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Frontier Health Markets (FHM) Engage

GUIDE TO RULES & REGULATIONS REFORM

To Expand Private-Sector Participation in Markets for Family Planning and Maternal, Newborn, and Child Health Products and Services

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Acronyms

FHM	Frontier Health Markets
IUD	intrauterine device
MDA	market development approach
MNCH	maternal, newborn, and child health
NGO	nongovernmental organization
NMRA	national medical regulatory authority
USAID	United States Agency for International Development
WHO	World Health Organization

Introduction

In low- and middle-income countries, the private sector operates alongside the public sector to deliver key health products and services, including for family planning and maternal, newborn, and child health (MNCH). Governments have an important role to play in engaging the private sector to ensure more equitable access to such products and services, by creating an enabling policy environment through an effective regulatory framework.

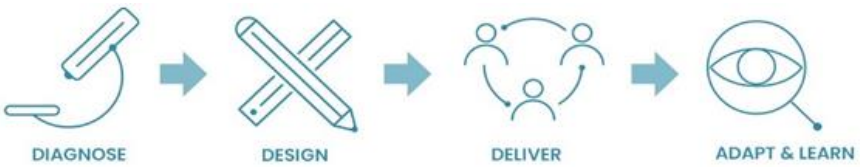
Frontier Health Markets (FHM) Engage is a United States Agency for International Development (USAID) project that supports developing country governments, donors, and their implementing partners in strengthening local health markets to ensure more equitable provision of and access to family planning and MNCH products and services. It uses a market development approach (MDA) that focuses on identifying and addressing the root causes of underperformance in core market functions in order to achieve sustainable changes to supply and demand.

This document is a companion guide to FHM Engage's *Guide to Rules, Regulations, and Norms Analysis*, which provides a step-by-step approach to analyzing the rules, regulations, and norms that affect local markets for family planning and MNCH products and services. The next step after the analysis is to apply the findings – that is, to reform rules and regulations so the market for family planning and MNCH products and services can develop and expand. This document explains how to do that, using the MDA Pathway to Impact process.

The Pathway to Impact has four phases: Diagnose, Design, Deliver, and Adapt & Learn (Figure 1).

- **Diagnose** the impact of existing rules and regulations on the operation and performance of market actors.
- **Design** reforms of the rules and regulations to enable market actors to expand their operations and improve their performance while safeguarding population health.
- **Deliver** the reforms in collaboration with market actors.
- **Adapt and learn** from the implementation of the reforms to enable further market development.

Figure 1. MDA Pathway to Impact PROCESS



Background

All markets have a set of supporting functions, rules and regulations, and norms that collectively determine how market actors on both the demand and supply sides behave and perform, the incentives they respond to, and the ways they are held accountable. This environment is referred to as the market system (Springfield Centre, 2015).

The companion *Guide to Rules, Regulations, and Norms Analysis* focuses on understanding the core operations of the market for family planning products and services. This involves closely examining the supporting functions, rules and regulations, and norms that shape and influence the market as well as the institutional arrangements that govern the market – that is, the key agencies and actors that set the rules and regulations.

- **Supporting functions:** Attributes of a market system – such as stewardship, financing, market intelligence and information, and access to finance – that influence incentives for consumers and suppliers and their ability to perform their respective roles in that system.
- **Rules and regulations:** Formal mechanisms that govern the behavior of market actors. In this document, "rules and regulations" encompasses policies, laws, and regulations issued by public authorities as well as rules, guidelines, and standards (not to be confused with clinical standards) issued by professional associations and industry bodies, such as codes of conduct.
- **Norms:** Informal rules that govern the behavior of individuals, groups, and societies and are products of local culture, religious traditions, value systems, cultural practices, and other factors. Norms influence the extent to which formal rules are accepted.

Methodology

This document explains how to apply the findings that emerge from using the *Guide to Rules, Regulations, and Norms Analysis*. Both guides are based not on theories about appropriate rules and regulations but on the actual experiences of countries in implementing and reforming rules and regulations to promote market development in family planning and MNCH.

The methods, approaches, and findings in this document draw on data collected through a desk review, key informant interviews, and consultative meetings with FHM Engage technical leaders. We used a desk review search methodology that focused on peer-reviewed and grey literature (including USAID and World Bank websites) from the past 10 years. We also conducted a targeted search of all relevant documents from previous and current USAID-funded programs, including regulatory reviews, technical briefs, and private-sector assessments. We conducted interviews with 14 experts with multi-country experience in regulatory reforms relating to family planning and/or MNCH market systems. (They are listed in Annex 1.) We used thematic content analysis to identify key themes emerging from the review and the interviews. Finally, we convened USAID experts, FHM Engage technical leaders, and researchers to test and validate the findings.

The Pathway to Impact

Diagnose: Analyze the Impact of Existing Rules and Regulations

The **Diagnose** phase involves analyzing the impact of existing rules and regulations on the operations and performance of local health market actors and the root causes of underperformance. This process should be inclusive and involve both state and non-state actors. An experienced facilitator (such as FHM Engage) can play a key role in gathering data and analyzing it to help market actors diagnose issues and design interventions. The Diagnose phase consists of three steps, each with guiding questions. (See Table 1, which also provides an example based on the market for youth-friendly family planning products and services.)

TABLE 1: THREE STEPS IN THE DIAGNOSE PHASE

Steps	Guiding questions	Youth market example
1. Identify which market to focus on	▪ Which markets can contribute to better family planning and MNCH outcomes?	▪ Market for youth-friendly family planning products and services
2. Identify how the market is structured and analyze supply and demand	▪ What rules and regulations are needed to address the structure of demand and supply in the market? ▪ How can specific rules and regulations address the demand opportunity identified? ▪ What rules and regulations are needed to address any private-sector supply opportunities to respond to demand? ▪ What rules and regulatory frameworks govern data and information management?	▪ What drives youth demand for family planning products and services in terms of culture, preferences, and where young people prefer to seek such products and services? ▪ If services are available in the public and private sectors, why are young people not seeking them out? ▪ Use the answers to the questions above to identify the market opportunity and then carry out a supply-side analysis to understand the constraints that private providers may face in delivering youth-friendly family planning products and services. For example, the private sector may face restrictions on offering family planning, MNCH, or HIV/AIDS services to youth.
3. Understand market performance	▪ What rules and regulations are needed to address market underperformance in terms of quality, affordability, and/or access? ▪ Are such rules and regulations present or absent?	▪ If the analysis finds that the private sector has an important role to play in delivering these products and services to youth, what rules and regulations are needed to

	▪ If they are present, is implementation adequate? Are they having the necessary impact in terms of market development? If the rules and regulations are being implemented but have inadequate impact, is it because they are poorly designed? Or are incentives lacking? ▪ If rules and regulations are absent, why is that the case? Is the government unaware of this deficiency, or does it lack the capacity to design and implement such rules and regulations?	address quality, access, and affordability? For example, are there restrictions on the provision of certain family planning products or services based on age?

The answers to these questions will provide a preliminary idea of the kinds of interventions that might address the root causes of market underperformance. The *Guide to Rules, Regulations, and Norms Analysis* outlines the full range of regulatory and normative areas to consider during the Diagnose phase. It also provides a worksheet to help determine how well these regulatory functions are performing and how norms may be constraining the performance of the family planning or MNCH market.

The evidence review and interviews with experts found several common barriers to accessing family planning and MNCH products through the private sector (Table 2).

TABLE 2: BARRIERS TO PRIVATE-SECTOR PARTICIPATION IN FAMILY PLANNING AND MNCH MARKETS

Barriers to private-sector participation in the market for family planning products	Barriers to private-sector participation in the market for MNCH products
Large donor presence. In low- and middle-income countries, the public sector often receives family planning products from donor organizations that purchase the products through vertical programs, thereby controlling procurement and supply. These organizations can negotiate bulk purchases at lower prices and guarantee the quality of the products. Commercial private providers are expected to negotiate volume and price on their own. Local rules and regulations that incentivize the private sector to deliver affordable, quality family planning products may be lacking. Because donors provide subsidized products through the public sector, the public sector may be unaware that a private sector for family planning products even exists. **Example:** To encourage private-sector provision of family planning products at affordable prices in Jordan, the country's National Population Commission successfully lobbied the Ministry of Finance and the Ministry of Industry and Commerce to remove taxes, duties, and tariffs on all imported contraceptive commodities except intrauterine devices (IUDs). This was possible because family planning products were	**Lack of donor support and constrained local markets.** Unlike with family planning markets, no international donors provide large amounts of MNCH products. **Example:** Low- and middle-income countries procure oxytocin themselves; the quality is variable because resource constraints lead them to buy the cheapest products. *Diagnose phase: Focus on the rules and regulations that are preventing the development of high-quality local markets for MNCH products.*

categorized as nonpharmaceutical products. This reform reshaped the market, and the private sector was able to introduce a newer generation of oral contraceptive pills at affordable prices. *Diagnose phase: Focus on understanding the sustainability of family planning products, the levels of donor support, how donor support contributes to local market underperformance, and what rules and regulations are preventing local market development. In countries where the total market approach has been implemented, data may already be available on the rules and regulations needed to support sustainable commercial provision of family planning products.*	
Supply constraints on the private sector. Private-sector providers purchase in smaller amounts, so they often pay higher prices. *Diagnose phase: Collect data to understand the role of rules and regulations in supply and pricing constraints. What are the barriers to bulk purchasing for the private sector? Can the private sector benefit from government-negotiated prices with international manufacturers?*	**Product quality and market incentives.** MNCH products are often cheap products with very small profit margins. Many are locally produced—particularly oxytocin and magnesium sulfate (less often for misoprostol). Therefore, international companies have no business incentive to enter the market. Local production is not necessarily bad, but quality assurance for locally produced products should be a priority. **Example:** A 2016 review found that of 559 samples of oxytocin collected from 15 low- and middle-income countries, the highest proportion of samples with inadequate amounts of active pharmaceutical ingredient were from Africa, where 60% of the samples tested failed to meet minimum standards. A 2019 study by the Clinton Health Access Initiative in Nigeria's Kano State found that clinicians typically administered up to four times the recommended dose of oxytocin to prevent postpartum hemorrhage due to potency concerns. Aside from the risk of patient overdose, this practice risks oxytocin wastage and inefficient use of limited health care funds. The oxytocin market is highly competitive, and manufacturers may feel compelled to compromise quality to lower costs and increase sales. National policies—such as those that regulate pharmaceutical prices and reimbursement rates—may increase pressure to reduce the price of oxytocin while focusing less on quality. By contrast, the two prequalified suppliers and 12+ suppliers approved by stringent regulatory authorities typically set prices above those of competitors, partly for cost recovery reasons.

	Diagnose phase: Focus on gaps in local rules and regulations to support a strong local industry.
Barriers to entering the market for youth-friendly family planning products and services. Studies show that youth in low- and middle-income countries avoid the public sector when accessing family planning and other health products and services due to a lack of confidentiality as well as social stigma. Rules can restrict the private sector's ability to deliver those products and services to youth, resulting in market failure even if demand exists. Cultural norms and values around sex and contraceptive use by young people as well as health worker bias against providing reproductive and maternal health services to youth are also key barriers. *Diagnose phase: Determine whether any rules and regulations prevent private providers from delivering family planning products and services to youth.*	**Oxytocin cold chain challenges.** Oxytocin is not heat stable. Manufacturers say it is heat stable up to 21 degrees Celsius for six months, but temperatures in many countries can go up to 30 to 40 degrees Celsius. Also, during transport the medicine can sit in trucks for long periods, at very high temperatures, which can compromise its quality. When oxytocin is destabilized, as many as five vials may be needed to manage postpartum hemorrhage compared to one vial of a quality product. *Diagnose phase: Determine whether any laws or regulations could incentivize the private sector to innovate around heat-stable oxytocin. Also determine whether some rules and regulations exclude oxytocin from the cold chain in favor of other products (including non-health products).*
Restrictive national policies. **Example:** India's health and population regulations focused on population control from 1970 through 2000. This translated to rules that promoted family planning methods that served the goal of population control—namely, sterilization (bilateral tubal legation) and long-acting and reversible contraceptive methods such as 10-year IUDs and five-year implants. Choice and availability of family planning products and services were limited and generally determined by the national policy direction. *Diagnose phase: Identify ways that rules and regulations could help address national policy restrictions.*	**Carbetocin registration and labeling.** Unlike oxytocin, carbetocin is a heat-stable product that does not have cold chain issues. However, in some countries health workers are not aware that carbetocin has the same range of uses as oxytocin, so they use it only for inducing labor and preventing postpartum hemorrhage when it can also be used to manage postpartum hemorrhage. Carbetocin is also less available than it could be due to difficult registration processes in some countries. *Diagnose phase: Analyze rules and regulations to ensure that labeling for products on the essential medicines list aligns with indicated uses.*
Advertising restrictions. Advertising of family planning products is often limited or banned in low- and middle-income countries. This leads to low demand because communities are unaware of the availability of good-quality services or new family planning products in both the public and private health sectors. Broad communication is needed to increase demand for those products. *Diagnose phase: Understand the root causes of restrictions on advertising of family planning products.*	**Packaging requirements.** Misoprostol is highly affected by humidity and requires double aluminum foil to protect against moisture when being transported to more remote areas. Unfortunately, this packaging increases production costs. *Diagnose phase: Explore rules and regulations related to tax subsidies for the private sector to enable distribution of quality products to more remote populations.*
Unharmonized product registration and renewal processes. Some regulatory processes and procedures have been harmonized across countries, but uniformity is still lacking. Manufacturers must go through the registration process in each country where they want their product to be available. This results in significant costs for manufacturers, who have to consider the market potential before they try to register in a country.	

Product registration must also be renewed annually. There is an urgent need for harmonization of registration and renewal processes across countries, regions, and eventually continents.

Design: Reform Rules and Regulations to Address Challenges

In the **Design** phase, the facilitator and partners work with local health market actors to reform the current rules and regulations so market actors can expand the scale and scope of their operations and improve their performance. This section provides examples of common regulatory and policy challenges as well as opportunities for improving access to family planning and MNCH services and products. Note that these examples are illustrative and not generalizable to all market systems.

Family Planning

According to Demographic and Health Survey data from 36 low- and middle-income countries, about 34 percent of users of modern contraceptive methods rely on private-sector sources, and 41 percent of those users obtain the contraceptives from pharmacies or drug shops (Bradley, SEK, 2022). These retailers are often the first line of health care for many people, particularly underserved populations and those in rural areas with limited access to public-sector health facilities (Bradley, SEK, 2020; Riley, P, 2017). Pharmacies and drug shops are also preferred by people who value the convenience, anonymity, and cost savings they provide compared to private clinics. Therefore, influencing the incentive and accountability environment in which retail pharmacies and drug shops operate – including through regulation – is crucial to ensuring that the reproductive needs of women in low- and middle-income countries are met.

World Health Organization (WHO) recommendations on the dispensing of family planning products by drug shops and pharmacies are based on the cadre of providers delivering the products, not the type of outlet (Riley, P, 2017). The desk review, interviews, and technical consultations found that the rules governing the operation of pharmacies and drug shops that sell family planning products had several common shortcomings in their design and/or enforcement, and in a few areas the rules were found to impede market development. See Table 3 for recommendations for addressing these shortcomings.

TABLE 3: FRAMEWORK FOR REGULATORY REFORM TO IMPROVE ACCESS TO FAMILY PLANNING PRODUCTS AND SERVICES IN PRIVATE PHARMACIES AND DRUG SHOPS

Objective of regulatory reform	Regulatory domain	Recommendations and considerations
Addressing regulatory gaps and inadequacies	**Products** *Including rules on methods offered by different providers and rules on inventory management, storage, packaging, listing on national essential medicines lists, and prescriptions*	▪ Strengthen existing regulations to ensure that injectables can be provided only by pharmacists with additional training or other pharmacy workers under the direct supervision of trained pharmacists. Drug shops should not be able to provide such products.
	Services	▪ Address the lack of rules relating to counseling, screening, and referrals to clinics.

	Including rules on informed-choice counseling, referrals, diagnoses, and injections	▪ Introduce rules that strengthen the capacity of providers to safely provide family planning products and associated services (e.g., rules that connect the ability to sell oral contraceptives over the counter to requirements on refresher training in counseling clients on the use of those products).
	Pricing *Including rules on markups (e.g., over the prices set by wholesales or manufacturers) and user subsidies*	▪ Price regulations at the distributor/retailer level can help address markups over manufacturer prices to some degree (though even efficient prices may still limit access to poorer consumers). The lack of price controls and market transparency, such as a recommended retail price, means that additional costs are added to the products as they are distributed to the last mile, resulting in clients paying high prices. ▪ Evidence shows that price regulation works better when adequate supplies of nonbranded prescriptions are available.
	Reporting and information *Including rules and regulations that require private pharmacies and drug shops to report data to the national health management information system*	▪ Rules and regulations, including incentives for private pharmacies and drug shops to report to the national health management information system, can help state actors manage access and quality and address demand-side barriers. Effective policies and regulations on reporting must provide tangible value for private providers. For example, such policies could tie professional licensure, facility registration, or eligibility for public-private partnerships to specific reporting targets. ▪ Engagement with, and/or delegation of responsibility to, professional associations can help shape and enforce these policies with different types of providers.
Addressing unnecessary restrictions on market development	**Family planning products and services** *Including rules on the range of products and related services that pharmacies and drug shops can safely provide*	▪ According to WHO guidance, operators of retail outlets such as pharmacies and drug shops can safely provide combined oral contraceptive pills, progesterone-only pills, emergency contraceptive pills, and male and female condoms. ▪ Low- and middle-income countries are typically more restrictive than WHO recommendations in their regulations on what pharmacists and drug shops can dispense.
	Marketing *Including rules that govern the range of products and services that can be advertised in specific ways*	▪ Remove restrictions on advertising contraceptives because such policies can perpetuate the perception that contraceptives are a taboo topic.

	Access to public funds *Including rules that enable covered users to access essential family planning products from private-sector retailers*	▪ Where possible, include family planning products in benefit packages and contract with retailers to provide the products on a free or subsidized basis. This will reduce out-of-pocket spending on medicines and support the goals of greater access and use of family planning products.
	Over-the-counter sales *Including rules that enable covered users to access essential family planning products from private-sector retailers*	▪ Restrictions on who can fill prescriptions are widespread in low- and middle-income countries. However, some countries have approved several essential medicines for over-the-counter sale, thereby enhancing access in places with few clinics. This suggests opportunities to consider reforms on a case-by-case basis.

Addressing regulatory gaps and inadequacies

Family planning products. According to WHO guidance, provision of injectable contraceptives should be restricted to pharmacists and clinical professionals (nurses, midwives, associate clinicians, and doctors) as well as other pharmacy workers who have received additional training and are under the direct supervision of a pharmacist – a stipulation that is often lacking in regulations in low- and middle-income countries (Gerrard, A, 2022; WHO, 2012). More rigorous evidence is needed about the effectiveness or acceptability of lay health workers (e.g., drug shop owners or workers) providing injectable contraceptives in various contexts or conditions, especially before such a policy is implemented or scaled up. The WHO guidelines also recommend against allowing insertion and removal of IUDs outside of clinical settings (e.g., in pharmacies or drug shops).

In addition, the safety and efficacy of such products in low- and middle-income countries are affected by a range of variables, including 1) whether the products have been protected from the adverse effects of light or temperature, 2) whether drugs have passed their expiration date or are counterfeit, and 3) whether regulatory enforcement is weak, leading to leakage of products between the public and private sectors.

According to Riley et al. (2017), close to half of the 32 low- and middle-income countries studied have rules on inventory management, storage, and packaging, although actual practices remain poor. Counterfeit drugs are increasingly flooding markets globally, and regulations for retailers, such as prohibitions on knowingly stocking or selling counterfeit medicines, are far from universal. Even where rules exist alongside related penalties and procedures, enforcement is often inadequate. Many factors could explain this, including too few inspectors, corrupt inspectors, or a lack of laboratories to verify the contents of packages (Feeley, R, 2009).

Family planning services. WHO has recognized that operators of retail outlets such as drug shops and pharmacies can safely and effectively provide family planning products and services commensurate with their clinical qualifications (WHO, 2017a). Counseling on informed choice and on the safe and effective use of medicines is a basic function of pharmacists, but actual performance varies across low- and middle-income countries (Odegard, PS, 2011). Drug shops and less qualified vendors often have no

training in informed-choice counseling, which raises concerns about the appropriateness and quality of their advice to clients (Rutta, E, 2015). A scan of regulations governing pharmacies and drug shops in 32 countries revealed that in a majority of those countries, rules for services were less adequate than rules for products (Riley, P, 2017). Rules related to counseling, screening, and referrals to clinical providers are often lacking. Evidence suggests that most regulators in low- and middle-income countries can learn from the experience of India, which has provided directive language on counseling since 2016, with rules linking the sale of oral contraceptives over the counter to requirements on refresher training in counseling clients on their use.

Pricing. Regulations on markup of retail prices over wholesale or manufacturer prices for specified family planning products are common but not universal, raising the risk that prices set by private retailers are unaffordable to many or yield excessive profit. Even without excessive markups, the affordability challenge may remain for many patients. Ultimately, the solution to this problem will be found in including private pharmacies and drug shops in government-sponsored programs or insurance schemes, but this is still comparatively rare in low- and middle-income countries (Callahan, S, 2017).

Data sharing and use policies. Lack of clarity on how private provider data will be shared and who will use it frequently inhibits private providers from reporting. Private providers are concerned that the ministry of health will use the data to regulate, audit, tax, or punish them. Financial data can be particularly sensitive. Private providers have also voiced concerns that competitors will gain access to their data and thereby gain a competitive advantage. Given these reservations, misconceptions, and lack of enforcement of data submission policies, many private providers refuse to share data or share only partial data.

Addressing unnecessary restrictions on market development

Family planning products and services. According to WHO guidance, operators of retail outlets such as pharmacies and drugs shops can safely and effectively provide the following family planning products (Gerrard, A, 2022):

- Combined oral contraceptives
- Progesterone-only oral contraceptives
- Emergency contraceptive pills
- Condoms (male and female), barrier methods, and spermicides

WHO recommends that provision of injectable contraceptives should be restricted to pharmacists and clinical professionals (nurses, midwives, associate clinicians, and doctors) and pharmacy workers who have received additional training and are under the direct supervision of a pharmacist (WHO, 2012; WHO 2015). Low- and middle-income countries are typically more restrictive than WHO recommendations in their regulations on what pharmacists and drug shops can dispense.

Marketing. Cultural norms have an impact on rules – both in their substance and the extent to which they are accepted by market actors. This is especially apparent when it comes to rules on marketing products, which in many countries unnecessarily impede market development. For example, India has a general ban on advertising contraceptives that require prescriptions. In 2017, India also imposed restrictions on advertising condoms – which do not require a prescription – on television (Gerrard, A, 2022). Such advertisements are allowed only between 10 p.m. and 6 a.m. This undermines market

development in ways that are likely to constrain the use of condoms, with what appears to be an extremely weak population health rationale. These restrictions may further perpetuate the perception that contraceptives are a taboo topic in India.

Access to public funds. State-supported health insurance schemes are being introduced in many low- and middle-income countries as part of efforts to accelerate progress toward universal health coverage. If essential family planning products are included in benefit packages and retailers are contracted to provide them on a free or subsidized basis, this could reduce out-of-pocket spending on these products and support family planning goals. When a national health insurance scheme contracts with private providers to deliver family planning products and services, those providers can get a big boost in expanding that line of business – including to sell to specific groups such as youth. However, supply-side barriers faced by private providers would have to be addressed simultaneously – for example, in areas such as taxes, duties, and tariffs.

Over-the-counter sales. In some low- and middle-income countries, several products classified as essential medicines have been approved for over-the-counter sale, thereby enhancing access in settings with few clinics (Riley, P, 2017). According to Riley et al.'s international review, sales of oral contraceptives are permitted without a prescription in 15 of the 32 countries studied, by both pharmacies and drug shops, while prescriptions are required by regulation in 14 of the countries. However, prescription rules are often disregarded in many countries due to enforcement challenges. As with referrals, most countries' regulations make no mention of the duty of drug retailers to assess eligibility for and appropriateness of certain medicines.

Analysis shows that the existing configuration of rules in many countries is inadequate due to gaps and challenges relating to enforcement. To protect population health, a more comprehensive collection of rules is often needed. On the other hand, some existing rules disadvantage private-sector retailers and place unnecessary constraints on their growth. The best way forward is to establish a principle that lower regulatory barriers should be conditioned on compliance. That is, the right to sell oral contraceptives without a prescription, or the right to receive public funds, or the right to engage in advertising and other marketing strategies, should be tied to more robust compliance with a more comprehensive regulatory regime that addresses products, services, and pricing.

Such an approach, if properly formulated, could serve both population health and the commercial interests of private pharmacies and drug shops.

Taxes, tariffs, and duties. Many countries have restrictions on importing contraceptive products. When looking at the barriers that providers face in introducing new family planning products or sustaining the supply of quality and affordable family planning products, it is important to look at the rules on importation and how these might be reformed.

Maternal, Newborn, and Child Health

Progress toward the MNCH targets in United Nations Sustainable Development Goal 3 (Good Health and Well-Being) depends on access to quality medicines, products, and services for MNCH, including the 13 commodities identified by the UN Commission on Life-Saving Commodities for Women and Children. However, access in low- and middle-income countries is hampered by a lack of supportive policies and regulations, staffing shortages, lack of finances, and weak supply chains.

The four central objectives of regulation of MNCH products and services are:

- To control market entry and structure (quantity of care)
- To improve and maintain good-quality health services and products (quality of care)
- To improve efficiency in health service provision (cost-effectiveness of care)
- To ensure equitable health service provision (access to and affordability of care) (Morgan, R, 2016; Afifi, N, 2003)

Regulations can help ensure the technical quality of service providers, limit the availability of harmful drugs and unregistered products, minimize drug misuse, control the sale of specific drugs through prescriptions, and regulate drug manufacture and importation. Regulation has a crucial balancing role within the private sector, although the resources for monitoring and enforcing regulations are typically insufficient (Wiysonge, C, 2016; Lamba, G, 2021). Co-regulation with professional associations, civil society organizations, and communities can be beneficial (WHO, 2020; Lamba, G, 2021).

Table 4 identifies common regulatory and policy measures in MNCH markets, regulatory challenges, and recommendations for improving access to MNCH services and products.

TABLE 4: FRAMEWORK FOR REGULATORY REFORM TO IMPROVE ACCESS TO MNCH PRODUCTS AND SERVICES

Objective of regulatory reform	Current regulatory environment	Regulatory challenges	Recommendations
Control market entry and structure *Quantity of care*	All countries have strong regulatory measures for market entry, including for registration and licensing of new health providers and new health products.	High regulatory burden for market entry of new health products; Weak enforcement	Harmonize registration policies for medicines across neighboring countries/regions. Align approval decisions with authorization by well-established regulatory agencies and WHO prequalification. Use special import licenses for priority products if necessary.
Maintain good quality of health products and services *Quality of care*	Regulation of providers beyond market entry is limited. Only about 30% of countries can regulate medical products effectively and efficiently.	Generally weak regulatory capacity beyond market entry	Coordinate private providers using intermediary bodies such as faith-based organizations, franchises, and professional organizations. Use external regulatory agencies as a reference.
Improve the efficiency of health service delivery *Cost-effectiveness of care*	There is limited regulation governing the geographical location of private providers within health systems. Most private	Absence of incentives for private providers to set up in rural and remote areas	Strengthen incentives through market entry regulations and financial mechanisms.

	providers are in towns and cities.		
Ensure equitable health service provision *Access to and affordability of care*	Few countries have social health insurance systems. Private health providers are concentrated in urban areas.		

Addressing the effects of regulation on market entry, competition, production, and pricing

In nearly 99 percent of countries, medical products cannot be sold without approval from the national medical regulatory authority (NMRA). NMRA functions include market authorization, licensing of manufacturers, import and export control, inspection of manufacturing premises and distribution channels, market surveillance (product quality monitoring, pharmacovigilance, control of drug promotion and advertising), quality control, and oversight of clinical trials. The absence of well-resourced and functional NMRAs restricts access to life-saving commodities (Ndomondo-Sigonda, M, 2017; Guzman, J, 2020).

Only 30 percent of NMRAs in WHO member states have the capacity to regulate medical products effectively and efficiently (WHO, 2017b). And only seven percent of countries in sub-Saharan Africa have moderately developed capacity for carrying out core regulatory functions; 90 percent have minimal or no capacity. In that region, the time between initial regulatory submission and final approval is typically four to seven years. This deters companies from supplying medicines to certain African countries. Legal and regulatory frameworks are also fragmented in some countries, which means the NMRA may not have the mandate and authority to perform all regulatory functions (Ndomondo-Sigonda, M, 2017).

Regulatory challenges include:

- **High regulatory burden** for manufacturers, most of which are in countries (e.g., India and South Africa) that lack the kind of stringent regulatory authorities found in Europe, the UK, and the United States. As a result:
    - Manufacturers face high costs, including for frequent good manufacturing practice inspections, registration renewals, and country-specific labeling requirements.
    - Manufacturers face long time lags between submission of dossiers to regulators and final registration, typically four to seven years. Approval of post-registration amendments to registration dossiers can also be delayed.
- **Weak enforcement**, which allows for the influx of counterfeit and substandard medicines. This is a deterrent to manufacturers of high-quality products.
- **Donor procurement policies** that disadvantage local producers and market development. Donors will not procure from local manufacturers that do not have WHO prequalification or approval from a well-established authority. Policies that provide priority products for free can also disadvantage private actors in the market.

All of these challenges can be addressed by harmonizing regulations across countries and basing local authorization on the decisions of well-established regulatory agencies. Such efforts are underway on different continents (Narsai, K, 2012; Brhlikova, P, 2020; Guzman, J, 2020). Specific solutions include the following:

- Harmonizing registration policies, to help ensure the safety, quality, and efficiency of medicines.
- Enabling centralized/regional processes and decisions for product registration.
- Aligning authorization decisions with approval by well-established regulatory agencies and WHO prequalification. Manufacturers can submit documents for review without the need for physical inspections. However, 80 percent of products in Africa come from India and other countries without such stringent regulatory authorities.
- Harmonizing processes for joint inspection of facilities and joint registration across regions.
- Employing alternatives to registration such as special import licenses for medicines that are not on the drug register in emergencies or extraordinary circumstances. These medicines could undergo a document review only.

Addressing the effects of regulation on product quality and access

The most common regulatory strategies are licensing and accreditation of providers; monitoring and supervision – particularly supportive supervision – are extremely effective but more rarely implemented. Unfortunately, most regulatory efforts focus on market entry, not post-licensing and post-registration quality control of health workers and health products.

The dominant strategy for engaging and coordinating private health providers is through the use of **intermediary organizations** that connect small-scale private providers with governments, patients, and vendors while performing key health systems functions that are challenging for individual providers to do on their own. Key examples of intermediary organizations identified in the literature are include social franchising networks, nongovernmental organizations (NGOs), and faith-based organizations, and professional organizations many of which create strong networks of private providers for service quality improvement, regulatory compliance, and provider representation (Dimovska, D, 2016).

Awor et al. conducted a scoping review of effective strategies for engaging private providers for improved access and quality of MNCH services at the primary health care level. The review identified key challenges as well as effective strategies related to regulation: incentives for private providers, use of intermediary organizations, and a greater role for private pharmacies and drug shops in diagnosis and treatment of common childhood illnesses. (See Table 5.)

TABLE 5: ADDRESSING THE CHALLENGES OF ENGAGING PRIVATE PROVIDERS FOR MNCH

Challenges (Awor et al. 2022)	Recommendations
Diverse and uncoordinated private health providers	▪ Use intermediary organizations (e.g., social franchising organizations, NGOs, faith-based organizations, and professional organizations) to help small-scale private providers interact with governments, patients, and vendors. ▪ Create an enabling environment for the creation of networks of providers or intermediaries that enable small providers to maintain their identity while engaging collectively with the government.

	▪ Use data to understand the types of providers and the services they provide, as well as influences on the providers and how to ensure access to and quality of care.
Weak government capacity to engage private providers and lack of resources for engagement, regulation, and enforcement	▪ Provide knowledge, strategic advice, and technical and implementation support for engagement strategies (e.g., contracting, social franchising, and accreditation). ▪ Improve government capacity to negotiate, develop, implement, and manage contracts (e.g., human resources, financial). ▪ Increase government resources for primary health care and private provider engagement. ▪ Create an enabling environment for intermediaries and provider networks to thrive and thereby stimulate self-regulation.
Unaffordable and inequitable service provision in the private sector	▪ Use demand-side interventions, particularly vouchers and social health insurance. ▪ Use market-shaping strategies (e.g., supranational or local subsidies of common medicines, products, and services).
Poor service quality (in both the private and public sectors)	▪ Use franchising and other intermediary approaches to ensure that standards are known and adhered to. ▪ Implement training, regulation, accreditation, social marketing, social franchising, and contracting. ▪ Implement supportive supervision and routine monitoring. ▪ Ensure date sharing and data use. ▪ Use the integrated management of childhood illness strategy and the integrated community case management strategy for malaria, pneumonia, and diarrhea to improve quality at private clinics and drug shops.

Annex 2 provides helpful checklists for use during the Design phase. These can be adapted to the local context.

Deliver: Implement Regulatory Reforms

In the **Deliver** phase, facilitators and partners collaborate with local health market actors to implement the reforms devised during the Design phase. This means improving the regulatory apparatus and enabling market system strengthening and growth while safeguarding population health.

All market systems require specific rules that are enforced. Where important rules are absent, they need to be established. Where such rules are present, but enforcement is inadequate, that must be addressed. Where rules create unnecessary barriers to access, that also needs to be addressed.

This phase includes co-creation of an action plan or roadmap by local health market actors and a government or other state actor (e.g., a provincial, regional, or district authority). Note that the focus should be not on the established roles of specific actors but on who is best placed to carry out important market functions. Often, the actors best placed – in terms of capacity, incentives, and credibility – to lead the effort to reform rules and regulations (and in some cases, to define and enforce those rules and regulations) are nonstate actors, such as outside agencies, councils, or professional/industry associations.

When identifying who should lead the effort to create an action plan, three interrelated factors are crucial to consider:

- **Capacity.** Who has the technical and managerial capacity to deliver the planned reconfiguration of rules? If certain actors have the incentives and credibility but lack the capacity, how can that capacity be built and sustained?
- **Incentives.** What are the motivations of the prospective leader, and will these be sustained in the long term? If the incentives are unclear, sustainability may be a concern.
- **Credibility.** Does the prospective leader have the ability to perform the role and a compelling incentive to do so but lack credibility among other market actors? Can that actor's credibility be enhanced? The status and reputation that would potentially flow from the effort may increase the incentive to take on the role and incur the costs, time, and effort involved.

Adapt and Learn: Share Lessons for Ongoing Improvement

The **Adapt and Learn** phase involves learning from the results of the reforms implemented in the Deliver phase and sharing that information so facilitators and partners can engage with local health market actors to further address the rules, regulations, and norms that impede market development. The guidance in this document will be applied and tested by FHM Engage in three countries – Nepal, Pakistan, and India – through workshops involving local health market actors and other relevant stakeholders. Further refinements to the MDA will be shared with both the FHM Engage staff and the global health community. Action plans and other outputs from the workshops will be closely monitored to note any changes resulting from the interventions and the application of the guide.

Conclusion

This document uses evidence to fill gaps in MDA application to support efforts to reform rules and regulations that enable or constrain development of family planning and MNCH markets. Like the companion *Guide to Rules, Regulations, and Norms Analysis*, it will be updated and revised in the future based on application and testing.

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Annex 1. Key Informants Interviewed

#	Name	Organization/project
1	Frank "Rich" Feeley	Boston University
2	Anna Gerard	Palladium
3	Nelson Gitonga	Insight Health Advisors
4	Walter Obita	Kenya Healthcare Federation
5	Farhan Yusuf	FHM Engage
6	Barbara O'Hanlon	O'Hanlon Consulting
7	Amit Thakker	Africa Healthcare Federation
8	Sarah Romorini*	Abt Associates
9	Milka Dinev	Reproductive Health Supplies Coalition – Maternal Health Supplies Working Group
10	Tanvi Pandit-Rajani	Zenysis Technologies
11	Safia Ahsan	Reproductive Health Supplies Coalition – Market Development Approaches Working Group
12	Shankar Naharayan	Population Services International
13	Deborah Armbruster	USAID
14	Jane Briggs	Medicines, Technologies, and Pharmaceutical Services (MTaPS) Program, Management Sciences for Health
* Provided inputs via email		

Annex 2. Checklists for the Design Phase

GENERAL CHECKLIST ON EXISTING RULES AND REGULATIONS AND PROPOSED REFORMS (ADAPTED FROM DOHERTY, JE, 2015)

Objectives of regulation		Do rules and regulations exist?	Challenges and constraints	Proposed reforms
Regulation of health professionals				
Regulations on registration of health professionals				
Regulations on licensing of health professionals to practice in the private sector				
Regulations that encourage health professionals to work in underserved areas				
Regulations on quality of services provided by health professionals	Sanctions for unprofessional behavior			
	Continuing education requirements			
Regulations on reimbursement levels for health professionals				
Regulations that promote fair competition between health professionals in private practice (apart from laws on competition)				
Regulation of organizations and facilities				
Regulations on facility licensing	Hospitals			
	Clinics			
Regulations that limit the number of organizations/facilities in each area	Hospitals			
	Clinics			
Regulations that encourage organizations/facilities to operate in underserved areas	Hospitals			
	Clinics			
Regulations on service quality (e.g., standard setting, quality assurance, reporting)	Regulations on curricula of training institutions			
	Process norms and standards in hospitals			
	Process norms and standards in clinics			

	Reporting requirements for hospitals			
	Reporting requirements for clinics			
Regulations on pricing (e.g., fees for certain services)	Hospitals			
	Clinics			
Regulations that promote fair competition between organizations (apart from laws on competition)	Hospitals			
	Clinics			
Regulation of insurers				
Regulations on insurer licensing				
Specific legislation on health insurance				
Regulations that limit the number/distribution of organizations in each area)				
Regulations on service quality (e.g., comprehensive benefit packages, solvency, and reporting requirements)	Standardized benefit package			
	Solvency (specific to health insurance)			
	Reporting (specific to health insurance)			
Regulations on pricing (e.g., premium levels and administrative fees)				
Regulations that promote competition between organizations				
Regulation of the market				
Competition law and commission				

CHECKLIST ON FAMILY PLANNING AND MNCH POLICIES AND MARKET CHARACTERISTICS (ADAPTED FROM BRIGGS, J, 2018)

	Existing policy and market characteristics	Yes	No
1	The essential medicines list has been updated within the past two years		
2	The essential medicines list includes all 13 family planning and MNCH products listed by the UN Commission on Life-Saving Commodities for Women and Children (tracer products)		
3	All of the tracer products are in the standard treatment guidelines (STGs)*		
4	All of the tracer products in the STGs are also on the essential medicines list*		
5	A national policy exists on the use of community management for pneumonia		
6	A national policy exists on the use of community management of diarrhea		
Regulatory system			
7	At least one product is registered for use in the country for each tracer product*		
8	Quality problems with medicines are reported		
9	Family planning and MNCH products are routinely sampled for quality testing		
Procurement			
10	MNCH products are procured centrally		
Financing			
11	The country has a costed MNCH plan		
12	The country uses fee-for-service payment in the public sector		
13	Fee-for-service is used even when women and children under age 5 are exempt from paying for family planning MNCH medicines or services		
14	The country has a policy to provide family planning and MNCH products free of charge in the public sector (report for each tracer product)		
Supply chain management			
15	The country has a pull (demand-based) distribution method for health facilities		
16	Stockouts of tracer products have been reported at the central medicines store during the past three years*		
Information systems			
17	The country has a logistics management information system (paper, electronic or mobile) to track stock-level consumption of products		
18	All tracer products are included in the information system*		

* Report for each tracer product

CHECKLIST ON FAMILY PLANNING AND MNCH COMMODITIES

		Policy			Registration	Procurement	Financial access	Logistics	
Category	**Product**	**On EML**	**In STGs**	**Both EML and STGs**	**At least one product registered**	**Procured centrally in the previous year**	**Provided free of charge**	**No CMS stockouts in past 3 years**	**Included in LMIS**
Reproductive	Female condoms								
Reproductive	Implants								
Reproductive	Emergency contraceptives								
Maternal	Oxytocin								
Maternal	Misoprostol								
Maternal	Magnesium sulfate								
Maternal	Calcium gluconate								
Neonatal	Gentamicin								
Neonatal	Penicillin injection (ampicillin or procaine penicillin)								
Neonatal	Ceftriaxone								
Neonatal	Antenatal steroids								
Neonatal	Chlorhexidine								

Child	Amoxicillin dispersible tablets (DTs)								
Child	Oral rehydration solution								
Child	Zinc DTs or syrup								
EML = essential medicines list STG = standard treatment guidelines CMS = central medical store LMIS = logistics management information system									

About FHM Engage

Frontier Health Markets (FHM) Engage is a five-year cooperative agreement (7200AA21CA00027) funded by the United States Agency for International Development. We work to improve the market environment for greater private sector participation in the delivery of health products and services and to improve equal access to and uptake of high-quality consumer driven health products, services, and information. FHM Engage is implemented by four core consortium partners: Chemonics International (prime and co-technical lead), Results for Development (co-technical lead), Pathfinder International, and Zenysis Technologies. FHM Engage Network Implementation Partners include ACCESS Health India, Africa Christian Health Association Platform, Africa Healthcare Federation, Amref Health Africa, Ariadne Labs, CERRHUD, Insight Health Advisors, Makerere University School of Public Health, Metrics for Management, Solina Group, Strategic Purchasing Africa Resource Center, Scope Impact, Stage Six, Strathmore University, Total Family Health Organization, and Ubora Institute.

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