	Yes	Yes
System to track product registration process within NRA	No	Partially	No	No	Partially	Partially	No	Yes	Partially
Defined time for registering a generic medicine specified	Yes (6 months)	Partially (citizens charter states 30 days)	Yes (90 days)	Yes (120 days)	Partially (internal SOP suggests 12 months)	Yes (18 months)	Yes (120 days; 90 days for renewals)	Yes (180 days)	Yes (18 months)
Defined average time for expedited registration of a generic medicine specified	No	No	No	Yes (15 days)	No	Yes (6 months)	No	Yes (90 days)	Yes (6 months)
Marketing authorization decision									
Validity	5 years	2 years	5 years	5 years	5 years[12]	5 years	5 years	5 years	5 years
A register of registered medicines available to public	Partially	No	Partially (last updated Nov 2020)	No	Yes	Yes	Partially	Yes	Yes
Process for post-authorization activities; variations, renewals	Partially	Partially	Partially	Partially	Yes	Partially	Partially	Yes	Partially

[11] Full compliance is noted with a "yes," partial compliance with "partially", and if not in compliance with a "no"
[12] Market authorization cancelled after two years if product is not in market

Product Assessment Process

- PRIORITY PROCESSES BASED ON PUBLIC HEALTH BENEFIT. None of the countries have formal priority processes in place to expedite the registration of essential MNCH medical products. Four countries (Mozambique, Rwanda, Senegal, and Uganda) have formal procedures in place for prioritizing selected medical products, but MNCH medicines are not included. The procedures for prioritizing medical products for registration do not consider the risk associated with only having a single supplier of an essential medicine. Bangladesh, DRC, Mali, and Tanzania prioritize certain medical products for registration on special request from the health ministry or for emergencies but not on a regular basis for priority lifesaving MNCH products.

- ABRIDGED REGISTRATION PROCEDURES BASED ON RELIANCE. Reliance enables NRAs to make the best use of resources; build capacity; increase the quality of regulatory decisions; reduce duplication of effort; and, ultimately, promote access to safe, efficacious, and quality-assured medical products (box 1). While four countries state they are using abridged registration procedures, none of the nine countries can fully apply good reliance practices and guidelines in practice, primarily because they lack clear legal provisions to do so. Seven are members of the WHO Collaborative Registration Procedure (CRP) and utilize the results of the WHO prequalification to expedite the registration of WHO-prequalified products (box 3). Mali participates in the WHO CRP, but only for vaccines. Bangladesh and Nepal are not members of the WHO CRP, and Nepal has no formal reliance mechanism in place.

BOX 3: What is the WHO Collaborative Registration Procedure?

Medicines that have been prequalified by WHO must still be approved for market entry by NRAs. To accelerate this process, WHO has established a collaborative registration procedure that enables NRAs to utilize the results of evaluations (assessments and inspections) carried out by WHO as part of the country registration process.[a] NRA participation is voluntary and available to all member states; NRAs are asked to sign a participation agreement and confidentiality undertaking. The organization that applies for WHO prequalification (generally the manufacturer) informs WHO of its interest in using the procedure for a WHO prequalified product in a country to accelerate registration and consent to WHO and communicating the results of the WHO assessments and inspection to the NRA focal point. NRAs that consent to the procedure commit to making a decision on market authorization within 90 days after submission of a product application and informing WHO and the applicant within 30 days thereafter. See https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration for more information on the CRP, including a list of participating countries.

[a]https://extranet.who.int/pqweb/medicines/collaborative-registration-faster-registration

- DOSSIER ASSESSMENT: Five countries (DRC, Rwanda, Senegal, Tanzania, and Uganda) utilize standard procedures for assessing dossiers in line with WHO Good Review Practice guidelines.[13] Bangladesh, Nepal, Mali, and Mozambique have procedures in place, but they are not aligned with the WHO guidance.

- DEFINED TIME FOR REGISTRATION: While faster registration times are not the only criteria for tracking performance—the rigor or quality of the regulatory review is also critical—countries should define, track, and publicly report on processing times. All countries have set a defined time for registering a generic product, which ranges from 30 days (Nepal) to 18 months (Rwanda and Uganda), although the actual processing time can vary widely from the time defined. Only four countries (Mali, Rwanda, Tanzania, and Uganda) also have a defined time for expedited registration of generic medicines, which ranges from 15 days to 6 months.

[13] According to WHO, Good Review Practices are documented best practices for any aspect related to the process, format, content, and management of a medical product review. For more information see Annex 9, Good Review Practices for national and regional regulatory authorities. Available at: https://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex9-TRS992.pdf.

- ELECTRONIC REGULATORY MANAGEMENT INFORMATION SYSTEMS: Electronic systems that can improve efficiency by facilitating direct submission of registration documents by applicants; managing dossier evaluations; and providing analytical reports on registration status, import quantities, site of manufacturing, and registration times, among other factors, are mostly lacking or only partially operational in all NRAs studied with the exception of Tanzania.

Marketing Authorization Decision

- VALIDITY: Marketing authorization validity is five years in all countries except Nepal, where it is only two years. A review of Nepal's Drug Act is under way, and one of the provisions under consideration pertains to extending the validity to the more usual five years to reduce the burden that more frequent renewals place on NRAs and manufacturers, thereby helping to improve regulatory effectiveness and efficiency and decrease the number of market authorizations that expire while waiting for renewals to be completed.

- PUBLICLY AVAILABLE REGISTERS: Six countries (Bangladesh, DRC, Mozambique, Rwanda, Tanzania, and Uganda) all publish a register of registered products online. However, Bangladesh's register does not include validity status. In Mali, Nepal, and Senegal, a register is maintained at the NRA but is not available online.

- VARIATIONS AND RENEWALS: In general, less attention is paid to renewals and variations,[14] and the default position is to treat these as new registrations, which is unduly burdensome for both the NRA and the manufacturer and contributes to longer registration times and backlogs. Few countries have fully implemented a risk-based approach to renewals, such as abridged processes for products where nothing has changed since it was last approved.

REGISTRATION OF MEDICAL DEVICES AND MEDICAL GASES

MEDICAL DEVICES: Registration of medical devices by NRAs is currently carried out in only three of the nine countries (Bangladesh, DRC, and Tanzania) (table 2). Bangladesh developed registration guidelines for medical devices in 2015 and has more than 2,000 registered devices. Tanzania's NRA has 675 registered medical devices, and key informants report that DRC has registered several products. Mali, Mozambique, and Senegal lack the legal provisions to mandate the registration of medical devices before they enter the market. Nepal, Rwanda, and Uganda all have the legal framework in place but do not as yet register medical devices.

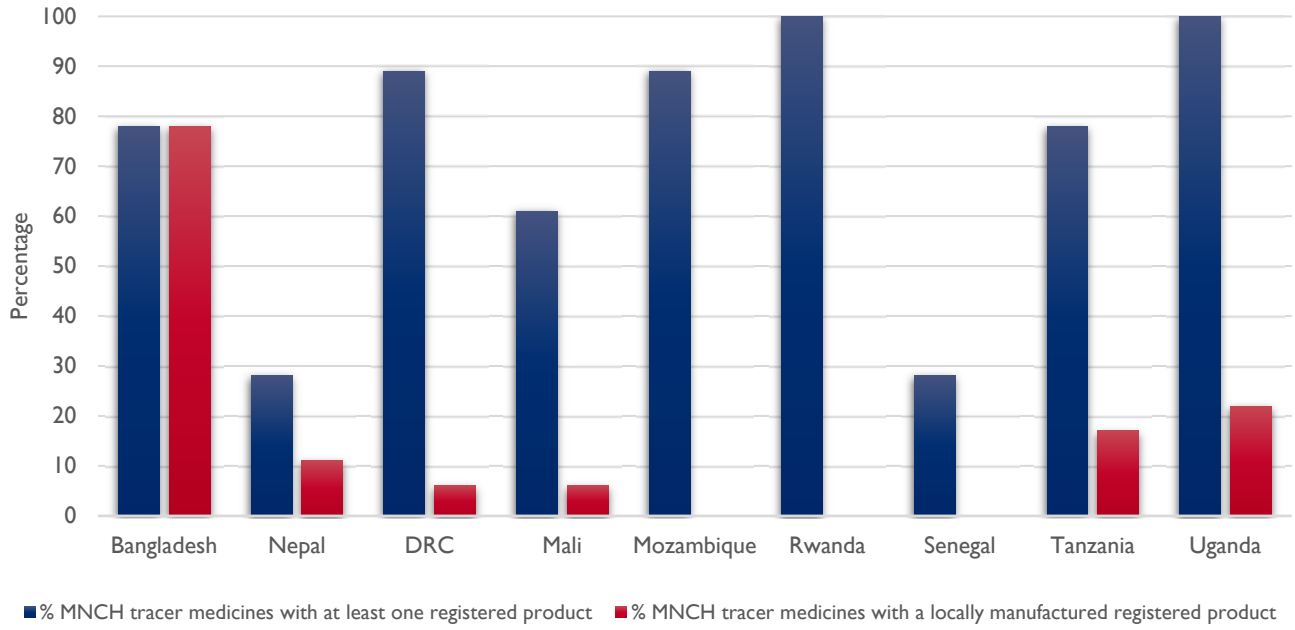
MEDICAL GASES: Medical gases are considered prescription medicines because their use is unsafe without the supervision of a licensed practitioner or by properly instructed emergency personnel. Medicines are registered by NRAs, and manufacturers of medicines are GMP certified after inspection and fulfilling requirements for GMP. Only Bangladesh and Tanzania have implemented registration of medical gases. Five countries (Nepal, DRC, Mali, Mozambique, and Senegal) lack a clear legal framework for registering medical gases, while Rwanda and Uganda have the framework but do not as yet register medical gases.

[14] Variation means a change to any aspect of a pharmaceutical product, including but not limited to a change to formulation, method and site of manufacture, specifications for the finished product and ingredients, container and container labeling, and product information. Renewal is reregistration of a registered product after end of marketing authorization validity.

REGISTRATION STATUS OF TRACER MNCH MEDICINES

MNCH TRACER MEDICINES WITH AT LEAST ONE REGISTERED PRODUCT: The percentage of tracer medicines with at least one registered product averaged 72% across the nine countries, ranging from 28% in Nepal[15] and Senegal to 100% in Rwanda[16] and Uganda (figure 2). Table 4 shows the number of registered products for each tracer medicine by country. Only one tracer medicine was registered in all nine countries—ceftriaxone 1g injection.

FIGURE 2: Key Indicators on MNCH Product Registration



Some key MNCH medicines were lacking registrations (table 4). Six countries do not have injectable hydralazine 20mg registered, four do not have magnesium sulphate 500mg/ml injection registered, and two do not have oxytocin 10IU/ml injection registered. Notably, for newborn health products, seven countries do not have a registered pediatric injectable formulation of gentamicin, and two lack a pediatric ceftriaxone product; however, an adult injectable formulation is registered in all cases except for gentamicin in Nepal and Senegal. Three countries lack a registered benzylpenicillin 600mg injectable product, and five lack a registered procaine benzylpenicillin 1g injectable product (Nepal and Senegal lack both). Amoxicillin 125 and 250mg dispersible tablets—formulations that are relatively newly recommended for LMIC markets—were each registered in six countries, respectively; Bangladesh had only the 250mg registered, Nepal had only the 125mg tablets registered, and Mali and Senegal had neither. All countries except Nepal had at least one registered amoxicillin 250mg/5ml suspension. Three countries (Nepal, Mali and Senegal) did not have a valid registered product for zinc 20mg tablets.

[15] This data is based on the current MIS system (DAMS) of the DDA in Nepal. Information related to the renewals of the registration is available in hard copies only. The DDA is in the process of updating the MIS after which the number of registered products appearing in the MIS system will increase.

[16] The newly established Rwanda NRA has not yet started formally registering medicines, and products currently authorized for use in the country were considered as "registered" for the purpose of this study.

NUMBER OF REGISTERED PRODUCTS PER TRACER MEDICINE: The number of registered products for the 18 tracer medicines varied widely across the nine countries (table 4). Bangladesh has the highest number of registered products (376), while Nepal has only six valid registered products for the 18 tracer medicines, primarily because most products (90%) have expired registration status due to the country's short (2 year) registration validity. Some countries only have one or two registered products for several of the MNCH tracer medicines. While some experts advise that having two registered products may be appropriate where margins are small and registrations are high, aiming for at least three is preferred to avoid vulnerability to shortages or stock-outs should the manufacturer experience production difficulties or decide to remove the product from the market. Antibiotic tracer medicines have the highest numbers of registered products; ceftriaxone 1g injection has 140 products registered in Bangladesh alone.

TABLE 4: Number of Registered Products for Each MNCH Tracer Medicine by Country

No.	Tracer Essential MNCH Medicines	Number of Registered Products									No. of countries with no registered products
		Bangladesh	Nepal	DRC	Mali	Mozambique	Rwanda	Senegal	Tanzania	Uganda	
	Maternal health medicines										
1	Oxytocin 10IU/ml inj.	3	0	2	6	1	8	0	3	4	2
2	Misoprostol 200mcg tab.	20	1	3	3	8	6	0	4	5	1
3	Tranexamic acid 100mg inj. for IV	18	1	0	0	2	3	0	5	4	3
4	Hydralazine 20mg amp.	0	0	0	0	3	2	0	0	1	6
5	Methyldopa 250mg tab.	10	0	1	4	6	12	2	5	4	1
6	Magnesium sulphate 500mg/ml inj.	5	0	1	0	2	5	0	0	1	4
7	Calcium gluconate 1g/10ml inj.	9	0	1	1	1	3	0	0	1	3
	Newborn health medicines										
8	Chlorhexidine 7.1% solution or gel	2	1	1	1	0	1	1	1	1	1
9	Benzylpenicillin 600mg inj.	3	0	4	2	2	4	0	0	3	3
10	a Ceftriaxone 250mg inj.	113	1	1	8	0	3	1	7	0	2
	b Ceftriaxone 1g inj.	140	1	14	12	12	22	5	30	31	0
11	a Gentamicin 20mg inj.	13	0	0	0	1	0	0	0	0	7
	b Gentamicin 80mg inj.	14	0	5	2	7	7	0	5	4	2
12	Procaine benzylpenicillin 1g inj.	0	0	1	0	0	6	0	1	3	5
	Child health medicines										
13	Amoxicillin 125mg dispersible tab.	0	1	1	0	2	3	0	3	3	3
14	Amoxicillin 250mg dispersible tab.	10	0	1	0	6	2	0	4	8	3
15	Amoxicillin 250mg/5ml syrup or suspension	4	0	5	12	23	10	1	1	3	1
16	a ORS low osmolarity 20.5g/1L sachets	3	0	2	2	1	3	0	5	3	2
	b ORS flavored 200ml sachets	1	0	0	0	0	0	1	2	1	5
17	Zinc sulphate 20mg dispersible tablets	8	0	2	0	3	5	0	4	6	3
18	Co-presentation of ORS/zinc	0	0	2	1	0	2	0	1	3	4
	TOTAL	**376**	**6**	**47**	**54**	**80**	**107**	**11**	**81**	**89**	

Number of registered products — *0* | *1–2* | *3–9* | *10+*

REGISTRATION OF WHO PREQUALIFIED TRACER MEDICINES: WHO has prequalified products for four of the MNCH tracer medicines (oxytocin 10IU/ml injection, misoprostol 200mcg tablets, magnesium sulphate 500mg/ml injection, and zinc sulphate 20mg dispersible tablets). The study revealed that in five countries (Bangladesh, Nepal, DRC, Rwanda and Senegal), none of these products are registered (table 5). No country had a WHO prequalified product registered for all four tracer medicines.

TABLE 5: Number of Registered WHO Prequalified Products for Each MNCH Tracer Medicine by Country

	NUMBER OF REGISTERED WHO PREQUALIFIED PRODUCTS FOR EACH MNCH TRACER MEDICINE BY COUNTRY			
COUNTRY	Oxytocin 10IU/ml inj.	Misoprostol 200mcg tab.	Magnesium sulphate 500mg/ml inj.	Zinc sulphate 20mg dispersible tab.
Bangladesh	0	0	0	0
Nepal	0	0	0	0
DRC	0	0	0	0
Mali	0	1	0	0
Mozambique	0	2	1	1
Rwanda	0	0	0	0
Senegal	0	0	0	0
Uganda	0	2	0	1
Tanzania	1	1	0	1

LOCAL MANUFACTURE OF REGISTERED TRACER MEDICINES: The number of the 18 MNCH tracer medicines with at least one locally manufactured registered product ranged from 14 (78%) in Bangladesh to none in Mozambique, Rwanda, and Senegal (figure 2). Of the other countries, Uganda had at least one locally manufactured registered product for 4 (22%); Tanzania for 3 (17%); Nepal for 2 (11%) and DRC and Mali for 1 (6%) tracer medicines.

SOURCES OF REGISTERED TRACER MEDICINES: For seven of the nine countries, India was the main source of registered MNCH products, ranging from over 60% in Mozambique and Nepal to 27% in Senegal. The exceptions are Bangladesh, where 100% of the 376 registered products are manufactured locally, and Senegal, where Europe is the main source, supplying 36% of the registered products.

MANUFACTURERS' PERSPECTIVES ON CHALLENGES TO REGISTERING MNCH MEDICINES

MNCH medicine manufacturers remarked that their decision on whether to proceed with registration in a country required a careful weighing of the potential market share and profit margin with the challenges, time, and effort involved in registering their products. Several identified registration challenges as an important deterrent to marketing their products. The following section summarizes the key challenges identified by MNCH medicines manufacturers. It includes perspectives from manufacturers of WHO prequalified and non-prequalified products as well from informants that had registered their products through regional harmonization initiatives.

MEDICINES REGISTRATION REQUIREMENTS, PROCESS, AND DECISION: The timeline taken to register a medicine, particularly in Africa, is a key concern for manufacturers. In the experience of the manufacturers interviewed, registration of MNCH medicines takes on average about six months in Asia, but can take from one to nearly four years in African countries. Delays reportedly occur for various reasons, including backlogs at the NRA and complicated or bureaucratic procedures in some countries, such as for paying fees. The need to provide registration samples in commercial packaging materials was cited as burdensome by one respondent, while another reported holdups of several months due to having to obtain import permits for registration samples. Additionally, some manufacturers do not understand the complexity of the registration process and find it difficult to navigate the system.

NRAs require the presence of a local agent, and manufacturers do not communicate directly with the NRA but depend on a local agent to follow the process through. Manufacturers, particularly those that lack the capacity to manage registration themselves, said that it can be challenging to find a qualified, efficient local agent to help complete the registration and provide timely feedback. Another difficulty for manufacturers is the inability to track the progress of their application themselves through a web-based dashboard or other means. The manufacturers

interviewed considered registration costs, even for expedited registrations and especially GMP inspections, to be high, especially in Africa.

PHARMACEUTICAL MARKET: One of the major challenges manufacturers face is obtaining information on the local market and competitor products to determine whether they have a business case for marketing their products in a country. Lists of registered medicines that can enable manufacturers to identify where there may be demand for a given product are often not published or not easily accessible. There can be strong competition from local suppliers and, in some countries, a preference for purchasing locally manufactured products. Another challenge mentioned is the apparent lack of awareness and demand for some products, specifically chlorhexidine gel in some countries.

WHO PREQUALIFIED PRODUCTS: Manufacturers of WHO prequalified MNCH medicines reported several benefits of WHO prequalification. These include expedited registration in some WHO CRP participating countries; exemption of GMP inspection (but fees must still be paid); opportunities to supply global procurement organizations such as UNFPA who only procure WHO prequalified products; and increased product credibility, perhaps providing a competitive advantage in procurements where quality assurance requirements are enforced. The major challenge reported is that the high cost of the WHO prequalification process on top of registration and GMP fees results in higher priced products—sometimes two to three times that of competitor products—which is a disadvantage in countries where price is the overriding consideration in the award of tenders. In the view of manufacturers interviewed, the value of WHO prequalification is not always recognized by regulators or procurers, who may choose to buy a registered non-prequalified product that is cheaper. Also, consumers may lack the buying power to purchase the higher priced WHO prequalified product, even if they appreciate the added value. In countries that do not participate in the WHO CRP or recognize WHO prequalification, the product must be resubmitted for registration in each country and join the queue.

REGIONAL HARMONIZATION: Key informants reported a number of successful experiences with processing registration through regional harmonization initiatives, with approval times as quick as two months, reduced registration time in countries, and registration waivers from certain NRAs if the product is registered in any two other African countries. However, even if a product is approved by the regional initiative, the manufacturer still has to go through the individual country registration process and pay respective fees, including for GMP inspections, which are high in some countries. Some reported that the process was not clear and seemingly not fully transparent to all manufacturers.

KEY OBSERVATIONS

Changes are under way for improving NRAs' position in the health system hierarchy that should be encouraged and supported. Several of the countries studied are creating standalone/autonomous government agencies. This structural change increases the degree of administrative, technical, and financial autonomy and strengthens the regulatory system. If the change is not supported appropriately, it may pose risks to the NRAs by not providing sufficient financial and human resources and/or enforcement capabilities to successfully complete their mission. The transition to autonomy can provide an opportunity to modernize legislation, reconfigure the NRA organization structure, and upgrade the registration procedures, taking into consideration developments in the pharmaceutical industry.

Legal frameworks exist but do not include key provisions to support more efficient and smarter regulation. To incentivize the registration of quality-assured, low-cost/low-profit medicines such as for MNCH, it is essential to address issues such as the lack of legal provisions for reliance, including recognition of regulatory decisions made by other reference NRAs through regional harmonization initiatives and reference organizations and authorities such as WHO, European Medicines Agency, and US Food and Drug Administration. These decisions include marketing authorization and prequalification as well as GMP inspections. None of the nine countries surveyed belong to other international regulatory organizations (e.g., Pharmaceutical Inspection Co-operation Scheme [PIC/S][17] or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH]); however, the Association of Southeast Asian Nations, EAC, and SADC regional economic communities to which some of the nine countries belong are observers to the ICH, while Uganda is listed as a former pre-applicant of PIC/S. The WHO GBT explicitly addresses this requirement in its level 2 indicator (RS03.04) that that asks whether countries have "Documented policies, procedures and mechanisms, including written criteria, for recognition and reliance on decisions of other NRAs."[18] Ensuring legal provisions for the regulation of medical devices and medical gases is also important for increasing access to quality oxygen and ensuring its safe use (of the nine countries surveyed, only Bangladesh, Rwanda, Tanzania, and Uganda had a legal framework in place to regulate both devices and gases).

NRAs are challenged with inadequate funding and insufficient numbers of competent staff, which hinders the NRAs from implementing a stable and functional regulatory system. NRAs need a diverse pool of funding, including both government budget and user fees, instead of a single source of funding. The NRA should have the authority to collect and internally utilize the funds that it generates. The WHO GBT level 4 indicator (RS07.04) recommends that "the NRA has authority to manage the funds allocated and/or generated internally."[18] Fees could be increased to enable support for an increased number of qualified assessors (notably Bangladesh, Mali, and Nepal).

The WHO GBT defines the path to strengthen regulatory systems; many countries are using it, and countries should be supported in this endeavor. The GBT allows the systematic assessment of country

[17] PIC/S is a nonbinding, informal co-operative arrangement between NRAs in the field of GMP of medicinal products for human or veterinary use. It is open to any authority having a comparable GMP inspection system. PIC/S presently comprises 53 participating authorities from all over the world (Europe, Africa, America, Asia, and Australasia). PIC/S aims at harmonizing inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities and regional and international organizations, thus increasing mutual confidence. This is reflected in PIC/S' mission, which is to lead the international development, implementation, and maintenance of harmonized GMP standards and quality systems of inspectorates in the field of medicinal products. https://picscheme.org/en/about.

[18] The WHO GBT is available at https://www.who.int/medicines/regulation/benchmarking_tool/en/.

regulatory capacity for medicines and vaccines. The assessment is followed by the development of an institutional development plan intended to serve as a road map to improve the functioning of the regulatory system. Importantly, the GBT facilitates coordination, puts countries in the driver's seat, and improves the effectiveness of regulatory strengthening efforts. Bangladesh, Mozambique, Rwanda, Tanzania, and Uganda have developed a detailed, actionable institutional development plan that focuses national priorities and facilitates donor coordination, while the other four countries have completed the self-benchmarking exercise. Tanzania has reached maturity level 3—the first country to do so in Africa, followed shortly thereafter by Ghana—meaning that it is considered a stable, well-functioning, and integrated regulatory system.

Local manufacturing is an opportunity for improving access to essential MNCH medical products but also presents a challenge. In the countries with a government strategy for increasing local manufacturing, including incentives within the registration process, there is an opportunity to promote local manufacturing of medicines with substantial public health benefits, including MNCH products. Industrial development of the local pharmaceutical manufacturing sector, including for export, could be a strong argument for governments to support the strengthening of the regulatory system/NRA. In terms of challenges, the two Asian countries with a big manufacturing base have a high number of MNCH products registered for many of the tracer medicines, but opportunities may not be equal for all, excluding or making it difficult/more expensive for foreign manufacturers of quality-assured medicines to enter the market. It is notable that neither Bangladesh nor Nepal has a single WHO prequalified product registered.

In a low-cost/low-profit environment such as the markets for essential MNCH medicines, the need for efficacious and efficient regulation and having the right incentives in place is even more important. Unnecessary costs and inconvenience may deter manufacturers to register in small, low-margin markets. Examples of these disincentives include lengthy or burdensome processes, including for renewals and variations; lack of information on registered competitor products; and difficulty in identifying a qualified and efficient local agent. This low-cost/low-profit environment affects WHO prequalified medicines if tenders/buyers are primarily price sensitive and not quality sensitive as the higher prices due to the additional expenses incurred with obtaining prequalification and other disincentives will discourage manufacturers from entering the market. In addition to expanding the WHO prequalification process to more MNCH medicines, it is important to work with countries to reduce disincentives in the registration process. Countries may consider streamlined registration processes, provide incentives, and mitigate disincentives to motivate suppliers of quality-assured medicines to enter the market. Streamlining registration may include increasing adherence to appropriate timeframes for registration through consistent, predictable procedures that are aligned with international standards that promote quality of assessments and rigor of review processes and the use of electronic systems to optimize workflows and provide transparency to applicants. Full use of regional harmonization efforts to ensure quality, safety, and efficacy can also increase efficiency. The validity and use of waivers may need some caution to ensure that their use is not undermining the registration system. Priority procedures for medicines with substantial public health benefit such as essential MNCH medicines could further help to incentivize registration.

CONSIDERATIONS TO FACILITATE THE REGISTRATION OF MNCH MEDICAL PRODUCTS

This section summarizes the options for accelerating the registration of essential MNCH medical products across the nine countries.

Shaping the Market

1. In the countries with a government strategy for increasing local manufacturing, the Ministry of Health could advocate for the Ministry of Industry and Trade to establish policies and programs that favor local manufacturing of essential medicines, including MNCH medical products.
2. National and/or regional pharmaceutical trade organizations could encourage and support members to obtain WHO prequalification for their products. In Bangladesh, exporters could also be supported in this endeavor.
3. The African Union Development Agency, AUDA-NEPAD, and/or countries could work with WHO to carry out a cost benefit analysis to make the business case to African manufacturers of MNCH products for pursuing WHO prequalification.

Streamlining the Registration Process: Policy and Legal Framework

4. To advance reliance, regulations on medicines registration in Bangladesh, DRC, Mali, Mozambique, Nepal, and Uganda could be amended to enable the NRA to formally recognize the registration decisions of other reference NRAs and the WHO prequalification mechanism.
5. Amendments to the regulations could also be considered to allow for NRAs to recognize GMP certificates from WHO or other reference NRAs. In Nepal, the NRA could consider applying the same GMP standards to both local and foreign manufacturers and provide support to local entities to help them achieve the higher GMP requirements.
6. In countries with existing procedures for priority processes to expedite the registration of products of public health benefit, advocate for MNCH medicines to be added to this list, particularly for those with few or no products registered. In others without such procedures, consider incorporating legal provisions to allow for priority registration of essential MNCH medical products, particularly for those with few or no products registered.
7. In countries that lack adequate legal provisions for regulation of medical devices and medical gases, consider amending laws and regulations to address this gap.

Streamlining the Registration Process: NRA Organization and Resources

8. The NRA and the health ministry could advocate for the government to include an adequate budget line in the national budget to fund a proportion of the NRA's operational costs. Additionally, they could advocate for the government to provide greater financial autonomy, including passing legal provisions for user fees to be controlled by the agency. A diverse pool of funding allows the NRA to be more sustainable and reduce its dependence on fees.
9. In countries where fees are deemed to be low (possibly Bangladesh, Mali, Mozambique, Nepal, and Senegal), the NRA and the ministry of health could revise the fee system, exemptions, and fee level and increase the fees to better cover the actual costs.

10. To help increase access to essential, quality-assured MNCH products, the NRA could consider modifying the current fee structure to reduce retention fees, import fees, and/or inspection fees for essential MNCH medical products. DRC and Mali could consider offering a favorable fee for local manufacturers and/or for generic products.

Streamlining the Registration Process: Registration Requirements, Process, and Decision

NRAs could:

11. Align the medicine registration process with international standards (e.g., requiring but also properly applying the CTD format). In Bangladesh and Nepal, the NRA could introduce the CTD format for product registration to facilitate in depth scientific evaluation of product dossiers and align with international best practices.

12. Improve interactions with manufacturers by making an updated list of registered medicines available. They could also allow for meetings with manufacturers to reduce the challenges associated with the use of local agents, provide clear guidelines and instructions on the registration process, and enable manufacturers to track the progress of their application online.

13. Sign up for the WHO CRP for medicines in Bangladesh, Mali, and Nepal, and in all countries, use the WHO CRP to facilitate expedited registration of WHO prequalified medicines.

14. Modernize and optimize NRA registration processes by expediting the establishment, updating and implementation of Good Review Practice guidelines in line with WHO guidelines, and building the capacity of assessors to improve the efficacy of dossier evaluations.

15. Fully implement a Quality Management System based on the International Organization for Standardization for marketing authorization function to improve on efficiency and consistency of evaluations of dossiers for medical products.[19]

16. Strengthen electronic drug assessment procedures to improve the efficiency of dossier evaluations, thus making evaluation timelines shorter.

17. Revisit the requirements for renewal and variations of product registration to ensure that a risk-based approach is followed and only relevant documentation is requested from the applicant.

18. Consider limiting the period of validity of waivers and their use to exceptional circumstances since they can undermine the system.

19. Use existent regional platforms to enlist MNCH medicines as part of the priority medicines for joint assessments and subsequent registration in the member states.

20. Use regional counterparts and the best international practices as reference for development of a regulatory framework for medical devices and medical gases, including the use of model law and regional guidelines. NRAs could also initiate a phased approach toward regulating medical devices, placing a stronger emphasis on high-risk devices.

[19] Per WHO GBT indicator RS05: "Quality management systems (QMS) including the risk management principles are applied and realized." According to WHO "QMS is a valuable tool that helps NRAs to achieve greater credibility for their decisions and greater stability in their operations, to include systematic planning, control, and improved quality in all processes throughout all regulatory functions, and to ensure a comprehensive approach for all."

CONCLUSION

Most of the MNCH tracer medicines are registered in the nine countries studied, but the overall average of 80% of medicines with at least one registered product masks some important disparities. Some countries (Senegal, Mali, and Nepal) have lower levels of registered medicines, and some tracer medicines are registered in fewer countries. Notably, injectable hydralazine 20mg injection, magnesium sulphate 500mg/ml, gentamicin 20mg and procaine benzylpenicillin 1g, and ORS in 200ml flavored sachets are unregistered in four or more of the countries surveyed. Markets for essential MNCH medicines are for the most part high volume, but low cost and low profit, so important consideration must be given to streamlining the registration process to mitigate disincentives for market entry for manufacturers of quality-assured products. The findings indicate that this will involve legal, organizational, and procedural changes in the nine countries, namely short-, mid-, and long-term structural solutions. 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.

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