SHOPS PLUS

Regulation of Drug Shops and Pharmacies Relevant to Family Planning

A Scan of 32 Developing Countries

USAID
FROM THE AMERICAN PEOPLE

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Cover photo: Elizabeth Corley

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Summary

Private pharmacies and drug shops play an important role in providing family planning and other priority health services in many countries. Before designing programs to strengthen and expand this role, donors and implementing partners must first understand what is allowed within the current legal and regulatory framework. The SHOPS Plus project documented the policies, laws, and regulations that shape how pharmacies and drug shops operate and what modern family planning methods they can provide in 32 USAID priority countries. This report presents the result of that scan and discusses key findings that emerged across countries.

Acknowledgments

The authors would like to thank the numerous experts listed at the end of this report who generously contributed their time to validate our findings and identify additional resources. We would also like to express our gratitude to the participants in the WHO/USAID-sponsored meeting on modeling the impact of drug shops in April 2016 for their guidance regarding ongoing donor-funded initiatives, existing gaps in the literature, and background resources that were used to shape the scope and direction of this review. The authors also appreciate the suggestions offered by our reviewers May Post and Caroline Quijada of Abt Associates.

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Acronyms

ADDO	Accredited drug dispensing outlet
CMS	Central Medical Store
DRC	Democratic Republic of the Congo
DMPA	Depot medroxyprogesterone acetate
ECs	Emergency contraceptives
EML	Essential medicines list
IUD	Intrauterine device
NAFDAC	National Agency for Food and Drug Administration and Control
OCP	Oral contraceptive pill
PPMV	Proprietary patent medicine vendor
SHOPS Plus	Sustaining Health Outcomes through the Private Sector Plus
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

Private pharmacies and drug shops constitute a major source of modern family planning services and products in low- and middle-income countries. Donors and governments in many countries are exploring ways to expand the role of these drug retail outlets, which must start with an understanding of a country's legal and regulatory environment (HIP, 2013). World Health Organization (WHO) guidelines on Good Pharmacy Practice state that countries should establish a legal framework that defines the scope of practice, identifies who can practice, sets competency standards, and allocates resources to ensure compliance (FIP and WHO, 2011). This report provides an overview of the legal and regulatory requirements for pharmacies and drug shops in 32 developing countries with a focus on requirements affecting the provision of family planning.

Definitions used in this report

Pharmacies: Retail facilities, overseen by licensed pharmacists, that sell registered prescription–based medicines.

Drug shops: Lower–tier retail outlets, with no pharmacist on staff, that sell over–the–counter drugs, chemical products, and household remedies.

Note: *Countries use alternative names for drug shops including community pharmacy, medicine store, licensed chemical seller, chemist, patent vendor, proprietary drug vendor, and accredited drug dispensing outlet.*

Relevant policies, laws, and regulations were identified through a three-step process: a desk-based review, key informant interviews, and a consultative workshop to discuss findings with experts from USAID, implementing partners, and researchers.

Photo: Elizabeth Corley

What is covered in this report: Existing laws and regulations governing retail pharmacies and drug shops not affiliated with medical clinics, with a primary focus on relevance to family planning.

What is not covered in this report: Rules regarding import, registration, drug quality testing, warehousing, wholesaling, distribution and procurement practices, local manufacturing, reporting of adverse drug reactions, or the quality of regulatory enforcement.

Missing data is a significant limitation of our findings. This rapid assessment resulted in many instances where we were unable to locate any—or very few—regulations related to pharmacies and drug shops for countries on our list. When summarizing results by topic, we noted instances of missing data to distinguish from regulations that did not cover particular topics.

Findings in this report are organized in four ways:

- **Key findings** summarizes the main conclusions drawn from our comparative review.
- **Results by topic** summarizes provisions across the 32 countries, organized around seven elements of pharmacy and drug shop regulation (tiers, premises, products, personnel, marketing, services, and enforcement). This section addresses general operating rules and provisions specific to family planning.
- **Results by country** provides the same information on regulations collected for each country organized into four tables: general provisions, rules related to family planning products, rules for family planning-related services, and contraceptives included on essential medicine lists (EML).
- **Country highlights** feature more detail on nine countries with active donor-funded pharmacy and drug shop initiatives, each with a unique mix of stricter and lighter regulatory controls.

Pharmacies and drug shops are an important source of care in many countries.

Photo: Jessica Scranton

Key findings

General findings
Regulations for drug shops and pharmacies are not standardized, with wide variations in the level of detail included in the rules. We were unable to rank countries along a continuum from lightly to tightly regulated due to differences in topics covered, internal inconsistencies, and missing data.
There is a significant **trend toward licensing lower-tier drug shops**, which previously existed outside of regulatory oversight. This trend reflects the public health response to the rapid growth of retail sales points fueled by the dramatic increase of pharmaceuticals flowing into developing countries.
Drug shops are mostly confined to selling only over-the-counter medicines, but a small and **growing number of countries provide exceptions for drug shops to sell some prescription medicines** found on the national EML.
The **minimum education and training rules vary widely** for drug shop personnel. Requirements range from medical training such as nursing, to drug seller training programs, internships at pharmacies, and no formal training.
Findings with particular relevance for family planning
Regulations emphasize rules for products (e.g., prohibiting sales of counterfeit medicines), not services. **Rules are largely silent on issues related to screening, counseling, or referrals** to clinical providers.
Contraceptives are well represented on national EMLs, demonstrating growing recognition of their essential role in the health of populations. Inclusion on EMLs contributes to their availability at retail outlets.
Pharmacies, and drug shops in some countries, **are permitted to sell depot medroxyprogesterone acetate (DMPA) but are prohibited from providing injections**. Donor projects in three countries—Bangladesh, Nigeria, and Uganda—have obtained regulatory waivers to pilot drug shop provision of injections with training and supervision.
Sales of oral contraceptive pills (OCPs) are permitted without prescription at both drug shops and pharmacies in 15 of the 32 countries, with pre-screening required in 5 of those countries. Sales of emergency contraceptives (ECs) are permitted without prescription in 19 of the 32 countries.

Results by topic

This review looks at legal and regulatory issues surrounding general operating principles and provisions specific to family planning.

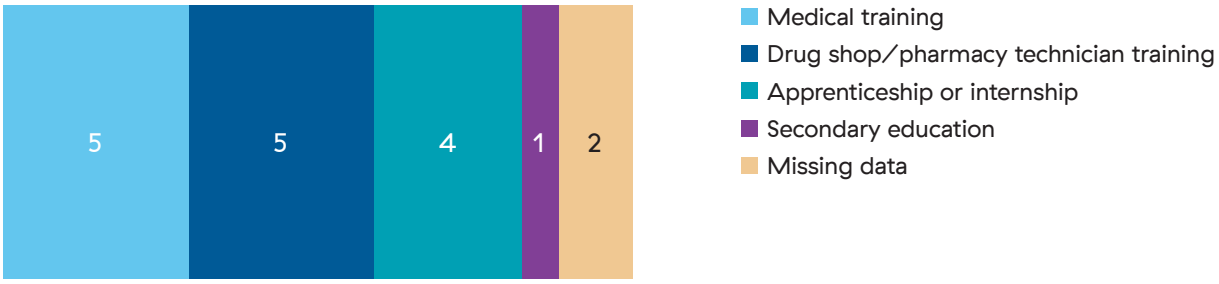
General operating rules

Tiers: Fifty-three percent, or 17 of the 32 countries, have sanctioned a second, lower tier of authorized drug retail outlets, in recognition of the shortage of trained pharmacists throughout the global south. The scopes of practice of the lower-tier drug shops vary. Most countries permit them to sell only over-the-counter drugs, although five countries permit them to sell selected prescription medicines for common illnesses: Liberia, Philippines, Senegal, Tanzania, and Uganda.

Premises: There is a wide range of regulations pertaining to the facilities themselves, with most countries covering some but not all categories of rules: licensure (24 countries); regulatory fees (17 countries); location restrictions (14 countries); minimum size (6 countries); hygiene and sanitation (18 countries); and record keeping (15 countries).

Personnel: In all countries where regulations were available, the basic training requirement for pharmacists was the same: a degree in pharmacy from an accredited university. Training requirements for staff at lower-tier drug shops were more varied, as shown in the figure below. Seven of the 17 countries that have a second tier require that someone with health training supervise the lower-tier drug shops.

Training requirements for lower–tier drug shops in 17 countries



Services: The majority of countries reviewed do not address permitted or prohibited services for drug retail outlets. We found language promoting referrals in four countries, screening requirements to determine appropriate treatment in five countries, and counselling requirements in seven countries.

Products: Provisions to prevent contamination of drug inventory were found in 17 countries, such as safe storage and prohibitions on sale of counterfeit drugs. Seventeen countries limit the mark-up of retail prices, while 6 countries provide no price regulation and no information on pricing was found in 13 countries. Four countries allow access to inventories at public Central Medical Stores to supply private shops, and nine countries have provisions related to drug packaging.

Marketing: A variety of restrictions on marketing was found in 15 countries. Examples include the content of sign boards, prohibitions on advertising to promote pharmacies, and preapproval for product advertisements.

Enforcement: Powers to inspect and enforce adherence to regulations were vested in either government agencies such as ministries of health or in private associations tasked with enforcement, with the countries divided equally between public and private institutional oversight.

Provisions related to family planning products and services

Essential medicine lists: Modern contraceptive methods were well represented on national EMLs, demonstrating recognition of their importance to health, and contributing to their availability at private retail outlets, as summarized in the table below.

Inclusion of modern contraceptive methods on EMLs

Contraceptive method	Number of countries including method on EML
Combined OCP	31
Progesterone–only contraceptive pills	11
Implants	19
Copper IUD	24
Hormonal IUD	4
Injectable contraceptives	27
Male condoms	26
Female condoms	16
ECs	15

Prescription requirements: Prescription requirements vary by method type. Across all countries, condoms are available at both levels without prescription or screening. Sales of OCPs are permitted without prescriptions in 15 countries and sales of ECs are permitted for sale without prescription in 19 countries. In a few countries, even when a prescription is not required, drug shops are limited to a resupply role.

Injectables: Because injectables are sold as prescription drugs, pharmacies are generally allowed to sell intramuscular DMPA. Drug shops are typically limited to over-the-counter medicines, and thus are not permitted to sell injectable contraceptive methods due to their prescription-only status. With few exceptions (noted below), the countries covered in this scan implicitly prohibit the delivery of injections of any kind by pharmacists and drug shops as broadly prohibited "medical procedures." Three countries—Bangladesh, Nigeria, and Uganda—are piloting programs to allow drug shop vendors to provide intramuscular contraceptive hormonal injectables under special regulatory waivers.

Other long-acting reversible contraceptives: We did not find any examples of regulations or policies that specified a role for pharmacies in the sale of IUDs or implants.

Results by country

We categorized the 32 countries in three groups to see if we could discern patterns in regulatory approach. Group 1 consisted of nine countries with active donor programs to support expansion of drug shops in the provision of family planning. These nine countries tended to have more comprehensive regulations than the others, although regulations in three of the nine had not been updated in more than 10 years. We attempted to rank the nine countries by level of regulatory oversight but found each country had a unique blend of lighter and stricter regulations that made clustering difficult. Our rough continuum of countries from most oversight to least oversight is: Tanzania, Ghana, Senegal, Liberia, Nigeria, Uganda, Kenya, Bangladesh, and India.

Group 2 consisted of eight countries with no known drug shop programs but high family planning market share through drug outlets. Group 3 consisted of 15 countries with no drug shop programs and low family planning market share. There were no discernable differences in regulatory approaches between Group 2 and Group 3. We also examined whether there were regional similarities in regulatory approaches but did not find any.

Discussion

This review highlights the growing official recognition (in the form of licensure) for a second tier of non-pharmacy drug retail outlets that has emerged in response to demand, and outside of existing regulatory oversight. These sources are responsible for a substantial share of modern family planning services and products, with recent research indicating that drug shops account for as much as 79 percent of the total family planning market (FPWatch, 2016a; JSI, 2016). By sanctioning the role of these outlets, regulations can potentially limit the illicit drug market and expand access to safe and appropriate medicines. To be effective, however, rules must take into account local realities and economic constraints. In addition to regulations, important factors that influence the practices and products of drug retail outlets include consumer demand, reliability of supply, linkages to clinical services, cultural practices, and the level of available technical, human, and financial resources for enforcement.

Uganda has two tiers of drug retail outlets—pharmacies and drug shops, one of which is pictured here.

Photo: Saiqa Panjsheri

To strike the balance between costs and benefits, regulations should align with risk. Regulatory frameworks apply broadly across all health issues. Improper dispensing of curative medicines for life-threatening illnesses poses great public health risks including the potential for the development of drug-resistant microbes. Dispensing hormonal contraceptives to first-time users requires screening for contraindications, but there is less evidence of counterfeit products, storage requirements affecting efficacy, or provision of inappropriate dose. The differences across health products suggests the need for a more layered approach tailored to specific health areas, and advocacy to exempt family planning products and services from some rules on premises, marketing, and personnel, especially those operating in rural areas. Enforcement constraints for key quality controls can be supported by stronger roles for professional associations and group self-regulation. The widespread inclusion of reproductive health pharmaceuticals on country EMLs, and the ability to sell OCPs and emergency contraceptives (ECs) without prescriptions, reflects the increasing prioritization for contraceptive access among national governments.

The popularity of injectables has increased globally, but this review indicates that blanket prohibitions still exist despite evidence that intramuscular hormonal contraceptive injections at drug shops are routinely provided in many countries (HIP, 2013). Intramuscular injections require proper infection prevention measures, including adequate sharps disposal and disinfection, medical supplies, and training. Programmatic efforts to promote evidence-based positive practices should continue, such as the distribution of posters to guide clients in self-screening, studies to assess adherence to protocols and track adverse events, and continuous education for drug shop staff. The review also found wide variation on drug shop training and education requirements, which could be made more standardized, and perhaps be better integrated into community health worker training programs.

Regulations exist for both retail pharmacies and drug shops in India.

Photo: Jessica Scranton

Introduction and Methodology

Photo: Jessica Scranton

Introduction

Drug retail outlets constitute a large proportion of primary health service providers. For many people, they are the first point of contact with the health system.

Private pharmacies and drug shops are important health system stakeholders in low- and middle-income countries. Drug retail outlets constitute a large proportion of primary health service providers. For many people, they are the first point of contact with the health system, especially in areas that lack higher-level facilities (Akol, 2014; Stanback et al., 2011; Hughes et al., 2012; Lui et al., 2015). Partially because of these factors, donors and governments have identified engagement of pharmacies and drug shops as a potentially high-impact practice for expanding access to and use of modern family planning methods (HIP, 2013). These sources are already responsible for a substantial share of modern family planning services and products for youth, unmarried, and urban populations (JSI, 2016), a trend that is even more pronounced in countries with lower contraceptive prevalence rates. In countries such as Benin, the Democratic Republic of the Congo (DRC), Côte d'Ivoire, and Guinea, pharmacies and drug shops deliver over one third of all modern family planning methods (Statcompiler, 2016). A recent study in Nigeria and a sample region of DRC found that drug shops account for 75 percent and 79 percent respectively of the total family planning market composition (FPWatch 2016a; FPWatch 2016b).

The abundance of pharmacies and drug shops means that they are more convenient than other sources of care; men and boys often prefer these facilities due to their proximity (Okonkwo and Okonkwo, 2010). Emerging evidence suggests they can safely deliver many short-acting methods, including condoms, oral contraceptive pills (OCPs), injectable contraceptives, and emergency contraceptives (ECs), at similar levels of quality and lower costs than higher-level facilities (Janowitz et al., 2012). Clients also cite other positive factors, including fewer stockouts, less provider bias, shorter wait times, and increased privacy (Akol, 2014).

Many donors and governments seeking to increase the use of modern contraceptive methods in pursuit of FP2020 and other national goals look to expand the role of pharmacies and drug shops. A first step in developing effective, sustainable interventions is to understand a country's legal and regulatory environment (HIP, 2013). As a core component of health systems, pharmacies and drug shops are governed by laws, regulations, and policies that establish quality standards, qualifications, and permitted practices. World Health Organization (WHO) guidelines on Good Pharmacy Practice state that countries should establish a legal framework that defines the scope of practice, identifies who can practice, sets competency standards, and allocates resources to ensure compliance (FIP and WHO, 2011). To support future interventions, this report provides a multi-country summary of the legal and regulatory requirements for pharmacies and drug shops. While relevant regulations cover all health areas, this survey focuses primarily on how they affect family planning products and services.

Objectives

This report presents a comprehensive overview of policy documents, laws, and regulations (definitions of these concepts are included in the next section) to inform the many interventions underway to strengthen quality, expand reach, and improve effectiveness of pharmacies and drug shops delivering family planning products and services. Numerous initiatives have launched in the past decade to build organizational capacity, explore market incentives, educate consumers, and expand access to training and finance for drug shops. To be successful, these efforts must take into account the legal and regulatory context, capacity, and priorities in a country that are enablers and barriers to reform.

How to use this report:

Key findings summarizes the main conclusions drawn from our comparative review, with particular relevance to access to family planning products and services.

Results by topic summarizes provisions across the 32 countries, organized around seven elements of pharmacy and drug shop regulation (tiers, premises, products, personnel, marketing, services, and enforcement). This section addresses general operating rules and provisions specific to family planning.

Results by country provides the same information on regulations collected for each country in table form, covering general provisions, family planning products, family planning–related services, and essential medicines lists (EMLs).

Country highlights feature more detail on nine countries with active donor–funded drug shop initiatives, each with a unique mix of stricter and lighter regulatory controls.

This report:

- Summarizes existing policies, laws, and regulations as a baseline to inform interventions.
- Identifies trends and variations that impact family planning availability, access, quality, and cost.
- Makes recommendations for advocacy and further research to improve the enabling environment for expanded provision of family planning through drug shops.

Definitions

Definitions used in this report

Pharmacies: Retail facilities, overseen by licensed pharmacists, that sell registered prescription–based medicines.

Drug shops: Lower–tier retail outlets, with no pharmacist on staff, that sell over–the–counter drugs, chemical products, and household remedies.

Note: *Countries use alternative names for drug shops including community pharmacy, medicine store, licensed chemical seller, chemist, patent vendor, proprietary drug vendor, and accredited drug dispensing outlet.*

In this report, the term "drug retail outlet" refers to any establishment where registered or over-the-counter drugs, chemical products, and household remedies are dispensed directly to the general public on a retail basis. This definition includes both pharmacies and drug shops, the latter where no pharmacist is required. The specific names for retail facilities vary by country, including pharmacy, drug shop, community pharmacy, medicine store, chemist, and patent or proprietary drug vendor. Pharmacy services provided in health facility settings under the supervision of medical personnel are not included.

"Drug sellers" is used to cover cadres at all levels, whether licensed or not. Similar to retail facilities, the labels used for personnel vary by country, including pharmacists, pharmacist assistants, pharmacist technologists, chemists, dispensing chemists, drug vendors, medicine sellers, chemical sellers, druggists, patent medical vendors, and accredited drug dispensers.

When referencing rules and requirements, we alternatively refer to policies, laws, and regulations. Public policy is an umbrella term used to describe an entire system of laws, regulatory measures, funding priorities, and courses of action to accomplish certain objectives. In the narrower sense, policies guide expectations but require government actions to operationalize. Laws stem from actions by legislative bodies such as parliaments which govern through the adoption of statutes, acts, and amendments. Regulations are issued by government agencies with statutory authority to craft rules to interpret, implement, and enforce the laws within their areas of jurisdiction.

Scope

This review is limited to documenting existing laws and regulations related to retail establishments, products, and personnel in 32 countries in sub-Saharan Africa, Asia, the Middle East, and the Caribbean. The scope does not include an examination of the rules regarding import, registration, drug quality testing, warehousing, wholesaling, distribution and procurement practices, or reporting of adverse drug reactions. Although beyond the scope of this paper, the regulation and distribution of imported drugs represent important elements in a strong supply chain needed to ensure drug quality and security. Donors are very active in this area through projects such as the USAID-funded Systems for Improved Access to Pharmaceuticals and Services project and the DELIVER project, as well as several bilateral efforts. These projects tend to focus comprehensively on pharmaceutical supply chain strengthening activities, including policy and governance, financing, procurement, information systems, and pharmacovigilance.

What is covered in this report: Existing laws and regulations governing pharmacies and drug shops, with a primary focus on relevance to family planning.

What is not covered in this report: Rules regarding import, registration, drug quality testing, warehousing, wholesaling, distribution and procurement practices, local manufacturing, reporting of adverse drug reactions, or the quality of regulatory enforcement.

Photo: Jessica Scranton

Methodology

This review covers 32 countries. Thirty-one are either a priority country for USAID's Office of Population and Reproductive Health or a member country of the Ouagadougou Partnership in West Africa. Indonesia was also included as a priority country for the Ending Preventable Child and Maternal Deaths initiative, which has a family planning component.

Relevant policies, laws, and regulations were identified through a three-step process: a desk-based review, key informant interviews, and a consultative workshop to discuss findings. The desk-based portion included a search of primary sources available online on country government, ministry of health, pharmacy council, pharmacy association, and WHO websites. Secondary sources (e.g., peer-reviewed journal articles and USAID-funded project reports and presentations) were identified through Google and the USAID Development Experience Clearinghouse.

In the second stage, we conducted key informant interviews with stakeholders in select countries in order to verify the results and fill in gaps from the initial search. In each interview, the stakeholder reviewed our initial list of primary sources (e.g., laws, decrees, acts, and policies) to ascertain if it was complete and currently in effect. They then answered questions that arose from the desk-based review and were tailored to their country context. Finally, we convened experts from USAID, implementing partners, and researchers to test and validate preliminary findings and conclusions.

Missing data is a significant limitation of our findings. This rapid assessment resulted in many instances where we were unable to locate any—or very few—regulations related to pharmacies and drug shops for the countries on our list. The fact that we did not find documentation through our web searches and in-country experts does not mean rules do not exist. It is likely in some cases that frameworks and regulations are in place but not yet published online or well disseminated.

When summarizing results by topic, we noted instances of missing data to distinguish from regulations that may not have covered certain topics. For example, when documenting the number of countries that require periodic training for registered drug shop owners, we distinguish countries with rules that are silent on any training requirements from those for which we found no licensing or registration framework.

To facilitate analysis, the countries were divided into three groups (see map in Figure 1 and the Results by Country section for a list of countries in each group):

- Group 1 (9 countries) are those countries with **active donor-funded initiatives** seeking to expand access to family planning through drug shop interventions such as improved organization, training, or access to finance.

  Bangladesh, Ghana, India, Kenya, Liberia, Nigeria, Senegal, Tanzania, Uganda

- Group 2 (8 countries) are those countries with no active donor-funded drug shop initiatives but **high pharmacy and drug shop market share** of family planning methods (i.e., more than 20 percent of women accessed their modern method through a pharmacy or shop, based on most recent Demographic and Health Survey data).

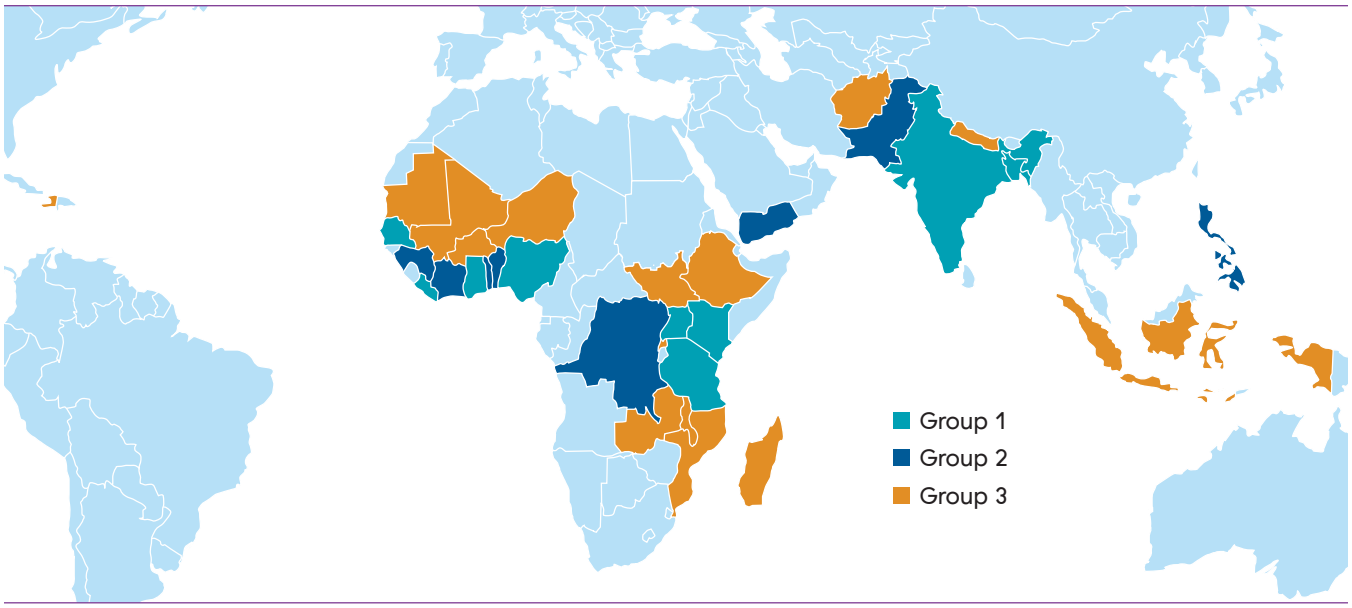
  Benin, Côte d'Ivoire, DRC, Guinea, Pakistan, Philippines, Togo, Yemen

- Group 3 (15 countries) are those countries with **low pharmacy and drug shop market share of family planning methods** and no known programs to strengthen drug shop quality or capacity.

  Afghanistan, Burkina Faso, Ethiopia, Haiti, Indonesia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, South Sudan, Zambia

We expected both factors (family planning market share and existence of projects) to make it more likely that policies would be more up-to-date and comprehensive to reflect the importance of drug retail outlets as a source for family planning.

Figure 1. Countries included in review



Framework

For each country, legal and regulatory provisions are organized by topics summarized in Table 1, including differences in regulations for pharmacies (with trained pharmacists) and drug shops (without trained pharmacists) where they exist.

Table 1. Legal and regulatory categories

Tiers	Premises	Personnel	Services	Products	Marketing	Enforcement
Defines levels, scope of services, rules on ownership	Covers rules related to building size, location, hygiene, privacy, infrastructure, and licensing	Includes rules related to training, credentials, supervision, licensing, age, citizenship, and continuing education	Includes rules related to counseling, referrals, diagnoses, and injections	Includes rules on inventory management, storage, packaging, pricing, EML, and prescription requirements	Covers rules related to the promotion of pharmaceutical products, drug establishments, or proprietor services	Covers rules related to inspections and sanctions

Pharmacies are the only type of legally recognized drug outlet in Nepal.

Photo: Jessica Scranton

Results by Topic

Photo: Jessica Scranton

Results by Topic

This section describes findings by topic areas, first in regard to general operating rules and then to provisions specific to family planning. In the following section (Results by Country), Tables 4, 5, 6, and 7 summarize the same information for each country included in the scan and provide a more detailed description of nine countries' frameworks.

Table 2 summarizes our top findings, supported by the analyses that follow.

Table 2. Primary findings from the 32 country comparison

General findings
Regulations for drug shops and pharmacies are not standardized, with wide variations in the level of detail in the rules. We were unable to rank countries along a continuum from lightly to tightly regulated due to differences in topics covered, internal inconsistencies, and missing data.
There is a significant **trend toward licensing lower-tier drug shops**, which previously existed outside of regulatory oversight. This reflects the public health response to the rapid growth of retail sales points fueled by the dramatic increase of pharmaceuticals flowing into developing countries.
Drug shops are mostly confined to selling only over-the-counter medicines, but a small and **growing number of countries provide exceptions for drug shops to sell some prescription medicines** found on the national EML.
The **minimum educational and training rules vary widely** for drug shop personnel. Requirements range from medical training such as nursing, to drug seller training programs, internships at pharmacies, and no formal training.
Findings with particular relevance for family planning
Regulations emphasize rules for products (e.g., prohibiting sales of counterfeit medicines), not services. **Rules are largely silent on issues related to screening, counseling, or referrals** to clinical providers.
Contraceptives are well represented on national EMLs, demonstrating growing recognition of their essential role in the health of populations. Inclusion on EMLs contributes to their availability at retail outlets.
Pharmacies, and drug shops in some countries, **are permitted to sell DMPA but are prohibited from providing injections**. Donor projects in three countries—Bangladesh, Nigeria, and Uganda—have obtained regulatory waivers to pilot drug shop provision of injections with training and supervision.
Sales of OCPs are permitted without prescriptions at both drug shops and pharmacies in 15 of the 32 countries, with pre-screening required in 5 of those countries. Sales of EC are permitted without prescription in 19 of the 32 countries.

General operating provisions

Tiers

While all 32 countries reviewed have legally recognized retail pharmacies, 17 countries have established a second, lower tier of authorized drug retail outlets: Benin, Burkina Faso, Côte d'Ivoire, Ethiopia, Ghana, India, Indonesia, Liberia, Malawi, Mali, Mauritania, Nigeria, Philippines, Senegal, South Sudan, Tanzania, and Uganda (Figure 2). Trained pharmacists are scarce in developing countries, and lower-level outlets extend the reach of essential medicines and primary health care services. Countries use different terms to describe the lower tiers, including Ghana's licensed chemical sellers, Nigeria's patent and proprietary medicine vendors, and Tanzania's accredited drug distribution outlets (ADDOs). They also permit different scopes of practice and levy different restrictions, as covered in more detail below.

Two tiers

Many countries have two tiers of retail outlets where clients can purchase pharmaceutical products:

- **Pharmacies** require a trained pharmacist and are allowed to sell both prescription and over the counter medicines.
- **Drug shops** (licensed chemical sellers, patent and propriety medicine vendors, accredited drug distribution outlets) have less restrictive training requirements and are generally restricted to prepackaged over–the–counter medicines.

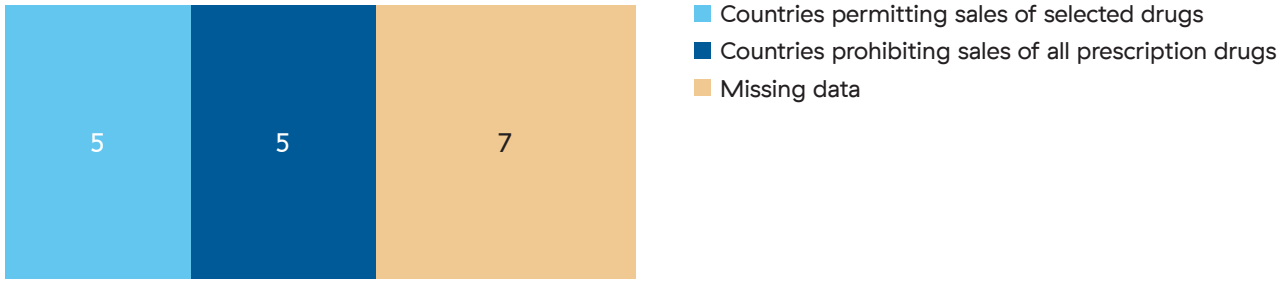
Figure 2. Number of sanctioned pharmaceutical tiers

15 countries
have 1 tier

17 countries
have 2 tiers

Countries maintain schedules of approved drugs for sale with categories for prescription only and for over the counter. While pharmacies are generally allowed to sell both categories, drug shops are generally more restricted. Of the 17 countries that have two tiers of drug sellers, 5 permit lower-tier facilities to sell only over-the-counter products (Figure 3): Burkina Faso, Ghana, India, Malawi, and Nigeria. Liberia, Philippines, Senegal, Tanzania, and Uganda permit lower-tier shops to sell selected prescription drugs or other essential medicines for common illnesses. No information was obtained on this topic from Benin, Côte d'Ivoire, Ethiopia, Indonesia, Mali, Mauritania, and South Sudan.

Figure 3. Sale of prescription medicines at drug shops in 17 countries



Premises

Regulatory frameworks generally include minimum requirements for the facilities from which drugs are sold, to ensure oversight through registration, sanitation standards, and rules to promote access.

Venue, location, size, and hygiene

Fourteen of the countries reviewed restrict where pharmacies and drug shops can be located. Typically, these rules stipulate a minimum distance between a new outlet and existing pharmacies or health facilities. In some cases, such as Ghana, the regulations make clear that the intention is to deny applications for new outlets in well-served areas such as the regional capital cities.

In countries with two tiers of drug outlets, only Burkina Faso, Liberia, Mauritania, and Senegal regulate both tiers in this way. Other countries only regulate the location of the lower-level drug shops, including Ghana, Tanzania, and Uganda.

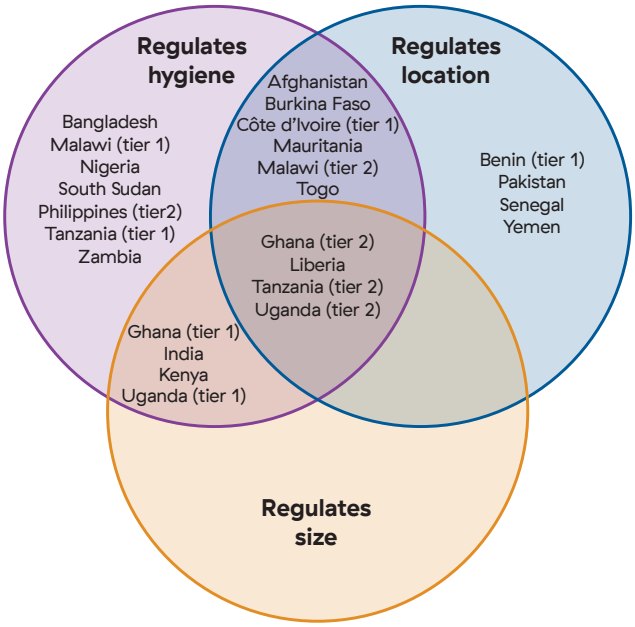
Only six of the countries reviewed regulate the size of a drug outlet (Ghana, India, Kenya, Liberia, Tanzania, and Uganda). All six countries have two tiers of drug retail outlets and apply similar rules to both levels. These regulations generally establish a minimum square footage for the facility to ensure adequate space for clients, display, and safe storage.

Eighteen countries have rules that address hygiene issues, including requirements for handwashing

facilities. These provisions are also intended to limit contamination of products, as exemplified by Côte d'Ivoire's requirement that premises are indoors, with no roadside sales permitted.

There is no discernable pattern in the overlap of the venue regulations (Figure 4). Only Ghana, Liberia, Tanzania, and Uganda have rules related to all three areas for drug shops. Additionally, Liberia was the only country to have rules in all three areas for pharmacies. India and Kenya have rules related to size and hygiene but not location; Afghanistan, Burkina Faso, Mauritania, and Togo have rules related to location and hygiene but not size for all drug retail outlets. Côte d'Ivoire and Malawi have similar findings for pharmacies only and drug shops only, respectively. Most countries have rules related to either location or size. We were unable to locate venue rules for the following countries: Benin (drug shops only), Côte d'Ivoire, DRC, Ethiopia, Guinea, Haiti, Indonesia, Madagascar, Mali, Mozambique, Nepal, Niger, the Philippines, and Rwanda.

Figure 4. Regulation of hygiene, location, and venue size



No data:
Benin (tier 2)
Cote d'Ivoire (tier 2)
DRC
Ethiopia
Guinea
Haiti
Indonesia
Madagascar
Mali
Mozambique
Nepal
Niger
Philippines (tier 1)
Rwanda

Recordkeeping

Provisions setting forth minimum requirements related to recordkeeping for both pharmacies and drug shops were identified in 15 countries. The failure to locate requirements in many countries may be because reporting rules are created and archived by different ministry departments and not incorporated in rules authorizing provision of pharmaceutical services. Among the provisions we located, Nigeria's language provides the most inclusive requirements:

"Retail outlets of drugs, poisons, and devices shall keep proper records of the following: (a) all receipts of purchases made; (b) disposal of poisons; (c) ledgers/bin cards; and (d) dispensed prescription" (Pharmacists Council of Nigeria Act (1992 No. 91)). Ghana's language is more representative of the general nature of recordkeeping requirements found: "All facilities storing and dispensing medicines shall maintain records on all drugs at the facility at all times" (Ghana National Drug Policy, 2004).

Licensure and fees

We identified regulations mandating licensing for establishments selling drugs in 24 countries. In some cases, these requirements apply exclusively to the pharmacists or pharmacist technicians working within the facility, while in others they apply to both the facility and its staff. These requirements apply equally to higher- and lower-level drug retail outlets (i.e., pharmacies and drug shops) in countries with more than one tier. Fee requirements varied, with two countries issuing free licensing, most imposing license fees, and no information on fees founds in seven countries.

Personnel

This section summarizes rules and regulations applicable to human resources including owners, staff, and supervisors of drug shops and pharmacies.

Education and training

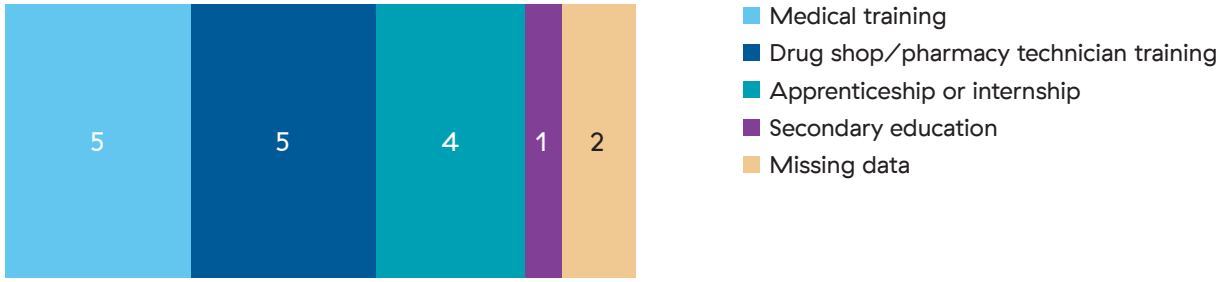
In all countries where regulations were available, the basic training requirement for pharmacists was the same: a degree in pharmacy from an accredited university. Some countries require additional training, such as internship (Ghana), continuing professional education (Burkina Faso, Kenya), professional exam (Uganda), and option for a two-year diploma plus internship (India). We were unable to obtain regulations related to pharmacist training requirements in seven countries: DRC, Guinea, Madagascar, Mali, Mozambique, Niger, and Rwanda.

Education and training requirements for drug shops show wide variation, from medical training to apprenticeships to no training requirements.

For lower-tier facilities, the training requirements were more varied (Figure 5):

- Apprenticeship or internship: Burkina Faso, Nigeria
- Secondary education: Ghana
- Accredited drug training program/pharmacy technician training: Benin, Liberia, Indonesia, South Sudan, Tanzania
- Medical training (such as nursing): Ethiopia, Malawi, Mauritania, Senegal, Uganda
- Missing data: Côte d'Ivoire, India, Mali, Philippines

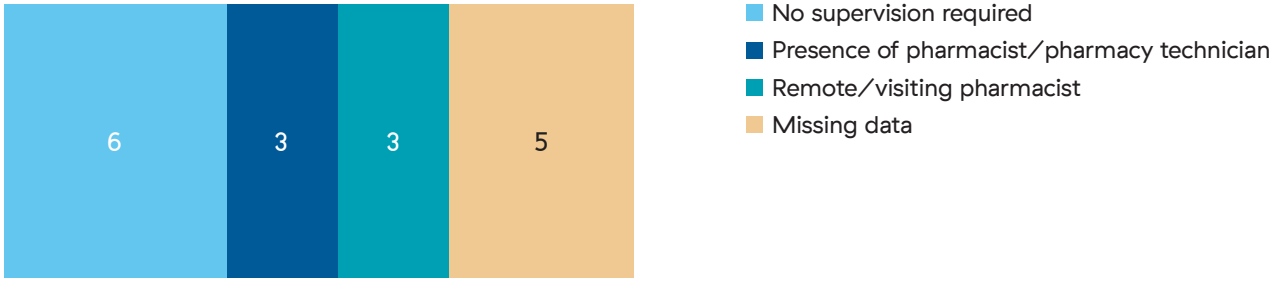
Figure 5. Training requirements for lower–tier drug shops in 17 countries



Supervision

Of the 32 countries, 21 require the presence of a pharmacist to supervise staff at registered pharmacies. No provisions related to supervision were found in nine countries. Six countries had additional provisions related to the need for supervision at lower-tier drug shops by someone with health or pharmacy training: Benin, Burkina Faso, Malawi, Indonesia, Philippines, and South Sudan (Figure 6). Language in the Philippines was the most prescriptive, requiring that a supervising pharmacist must visit at least two working hours every two weeks.

Figure 6. Supervision required for drug shops in 17 countries



Services

This section looks at rules permitting or prohibiting specific services by pharmacists and drug shop staff. For most of the countries reviewed, the documents located did not address these issues (see Tables 3 and 4 in the Results by Country section). The exceptions are summarized below.

Referrals

The vast majority of the countries reviewed (28) have no requirement for pharmacies or drug shops to refer clients needing clinical services to health facilities. Three Francophone countries—Burkina Faso, Côte d'Ivoire, and Senegal—direct community pharmacists to encourage customers to see a doctor "whenever necessary" (Senegal Décret n° 81-039 du 02 février 1981 portant code de déontologie des pharmaciens; Côte d'Ivoire Loi n° 2015-533 du 20 juillet 2015 relative à l'exercice de la pharmacie; Burkina Faso Receuil des Textes Reglementaires du Secteur de la Pharmacie, du Medicament et des Laboratoires du Burkina Faso). Nigeria has the most prescriptive language, which requires proprietary patent medicine vendors to make referrals for products and services out of their scope. Regarding family planning, they must refer first-time OCP users to qualified providers for consultation (Stanback et al., 2016).

The vast majority of the countries reviewed (28) have no requirement for pharmacies or drug shops to refer clients needing clinical services to health facilities.

Counseling

Counseling clients on the safe and effective use of medicines is a basic function of pharmacists (WHO and FIP, 2006). Pre-service training emphasizes the product and science curriculum, leaving counseling skills to be addressed by in-service training and continuing educational resources. Policies are needed to encourage pharmacists to advise patients about the safe and effective use of medicines (Odegard et al., 2011). For less qualified vendors, some with minimum or no clinical health training, counseling raises concerns about quality and efficacy (Rutta et al., 2015). The majority of countries reviewed do not address the topic in their regulations. We found only seven countries where regulations explicitly addressed counseling: Burkina Faso, Côte d'Ivoire, India, Nigeria, Rwanda, Tanzania, and Togo. India recently (2016) adopted directive language on counseling, with rules linking the sale of OCPs without prescriptions to requirements on refresher training to appropriately guide clients.

Products

Oversight of pharmaceutical practices includes protections for drug quality, efficacy, and instructions for use. Policies affecting retail sale of safe and effective drugs include requirements that drugs be registered and approved for sale in country as well as rules governing price, packaging, storage, and promotion. This section summarizes the provisions included in country requirements.

Inventory, storage, and expiration control

Rules governing practices related to storage of medicines were found in 16 countries. Examples include provisions related to the protection of products from adverse effects of light or temperature. Rules prohibiting the sale of expired drugs were found in 15 countries, such as a requirement to adhere to manufacturer use-by dates.

Most countries with these provisions addressed both issues, with the following exceptions:

- Rules found prohibiting the sale of expired drugs but no rules on storage: Ethiopia, Pakistan, and Yemen
- Rules found regulating storage but not sales of expired drugs: Burkina Faso and Zambia
- For countries with two tiers (n=17), there were no differences identified between rules on storage and expiration controls for Tier 1 pharmacies and Tier 2 venues with the following exceptions:
    - Storage rules found for Tier 2 but not Tier 1: Liberia and Senegal
    - Storage and expiration control rules for Tier 1 but not Tier 2: India

No rules related to storage or expiration of inventory were located for 13 countries: Benin, Côte d'Ivoire, DRC, Guinea, Indonesia, Madagascar, Mali, Mozambique, Nepal, Niger, Philippines, Rwanda, and Togo.

Controls against counterfeit medicines

The rapid rise of fake drugs flooding markets globally has generated a number of controls, including stronger cross-border enforcement, technologies to identify genuine medicines, and improved testing facilities. Regulation of retailers is generally in the form of prohibitions from knowingly stocking or selling counterfeit medicines. Rules prohibiting the sale of counterfeit drugs were found in 17 of the 32 countries: Bangladesh, Benin, Côte d'Ivoire, DRC, Ethiopia, Haiti, Kenya, Liberia, Malawi, Niger, Pakistan, Philippines, Senegal, South Sudan, Tanzania, Uganda, and Yemen.

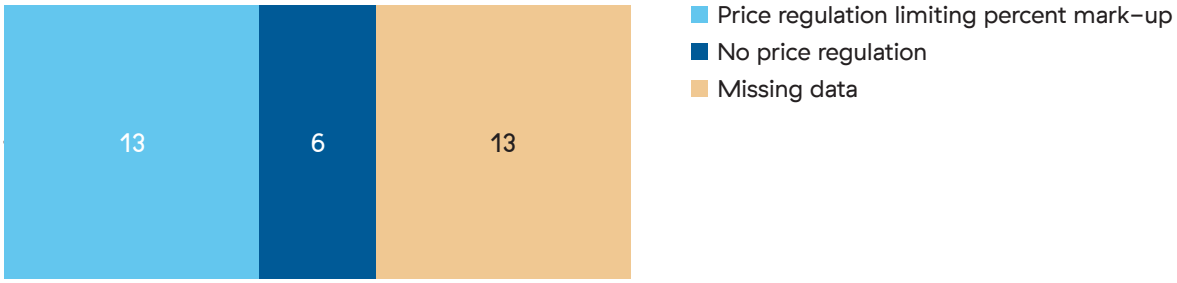
Regulations limit the percent mark–up of retail prices in 13 of 32 countries.

Pricing

Countries use a variety of mechanisms to promote affordability of life-saving medicines, including reliance on competitive market forces, providing targeted subsidies to increase access for the poorest, and adoption of price controls (Figure 7). We found evidence of regulations in 13 countries that limit the percent mark-up of retail prices over wholesale or manufacturer prices for specified drugs, setting a ceiling price but not a floor. These countries apply the same rules to both pharmacies and lower-tier drug shops where two tiers exist. Countries with price regulations for the sales of medicines are Bangladesh, Benin, Burkina Faso, Côte d'Ivoire, DRC, Guinea, India, Madagascar, Mali, Mauritania, Philippines, Senegal, and Togo.

These countries do not regulate retail prices: Ethiopia, Haiti, Nigeria, Ghana, Tanzania, and Yemen. No information was found on this topic for the following countries: Afghanistan, Indonesia, Kenya, Liberia, Malawi, Mozambique, Nepal, Niger, Pakistan, Rwanda, South Sudan, Uganda, and Zambia.

Figure 7. Price regulation of drugs in 32 countries



Inclusion in national insurance schemes

Government-sponsored and private health insurance schemes are being introduced in many developing countries as part of a global commitment to achieving universal health coverage. If a comprehensive essential medicines benefit is available in these plans, health insurance can reduce out-of-pocket spending on medicines and improve access. However, many of these insurance schemes are still fledgling, reaching mainly those employed in the formal sector, and fail to ensure essential medicines are included in benefits provided (Wirtz et al., 2016). As governments invest more in publicly financed insurance to expand access to medicines, drugs shops will have an increasingly important role to play. At this time, we found reference to a National Health Insurance Fund policy that allowed the insured to fill prescriptions at accredited drug shops in only one country, Tanzania (Rutta et al., 2015).

Access to a Central Medical Store supply

Countries vary in their approach to drug procurement practices in the private sector (Figure 8). Some permit access through public Central Medical Stores (CMS), while others rely on fully private wholesalers and distributors.

Countries permitting CMS access for private sector suppliers are Benin, Ghana, Guinea, and Senegal. Senegal supplies local wholesalers with lower-cost generics for essential medicines to ensure that consumers have lower-cost choices for critical treatments (Brunner et al., 2016).

Nine countries do not permit commercial private sector to purchase from the CMS: Afghanistan, Burkina Faso, Kenya, Malawi, Nepal, Philippines, South Sudan, Tanzania, and Uganda.

Regulations reviewed from the following countries did not state whether private suppliers could procure from the CMS: Afghanistan, Bangladesh, Côte d'Ivoire, DRC, Ethiopia, Haiti, Indonesia, Liberia, Madagascar, Mali, Mauritania, Mozambique, Niger, Nigeria, Pakistan, Philippines, Rwanda, Togo, Uganda, Yemen, and Zambia.

Figure 8. Source of private sector medicines in 32 countries

Dispensing and packaging

Packaging and labeling rules are designed to protect consumers in several ways. Requirements that medicines are sold only in the original containers, strips, bottles, or covers under which they are packed by manufacturers reduces risks of tampering, dilution, damage, and incorrect dose. Some countries permit drug shops to repackage into smaller portions in part to accommodate low-income populations who can only pay for a daily dose. Others impose maximum size units to prevent black market resale.

We were able to locate regulations related to drug packaging in the following nine countries: Benin, Burkina Faso, Ghana, India, Malawi, Nigeria, Pakistan, Philippines, and Senegal.

No documentation on this topic was located for: Afghanistan, Bangladesh, Côte d'Ivoire, DRC, Ethiopia, Guinea, Haiti, Indonesia, Kenya, Liberia, Madagascar, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, South Sudan, Tanzania, Togo, Uganda, Yemen, and Zambia.

We found one country, Liberia, with explicit language prohibiting retail sale of government-branded commodities, such as condoms designed for free distribution in public sector clinics.

Marketing

Marketing rules refer to restrictions on advertising products, establishments, or proprietors and thus cut across the categories represented above. We found marketing regulations in 15 countries, on a variety of topics. Below are examples of the types of restrictions in place.

Promotion of premises or personnel

Nigeria allows only registered pharmacists to display the pharmaceutical society emblem on their sign posts. Ghana restricts premises sign boards to a particular format. Burkina Faso and Senegal limit advertising of dispensing pharmacies only to notifying the public of their creation, transfer, or change in owner. In India, pharmacists cannot advertise in ways that invite attention to professional positions, skill qualifications, achievements, specialties, appointments, or affiliations. Benin bans promotion of premises.

Promotion of products

Bangladesh, Ethiopia, Kenya, and Tanzania require preapproval for any advertisement that makes claims with respect to any pharmaceutical product. Afghanistan and Ghana limit drug advertising to professional publications only. Côte d'Ivoire requires that drug advertisements use tact and moderation in form and content. The Philippines requires that information promoting the safe and rational use of drugs be displayed in a conspicuous area.

Enforcement

Enforcement of policies, laws, and regulations is critical to ensure quality in the pharmaceutical retail sector. This section examines which bodies are charged with overseeing licensure processes and facility inspections, and the powers that inspectors have vis-à-vis noncompliant facilities. We did not address the adequacy of resources to fulfill these functions or financing options to increase capacity for enforcement.

A range of public and private institutions are entrusted with enforcing pharmacy and drug shop regulations (Figure 9), with roughly half overseen by ministry of health or other government agencies and half by private fee-bearing associations.

Government agencies, including the ministry of health, the food and drug administration, and national- and state-level pharmacy councils, are responsible for inspecting drug shops in 28 of the countries in our review. For the remaining four countries (Côte d'Ivoire, Haiti, Yemen, and Zambia), we were unable to locate regulations that identified the relevant agencies. Of the 28 countries, 19 enumerate the powers granted to inspectors to deal with instances of noncompliance in their policies and regulations. Generally, inspectors are able to issue fines, revoke licenses, and close stores. In 15 countries (Bangladesh, Benin, Côte d'Ivoire, Ethiopia, India, Liberia, Malawi, Mauritania, Nepal, Nigeria, Pakistan, Philippines, Tanzania, Togo, and Uganda), inspectors also have the power to imprison offenders, depending on the severity of the infraction.

Figure 9. Licensure bodies for both pharmacies and drug shops in 32 countries

Provisions related to family planning

Inclusion on essential medicine lists

Countries develop EMLs to promote availability of medicines deemed most critical for basic health needs. Inclusion on the EML indicates that a country considers a particular medicine a priority for registration and procurement, based on evidence of efficacy and cost-effectiveness. We reviewed the EMLs for each of the 32 countries to catalogue the inclusion of specific methods. Table 3 summarizes the findings.

Table 3. Inclusion of modern contraceptive methods on EMLs

Contraceptive method	Number of countries including method on EML
Combined OCP	31
Progesterone–only contraceptive pills	11
Implants	19
Copper IUD	24
Hormonal IUD	4
Injectable contraceptives	27
Male condoms	26
Female condoms	16
ECs	15

Prescriptions, screening, and assessment

The requirement that druggists sell medicines only to customers with prescriptions from their health care providers is linked to service rules regarding screening and referrals. Clients with prescriptions are demonstrating that they are in the care of a health professional and not in need of assessment services from drug sellers.

A number of products classified as essential medicines have been approved for over-the-counter sales to increase availability where access to medical professionals is limited. Sales of hormonal contraceptives, specifically OCPs, are permitted without prescriptions in 15 of the 32 countries at both tiers: Afghanistan, Bangladesh, Benin, Ethiopia, Ghana, Guinea, Haiti, India, Kenya, Nepal, Pakistan, Rwanda, Senegal, Tanzania, and Uganda (OCsOTC, 2016). Formally, prescriptions are required by regulation in 14 countries to obtain OCPs (though as noted in the Discussion section, prescription rules are widely disregarded in many lower- and middle-income countries): Burkina Faso,

Côte d'Ivoire, DRC, Ghana, Liberia, Madagascar, Malawi, Mali, Mozambique, Nigeria, Philippines, Togo, Yemen, and Zambia. In Nigeria, prescriptions are only needed for the first dose and are not required for refills. In line with this requirement, Nigeria also limits the availability of OCPs at lower-tier drug shops to refills only (Stanback et al., 2016). No information regarding OCP prescription requirements was found for Indonesia, Mauritania, Niger, or South Sudan.

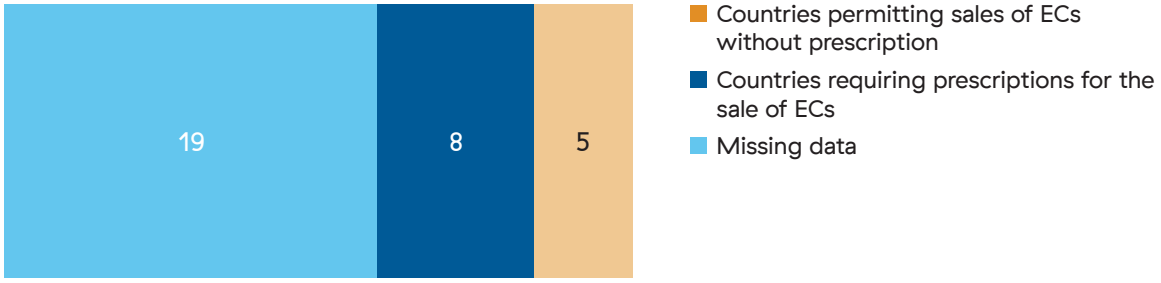
As with referrals, most country regulations make no mention of the duty of drug sellers to assess eligibility and appropriateness for particular medicines. For the sale of hormonal OCPs, screening is required in Ghana, Nepal, Rwanda, Tanzania, and Uganda. In Tanzania, drug sellers are required to use a checklist when dispensing OCPs. In the other 10 countries where OCPs are available without a prescription, no rules were found related to mandatory screening (OCsOTC, 2016).

Sales of OCPs are permitted without prescriptions in 15 of the 32 countries, with pre-screening required in 5 of those countries.

Figure 10. Prescription requirements for OCPs in 32 countries

No prescriptions are required in the majority of focus countries for the sale of EC: Bangladesh, Benin, Burkina Faso, Côte d'Ivoire, Ethiopia, Ghana, Guinea, Haiti, India, Liberia, Madagascar, Mali, Mauritania, Mozambique, Nepal, Niger, Nigeria, Pakistan, and Senegal (Figure 11). In Benin and Liberia, the lowest-level cadre permitted to sell EC in drug shops is auxiliary nurse. Prescriptions are required for the sale of EC in eight countries: DRC, Indonesia, Kenya, Malawi, Senegal, Tanzania, Uganda, and Zambia (ICEC 2016). Data on regulations regarding EC prescription requirements were not available for five countries: Afghanistan, Philippines, South Sudan, Togo, and Yemen.

Figure 11. Prescription requirements for ECs in 32 countries



For the other methods listed in Table 3, no country had any kind of regulation requiring screening, counseling, or prescriptions to access condoms. With the exception of injectable contraceptives (see below), we did not find any examples of regulations or policies that specified a role for pharmacies or drug shops in the sale of IUDs (either copper or hormonal) and implants. While anecdotal evidence indicates that pharmacies in some countries sell long-acting reversible contraceptives (LARCs), the regulations found in this scan only focused on the cadres allowed to actually deliver the clinical component of these methods at higher-level health facilities, and so did not directly address a role for pharmacies and drug shops. However, these regulations all did require a trained clinician at a higher-level health facility (clinic, hospital, etc.) to provide these services.

Providing injections

DMPA is an injectable hormonal contraceptive that is increasingly popular in many developing countries. With few exceptions (noted below), the countries covered in this scan implicitly prohibit the delivery of injections of any kind by pharmacists and drug shops as broadly prohibited "medical procedures." The commodity itself is generally listed as a prescription drug in the countries we reviewed (APC 2014). While the regulations found were generally silent on the issue, this classification implies that injectable methods could be sold at pharmacies in line with overall rules about the sale of prescription drugs. Ghana was the only country in which we found explicit rules allowing the sale of DMPA intramuscular injections with concomitant referrals to health facilities for the injection. As prescription drugs, injectable contraceptives are almost never legally allowed to be sold at lower-tier drug shops (APC 2014). However, to increase DMPA access, three programs (in Bangladesh, Nigeria, and Uganda) are conducting a pilot, under special regulatory waivers, to assess the potential for trained drug shop personnel to provide the injections themselves (APC 2014; Evidence Project, 2016).

Results by Country

Photo: Jessica Scranton

Results by Country

The tables in this section summarize findings on a country-by-country basis, listed alphabetically. General operating rules are provided in Table 4, followed by rules relevant to family planning products in Table 5, rules relevant to family planning services in Table 6, and contraceptives included on EMLs in Table 7. The table format is intended to provide a quick visual of those countries with more comprehensive provisions and those with more limited frameworks.

We grouped the countries for analysis according to their level of family planning market share through retail outlets and/or support of donor-funded initiatives.

> Group 1 (9 countries) are those countries with **active donor-funded initiatives** seeking to expand access to family planning through drug shop interventions such as improved organization, training, or access to finance.
>
> Group 2 (8 countries) are those countries with **high pharmacy and drug shop market share** of family planning methods (i.e., more than 20 percent of women accessed their modern method through a pharmacy or shop, based on most recent Demographic and Health Survey data).
>
> Group 3 (15 countries) are those countries with **low pharmacy and drug shop market share of family planning methods** and no known programs to strengthen drug shop quality or capacity.

We hypothesized that countries with higher family planning market share and/or drug shop programs would have more recent and comprehensive policy revisions. We found the Group 1 countries were more likely to address the breadth of regulatory categories, perhaps resulting from the active engagement of the donor projects with government partners. We provided a more detailed overview of the regulations in the nine Group 1 countries in the following section, Country Highlights.

We did not discern a difference overall in the pattern between countries in Groups 2 and 3. Both sets of countries included a wider range of regulatory comprehensiveness compared with the countries in Group 1, from those missing any regulations and those with more limited sets of rules, to those with higher levels of regulatory oversight. We did not summarize the specific provisions in those 23 countries, but we listed the documents setting forth the rules and regulations for each country in Annex A.

General operating rules

Table 4 documents whether we found provisions related to:

- Premises: This includes location requirements (generally listing a minimum distance from existing facilities) and size requirements (establishing a minimum or maximum facility size).
- Personnel: This includes training requirements for staff related to pharmacy or non-pharmacy credentials, and supervision requirements, related to whether or not licensed pharmacists must perform any kind of supervisory functions.
- Marketing regulations relevant to premises, personnel, or products.

Table 4. Summary of general regulations by country

	Premises rules on:							Personnel rules on:		Marketing rules on:
Country	Ownership?	Location?	Size?	Hygiene practices?	Recordkeeping?	Licensure requirements?	Fee requirements?	Minimum training requirements?	Minimum supervision requirements?	Promotion of premises, products, or personnel?
Group 1: Countries with donor-funded pharmacy and drug shop initiatives										
Bangladesh										
Pharmacy	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Ghana										
Pharmacy	Yes	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not required	Yes
India										
Pharmacy	Yes	Not required	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	Yes	Not required	Yes	Yes	Yes	Yes	Yes	None found	None found	None found
Kenya										
Pharmacy	Yes	Not required	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Liberia										
Pharmacy	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not required	Yes
Nigeria										
Pharmacy	Yes	None found	None found	Yes	Yes	Yes	Yes	Yes	None found	Yes
Drug Shops	Yes	Not required	Not required	Yes	Yes	Yes	Yes	Not Required	Not Required	Not Required
Senegal										
Pharmacy	Yes	Yes	None found	None found	None found	Yes	Not Required	Yes	Not Required	Yes
Drug Shops	Yes	Yes	None found	Yes	None found	Yes	None found	Yes	Not Required	None found
Tanzania										
Pharmacy	Yes	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not required	Yes
Uganda										
Pharmacy	Yes	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes	None found
Drug Shops	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Not required	None found

	Premises rules on:							Personnel rules on:		Marketing rules on:
Country	Ownership?	Location?	Size?	Hygiene practices?	Recordkeeping?	Licensure requirements?	Fee requirements?	Minimum training requirements?	Minimum supervision requirements?	Promotion of premises, products, or personnel?
Group 2: Countries with significant role for pharmacies and drug shops in family planning										
Benin										
Pharmacy	Yes	Yes	None found	None found	None found	Yes	None found	Yes	Yes	Yes
Drug Shops	None found	None found	None found	None found	None found	None found	None found	Yes	Yes	None found
Côte d'Ivoire										
Pharmacy	Yes	Yes	None found	Yes	None found	Yes	None found	Yes	Yes	Yes
Drug Shops	None found	None found	None found	None found	None found	None found	None found	None found	None found	None found
DRC										
Pharmacy	None found	None found	None found	None found	None found	None found	None found	None found	None found	None found
Guinea										
Pharmacy	None found	None found	None found	None found	None found	Yes	None found	None found	None found	None found
Pakistan										
Pharmacy	Yes	Yes	Not required	Not required	Not required	Not required	Not required	Yes	Yes	Not required
Philippines										
Pharmacy	Yes	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	Yes	None found	None found	Yes	Yes	Yes	Only renewal	Yes	Yes	None found
Togo										
Pharmacy	Yes	Yes	None found	Yes	None found	Yes	Yes	Yes	Yes	None found
Yemen										
Pharmacy	Yes	None found	None found	None found	None found	None found	None found	Yes	Yes	None found
Group 3: Countries with limited role for pharmacies and drug shops in family planning										
Afghanistan										
Pharmacy	Yes	Yes	Not required	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Burkina Faso										
Pharmacy	None found	Yes	None found	Yes	None found	Yes	None found	Yes	None found	Yes
Drug Shops	Yes	Yes	None found	Yes	None found	Yes	Yes	Yes	Yes	Yes

Country	Premises rules on:							Personnel rules on:		Marketing rules on:
	Ownership?	Location?	Size?	Hygiene practices?	Recordkeeping?	Licensure requirements?	Fee requirements?	Minimum training requirements?	Minimum supervision requirements?	Promotion of premises, products, or personnel?
Group 3: Countries with limited role for pharmacies and drug shops in family planning										
Ethiopia										
Pharmacy	None found	None found	None found	None found	None found	Yes	None found	Yes	None found	Yes
Drug Shops	None found	None found	None found	None found	None found	Yes	None found	Yes	None found	None found
Haiti										
Pharmacy	Yes	None found	None found	None found	None found	None found	None found	Yes	Yes	None found
Indonesia										
Pharmacy	Yes	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	None found
Drug Shops	None found	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	None found
Madagascar										
Pharmacy	Yes	None found	None found	None found	None found	Yes	Yes	Yes	Yes	None found
Malawi										
Pharmacy	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Drug Shops	None found	Yes	None found	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Mali										
Pharmacy	None found	None found	None found	None found	Yes	None found	None found	None found	None found	None found
Drug Shops	None found	None found	None found	None found	None found	None found	None found	None found	None found	None found
Mauritania										
Pharmacy	Yes	Yes	None found	Yes	None found	Yes	Yes	Yes	Yes	None found
Drug Shops	None found	Yes	None found	Yes	None found	Yes	None found	Yes	None found	None found
Mozambique										
Pharmacy	None found	None found	None found	None found	None found	Yes	None found	None found	None found	None found
Nepal										
Pharmacy	Yes	None found	None found	None found	None found	Yes	Yes	Yes	Yes	None found
Niger										
Pharmacy	None found	None found	None found	None found	None found	None found	None found	None found	None found	None found

	Premises rules on:									Marketing rules on:
Country	Ownership?	Location?	Size?	Hygiene practices?	Recordkeeping?	Licensure requirements?	Fee requirements?	Minimum training requirements?	Minimum supervision requirements?	Promotion of premises, products, or personnel?
Group 3: Countries with limited role for pharmacies and drug shops in family planning										
Rwanda										
Pharmacy	Yes	None found	None found	None found	None found	None found	None found	None found	None found	None found
South Sudan										
Pharmacy	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	None found
Drug Shops	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	None found
Zambia										
Pharmacy	None found	None found	None found	Yes	Yes	Yes	Yes	Yes	Yes	None found

Rules related to family planning

Table 5 summarizes findings on regulations that are more explicitly tied to the provision of family planning products. This includes:

- Rules regarding the sale or delivery of OCPs
- Rules regarding the sale or delivery of ECs
- Rules about counterfeit drugs
- Rules on pricing regulations
- Ability to access products procured through the public sector supply chains

As discussed in other sections, prescription requirements for OCPs and ECs are routinely ignored in many countries. This scan did not investigate whether or not regulations are enforced, only what exists on paper.

Table 5. Summary of country regulations relevant to family planning commodities

Country	OCPs available from this outlet?	EC available from this outlet?	Rules about counterfeit drugs?	Are drug prices regulated?	Option to procure from public sector supply?
Group 1: Countries with donor–funded pharmacy and drug shop initiatives					
Bangladesh					
Pharmacy	Yes	Yes	Yes	Yes	Yes
Ghana					
Pharmacy	Yes, with screening	Yes	None found	No	Yes
Drug shops	Yes, with screening	Yes	None found	No	Yes
India					
Pharmacy	Yes	Yes	None found	Yes	No
Drug shops	Yes	Yes	None found	Yes	None found
Kenya					
Pharmacy	Yes	Yes	Yes	None found	Yes
Liberia					
Pharmacy	Yes, with prescription	None found	Yes	None found	None found
Drug shops	Yes, with prescription	None found	Yes	None found	None found
Nigeria					
Pharmacy	Yes	Yes	Yes	None found	Unclear
Drug shops	Yes, limited to refills	Yes	Yes	None found	Unclear
Senegal					
Pharmacy	Yes, with screening	Yes, with aux. nurse	Yes	Yes	No
Drug shops	Yes, with screening	Yes, with aux. nurse	Yes	Yes	No
Tanzania					
Pharmacy	Yes, with screening	Yes, with prescription	Yes	No	No
Drug shops	Yes, with checklist	Yes, with prescription	Yes	None found	No
Uganda					
Pharmacy	Yes, with screening	Yes, with prescription	Yes	None found	No
Drug shops	Yes, with screening	Yes, with prescription	Yes	None found	No
Group 2: Countries with significant role for pharmacies and drug shops in family planning					
Benin					
Pharmacy	Yes	Yes	Yes	Yes	Yes
Drug shops	Yes	Yes, with aux. nurse	Yes	Yes	No
Côte d'Ivoire					
Pharmacy	Yes, with prescription	Yes	Yes	Yes	None found
Drug shops	Yes, with prescription	Yes	None found	None found	None found
DRC					
Pharmacy	Yes, with prescription	Yes, with prescription	Yes	Yes	Unclear
Guinea					
Pharmacy	Yes, with screening	Yes	None found	Yes	Yes
Pakistan					
Pharmacy	Yes	Yes	Yes	None found	None found
Philippines					
Pharmacy	Yes, with prescription	None found	Yes	Yes	None found
Drug shops	Yes, with prescription	None found	None found	Yes	Yes

Country	OCPs available from this outlet?	EC available from this outlet?	Rules about counterfeit drugs?	Are drug prices regulated?	Option to procure from public sector supply?
Group 2: Countries with significant role for pharmacies and drug shops in family planning					
Togo					
Pharmacy	Yes, with prescription	Yes, with aux. nurse midwife	None found	Yes	None found
Yemen					
Pharmacy	Yes, with screening	None found	Yes	No	None found
Group 3: Countries with limited role for pharmacies and drug shops in family planning					
Afghanistan					
Pharmacy	Yes	None found	None found	None found	No
Burkina Faso					
Pharmacy	Yes	Yes	None found	Yes	Unclear
Drug shops	None found	None found	None found	Yes	None found
Ethiopia					
Pharmacy	Yes	Yes	Yes	No	None found
Drug shops	Yes	None found	Yes	None found	None found
Haiti					
Pharmacy	Yes	Yes, with aux. nurse	Yes	No	None found
Indonesia					
Pharmacy	Yes, with prescription	Yes, with prescription	None found	None found	None found
Drug shops	Yes, with prescription	Yes, with prescription	None found	None found	None found
Madagascar					
Pharmacy	Yes, with prescription	None found	None found	Yes	None found
Malawi					
Pharmacy	Yes	Yes, with prescription	Yes	None found	No
Drug shops	Yes	None found	Yes	None found	No
Mali					
Pharmacy	Yes, with prescription	Yes	None found	Yes	None found
Drug shops	Yes, with prescription	None found	None found	Yes	None found
Mauritania					
Pharmacy	None found	Yes	None found	Yes	None found
Drug shops	None found	None found	None found	Yes	None found
Mozambique					
Pharmacy	Yes, with prescription	Yes	None found	None found	Unclear
Nepal					
Pharmacy	Yes, with screening	Yes	None found	None found	No
Niger					
Pharmacy	Yes, with prescription	Yes	None found	None found	None found
Rwanda					
Pharmacy	Yes, with screening	Yes	None found	None found	Unclear
South Sudan					
Pharmacy	None found	None found	Yes	None found	No
Drug shops	None found	None found	Yes	None found	No
Zambia					
Pharmacy	Yes, with prescription	Yes	None found	None found	None found

Table 6 summarizes regulations relating to the provision of family planning-related services at pharmacies and drug shops. These include rules on:

- Referrals
- Counseling requirements
- Diagnosis
- Testing
- Injection services

Table 6. Summary of country regulations relevant to family planning–related services

Country	Language on referrals?	Language on counseling?	Language on diagnosing?	Language on testing?	Language on injections?
Group 1: Countries with donor–funded pharmacy and drug shop initiatives					
Bangladesh					
Pharmacy	None found	None found	None found	None found	Waiver for donor program
Ghana					
Pharmacy	Allowed	Allowed	None found	None found	None found
Drug shops	Allowed	Allowed	None found	None found	No
India					
Pharmacy	None found	Required	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Kenya					
Pharmacy	None found	None found	None found	None found	None found
Liberia					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	No
Nigeria					
Pharmacy	Required	Required	None found	None found	No
Drug shops	Required	Required	No	No	No
Senegal					
Pharmacy	Required	None found	None found	Allowed	None found
Drug shops	None found	None found	None found	None found	None found
Tanzania					
Pharmacy	None found	None found	None found	None found	No
Drug shops	None found	Required	None found	None found	No
Uganda					
Pharmacy	None found	None found	None found	None found	No
Drug shops	None found	None found	None found	None found	Waiver for donor program

Country	Language on referrals?	Language on counseling?	Language on diagnosing?	Language on testing?	Language on injections?
Group 2: Countries with significant role for pharmacies and drug shops in family planning					
Benin					
Pharmacy	None found	None found	None found	No	None found
Drug shops	None found	None found	None found	None found	None found
Côte d'Ivoire					
Pharmacy	Yes	Yes	No	No	No
Drug shops	None found	None found	None found	None found	None found
DRC					
Pharmacy	None found	None found	None found	None found	None found
Guinea					
Pharmacy	None found	None found	None found	None found	None found
Pakistan					
Pharmacy	None found	None found	None found	None found	None found
Philippines					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Togo					
Pharmacy	None found	Required	None found	None found	None found
Yemen					
Pharmacy	None found	None found	No	None found	None found
Group 3: Countries with limited role for pharmacies and drug shops in family planning					
Afghanistan					
Pharmacy	None found	None found	None found	None found	None found
Burkina Faso					
Pharmacy	Yes	Yes	No	No	None found
Drug shops	None found	None found	None found	None found	None found
Ethiopia					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Haiti					
Pharmacy	None found	None found	None found	None found	None found
Indonesia					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Madagascar					
Pharmacy	None found	None found	None found	None found	None found
Malawi					
Pharmacy	None found	Required	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Mali					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Mauritania					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found

Country	Language on referrals?	Language on counseling?	Language on diagnosing?	Language on testing?	Language on injections?
Group 3: Countries with limited role for pharmacies and drug shops in family planning					
Mozambique					
Pharmacy	None found	None found	None found	None found	None found
Nepal					
Pharmacy	None found	None found	None found	None found	None found
Niger					
Pharmacy	None found	None found	None found	None found	None found
Rwanda					
Pharmacy	None found	Required	None found	None found	None found
South Sudan					
Pharmacy	None found	None found	None found	None found	None found
Drug shops	None found	None found	None found	None found	None found
Zambia					
Pharmacy	None found	None found	None found	None found	None found

As discussed, EMLs are important tools for understanding which health priorities exist in individual countries. Inclusion of a greater number of modern family planning methods can indicate that a country has sought to increase access to a greater range of methods. Table 7 highlights the different types of methods included in each country's EML.

Table 7: Inclusion of family planning methods on EMLs by country

Country	Combined OCPs	Progesterone–only OCPs	Implant	Copper IUD	Hormonal IUD	Injectable	Male condom	Female condom	ECs
Group 1: Countries with donor–funded pharmacy and drug shop initiatives									
Bangladesh	X						X		
Ghana	X	X	X		X	X	X	X	X
India	X			X	X		X		
Kenya	X		X	X		X	X	X	X
Liberia	X	X		X		X	X	X	
Nigeria	X		X	X		X			
Senegal	X		X	X		X	X	X	X
Tanzania	X	X	X	X		X	X	X	
Uganda	X		X			X	X		X

Country	Combined OCPs	Progesterone–only OCPs	Implant	Copper IUD	Hormonal IUD	Injectable	Male condom	Female condom	ECs
Group 2: Countries with significant role for pharmacies and drug shops in family planning									
Afghanistan	X			X		X	X	X	
Benin	X		X	X	X	X	X	X	X
Côte d'Ivoire	X			X		X	X	X	
DRC	X			X		X	X	X	X
Guinea									
Indonesia	X		X	X		X			
Madagascar	X	X	X	X		X	X	X	
Pakistan	X		X	X		X	X		X
Philippines	X					X			
Yemen	X	X		X			X		
Group 3: Countries with limited role for pharmacies and drug shops in family planning									
Burkina Faso	X		X	X		X	X	X	X
Ethiopia	X	X	X	X		X	X	X	
Haiti	X		X	X		X	X		X
Malawi	X	X	X	X		X	X	X	X
Mali	X	X	X	X		X	X	X	X
Mauritania	X			X		X	X		
Mozambique	X					X			
Nepal	X		X	X		X	X		X
Niger	X	X		X		X	X		
Rwanda	X		X	X	X	X	X		X
South Sudan	X	X		X		X	X	X	X
Togo	X		X			X			
Zambia	X	X	X	X		X	X	X	X

Note: EML for Guinea was not found.

Country Highlights

Photo: Jessica Scranton

Country Highlights

We took a more detailed look at the regulatory requirements in the nine countries with ongoing donor-funded initiatives (Group 1 countries): Bangladesh, Ghana, India, Kenya, Liberia, Nigeria, Senegal, Tanzania, and Uganda. These countries were selected for a closer analysis because they have active donor-supported programs to improve contraceptive access through drug shop interventions. These initiatives include efforts to formalize second tier drug shops in line with the Tanzanian ADDO model (discussed more below) in Bangladesh, Liberia, and Uganda; studies and pilots to demonstrate the feasibility of delivering injectable contraceptives through lower-tier drug shops in Bangladesh, Ghana, Nigeria, Senegal, and Uganda; and efforts to improve quality for a wider range of methods in Kenya, India, Nigeria, and Tanzania.

We looked for commonalities among the nine countries to suggest emerging best practices, but did not find clear patterns. We also examined whether regional approaches were discernable. Of the nine countries, four are in West Africa, three in East Africa, and two in Asia. We found no particular patterns to suggest that elements of a country's framework were predicated on regional influences.

We attempted to rank the nine countries with ongoing donor–funded initiatives by level of regulatory oversight, but found each country had a blend of light and strict regulations that made clustering difficult.

Table 8 summarizes some of the variations identified among the nine profiled countries. We attempted to rank the nine countries by level of regulatory oversight, but found each country had a blend of light and strict regulations that made clustering difficult. The two columns help to highlight the unique mix of approaches that countries have adopted. We listed them in rough order from more comprehensive to less comprehensive oversight. Additional details about each country follow.

Table 8. Highlights from nine countries with donor–supported drug shop activities

Country	Gaps and provisions suggesting low regulatory guidance, oversight, control	Provisions suggesting active regulatory guidance, limits, oversight
Tanzania	• Supervision requirements not specified • No price regulation	• Comprehensive set of regulations requires mandatory training, accreditation, business incentives, and regulatory enforcement under the ADDO model • Drug shops are authorized to sell subset of approved EML products • Location rules to encourage establishment in underserved areas
Ghana	• Low level (secondary education only) credential required to own or manage drug shops • No price regulation	• Largest number of contraceptives included on EML • Screenings required before pharmacies or drug shops can provide OCPs and ECs • Drug shop locations limited to areas underserved by pharmacies • Counseling and referrals to clinics allowed though not mandatory
Senegal	• No license fee for drug shops or pharmacies; registration is free • No provisions requiring supervision of drug shops	• Personnel at drug shops must have medical technician training at minimum • Private shops are not able to procure products from public sector supply • Price controls are imposed at wholesale and retail levels • Location restrictions are in place
Liberia	• Regulatory authority is in process implementing rules to provide for accreditation and regulatory enforcement over drug shops	• Participation in government–sponsored training program is mandatory for accredited drug shops • Drug shops currently permitted to sell preapproved list of medicines on EML • Prescriptions required for OCPs • EC sales require personnel with minimum qualifications of auxiliary nurse
Nigeria	• No minimum educational requirements • No training or supervision requirements • No price regulation	• Counseling to clients is required, and proprietary patent medicine vendors must refer first–time OCP users to higher facilities • EC sales require personnel with minimum qualifications of auxiliary nurse
Uganda	• Regulatory environment in transition toward drug shop accreditation model with ability to sell subset of prescription drugs	• Drug shops must be staffed by nurse aide or midwife • Screenings for dispensing OCPs required • ECs require prescriptions in both pharmacies and drug shops
Kenya	• Only pharmacies can be licensed • No rules on services that ban, regulate, or require counseling, screening, referral, testing, or injections • OCPs and ECs are legally available without prescriptions • No rules related to location of establishments	• Marketing rules limit product advertising • Largest number of contraceptives included on EML (condoms, OCPs, copper IUDs, ECs, DMPA, and implants)

Country	Gaps and provisions suggesting low regulatory guidance, oversight, control	Provisions suggesting active regulatory guidance, limits, oversight
Bangladesh	• Only pharmacies can be licensed • Limited number of contraceptives included on EML (condoms and OCPs only) • OCPs and ECs are legally available without prescriptions	• All drug prices are regulated • Services including diagnosis, testing, and injections are expressly prohibited (absent waiver)
India	• Authors unable to locate rules on drug shop training and credentials • Three contraceptives on EML (IUDs, OCPs, condoms) • No rules related to location of establishments	• Strict price controls by state governments; maximum prices and mark–ups must be printed on packages • Pharmacists required to offer counseling on all prescription medications

Of the nine countries, three have rules that have not been updated in at least 10 years (Bangladesh, Kenya, and Senegal). Each of the three has provisions that are outliers compared with the six countries with more recent amendments. Bangladesh and Kenya are the only two to not endorse a second tier of drug shops. Bangladesh also maintains strict price controls, prohibitions on promotion, and includes only two methods on its EML. Senegal has the strictest educational criteria, which can limit the pool of eligible licensed vendors. On other measures, the three are less prescriptive compared with countries with more recently updated frameworks, such as no requirements for prescriptions, screenings, or referrals for OCPs and ECs.

The six countries with more recent updates do not reflect a pattern to suggest a consensus on best practices for regulatory reform. Those with the widest number of contraceptives included on their EMLs are Ghana, Nigeria, Tanzania, and Uganda. India's EML does not include DMPA and Liberia's does not include implants. Regarding requirements to obtain OCPs or EC through drug shops, Liberia requires prescriptions, Ghana, Tanzania, and Uganda require screening, and Nigeria requires referrals to clinics. We were unable to locate regulatory language in India related to requirements for drug shop training, supervision, or service provision.

Regarding regulatory guidance on minimum training and credentials, the subset of focus countries shows the same diversity of approaches as the broader set of 32. Liberia and Tanzania require participation in mandatory government-sponsored training to achieve accreditation; Bangladesh requires drug shops to be supervised by pharmacists; Senegal and Uganda require minimum nursing training for drug shop proprietors; and Ghana and Nigeria do not require training or supervision for drug shops.

Overall, our analysis indicates that drug retail outlet regulations are evolving on a case-by-case basis as dictated by local needs.

Bangladesh

Key documents: The Drugs Act (1940), The Bengal Drug Rules (1946), The Drugs Control Ordinance (1982), National Drug Policy (2005), List of Essential Drugs (2008), Pharmacist Code of Ethics, The Pharmacy Ordinance (1976)

Types: Bangladesh currently has one tier. Private retail pharmacies have trained pharmacists who sell over-the-counter and prescription medicines, although there are slight differences in scope based on the owner's classification. Grade A pharmacists have earned a degree in pharmacy from a university or training institution that has been approved by the Pharmacy Council; Grade B pharmacists have earned a Pharmacy Council-approved diploma in pharmacy (i.e., lower than a bachelor's degree); and Grade C pharmacists have passed the Pharmacy Council's exam but may not have earned a degree or diploma. Recognizing that many unregulated retail drug outlets also exist and operate, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services project, led by Management Sciences for Health, is attempting to formalize a second tier of drug shops based on Tanzania's ADDO model.[1]

Premises, personnel, marketing, and enforcement: Regulations do not include rules on location and facility size, but do have requirements that owners be professionally licensed and pay an annual fee. Additionally, pharmacies must adhere to rules regarding hygiene practices and facility recordkeeping. Drugs must be sold under the supervision of a trained pharmacist—the key difference is that prescription drugs are limited to retail pharmacies operated by pharmacists with more training requirements (Grades A and B), while retail drug shops owned by Grade C pharmacists are restricted to non-prescription medicines. Both tiers are inspected by representatives of the Directorate General of Drug Administration, which has the power to close shops, repossess stocks, issue fines, and order imprisonments when infractions are found.

Products and services: Pharmacies abide by rules regarding storage and expiration of pharmaceutical products, sales of counterfeit products, and restrictions on prices for medicines. All pharmaceutical products sold in Bangladesh are registered and inspected by the Directorate General of Drug Administration in the Ministry of Health and Family Welfare. Family planning products on Bangladesh's EML are limited to condoms and OCPs, although earlier versions of the list included DMPA (c. 1993). Pharmacies are not allowed to offer diagnoses or testing services; in addition, they are not allowed to offer injection services, except for those participating in the BlueStar social marketing organization pursuant to a regulatory waiver.

OCPs can be provided without a prescription. While ECs are not on the EML, pharmacies can provide them without a prescription.

[1] The ADDO model was developed and launched in 2003 by the Tanzanian Food and Drug Authority and Management Sciences for Health under the Gates Foundation–funded Strategies for Enhancing Access to Medicines program. The model combined several interventions (targeted trainings, accreditation, supportive supervision, etc.) designed to improve the skills, knowledge, and practices of drug shop owners. Once accredited, ADDOs are allowed to deliver a wider range of health products and pharmaceuticals from the EML.

Ghana

Key documents: Public Health Act, Act 851 (2012), Health Professions Regulatory Bodies Act, Act 857 (2013), National Drugs Policy (2004), Food and Drug Act of 1992, Pharmacy Act of 1994, Essential Medicines List (2010)

Types: Ghana has two tiers: retail pharmacies are able to sell prescription and over-the-counter medicines, and lower-tier licensed chemical sellers, commonly known as over-the-counter medicine sellers, are only able to sell over-the-counter drugs. Pharmacies must be run by a trained pharmacist, while licensed chemical shops can be owned by any non-prescriber who is a Ghanaian citizen with a minimum of a secondary education.

In Ghana, regulations promote drug shops in areas underserved by pharmacies.

Photo: Elizabeth Corley

Premises, personnel, marketing, and enforcement: Both tiers operate under rules that establish a minimum size, dictate hygiene practices, and require recordkeeping. Licensed chemical shops also face additional regulations designed to promote their location in underserved communities. Both facilities must be licensed and pay an annual fee to the Pharmacy Council of Ghana. Retail pharmacists must include a trained and registered professional pharmacist who is on site at all times to supervise the dispensing of medicines. Licensed chemical sellers are only required to have a secondary education and are not required to be supervised by any staff with greater medical training. Prescription drugs in general can only be advertised in professional publications. In addition to licensure duties, the Pharmacy Council of Ghana is responsible for inspecting retail outlets and can revoke licenses when infractions are found.

Products and services: Pharmacies and outlets abide by similar rules regarding storage, repackaging, and expiration of pharmaceutical products. Pharmaceutical products are not under any price restrictions or regulations, generally. All pharmaceutical products sold in Ghana are registered and inspected by the Ministry of Health's National Quality Control Laboratory. The EML in Ghana is expansive, including condoms, injectable methods, several OCPs, ECs, implants, and hormonal (but not copper) IUDs. While OCPs and ECs are both available without a prescription, screenings are required at both levels for OCPs. Similarly, while counseling and referrals for family planning are not required at either level, they are allowed.

India

Key documents: Pharmacy Act of 1948 (and 1986 Amendment); Pharmacy Practice Regulations of 2015; Drugs and Cosmetics Act of 1948 (and 2005 Amendment); National List of Essential Medicines (2011)

Types: India has two tiers of drug outlets: retail pharmacies, which have a supervising registered pharmacist and can sell prescription drugs as well as compound medicines, and drug stores, which sell non-prescription medicines only. Both tiers can be owned by an individual, a partnership, or a corporation.

Premises, personnel, marketing, and enforcement: While India does not regulate the location of either tier, both levels must operate under size, hygiene, and recordkeeping requirements. Similarly, both are required to pay for licenses from the Food and Drug Administration of India. Pharmacies require a staff member with a degree in pharmacy and over 500 hours of practical training. To keep registration current, pharmacists must also participate in continuing medical education programs. Non-pharmacist staff are allowed to perform various functions (e.g., removing drugs from packaging, filling prescriptions) under the supervising pharmacists. Only the supervising pharmacist is allowed to actually dispense drugs to clients. Licensed pharmacists are also restricted in how they can market their practices. State Pharmacy Councils are responsible for inspecting pharmacies and drug stores and can issue fines, close facilities, and revoke licenses.

Products and services: The key difference between pharmacies and drug stores is the ability of pharmacies to compound drugs; drug store chemists are restricted from doing so. Additionally, this review found rules on storage and expiration for retail pharmacies but none for drug stores. All pharmaceutical products are inspected and registered by the Drug Controller of India. At both levels, maximum prices and mark-ups are set by state governments and must be printed on medicines. For any kind of service, pharmacists are required to counsel clients on any drugs or prescriptions sold. For family planning, the EML includes OCPs, IUDs (both copper and hormonal versions), and condoms. DMPA is not on the EML but is registered for use in the country. We did not find any rules on the ability of pharmacies and drug shops to administer it.

Kenya

Key documents: Pharmacy and Poisons Act of 1989; Public Health Act of 1989; Guidelines for Good Distribution Practice of Pharmaceuticals (2006); Kenya Essential Medicines List (2010)

Types: Kenya is the only country in Group 1 that only has one legally recognized tier of retail drug outlet. Retail pharmacies are allowed to sell over-the-counter and prescription medicines and can be owned by an individual, partnership, or limited company.

Premises, personnel, marketing, and enforcement: There are no rules that limit the location of pharmacies in Kenya. There are minimum sizes (8 ft. by 10 ft. for the dispensary and 10 ft. by 10 ft. for the general shop), and rules on hygiene and recordkeeping. Rules regulate how drugs are advertised in the country. Both premises and pharmacists must pay an annual licensure fee to the Pharmacy and Poisons Board, which is also responsible for inspecting facilities. In the case of infractions, pharmacies can have their licenses revoked.

Products and services: Kenyan pharmacies operate under rules that regulate storage of drugs, expiration control, and counterfeit drugs. All pharmaceutical products are inspected and registered by the Pharmacy and Poisons Board. For family planning, the EML includes OCPs, copper IUDs, ECs, condoms, implants, and DMPA. Both OCPs and ECs are available at pharmacies without a requirement for a prescription or screening. We did not find any rules requiring, banning, or regulating referrals, counseling, diagnostic services, testing, or injections.

Liberia

Key documents: Standards for Accredited Medicine Stores (2012); National Drug Policy (2001); Medicines and Health Products Regulatory Authority Act (2010); National Therapeutic Guidelines and Essential Medicines List (2011)

Types: Liberia has two tiers of retail drug outlets: pharmacies that can sell prescription, over-the-counter, and other medicines, and medicines stores that can sell a preapproved list of medicines. There is a growing movement to accredit these medicine stores based on the Tanzania ADDO model.

Premises, personnel, marketing, and enforcement: Both tiers operate under similar rules regarding location (minimum of two miles between outlets), size, hygiene, and recordkeeping. While both tiers must have a license from the Pharmacy Board, the annual renewal fee is almost three times as much for pharmacies as it is for medicine stores. Pharmacies must have a trained (i.e., degree in pharmacy) pharmacist on staff to supervise operations. Accredited medicine stores require dispensers to participate in a government-sponsored training program. No supervising pharmacist is required at medicine stores. Marketing of drugs sold at these facilities is regulated by the government. In addition to licensure, the Pharmacy Board of Liberia is also responsible for inspecting pharmacies and medicines stores. When infractions are found, drugs can be confiscated, licenses revoked, fines issued, and owners imprisoned.

Products and services: Sales of expired, counterfeit, and government-branded products are illegal at both pharmacies and medicine stores. Accredited medicine stores also are required to ensure proper storage of medicines and dispense medicines at full dosage; both storage and dispensing must be done in original containers at these outlets. All pharmaceutical products are inspected and registered by the Liberia Medicines and Health Products Regulatory Authority. The EML includes OCPs, DMPA, copper IUDs, and condoms. OCPs are available but require a prescription. It is unclear if ECs require a prescription; however, the lowest level of health worker allowed to sell or dispense them in the private sector is auxiliary nurse.

Nigeria

Key documents: Pharmacy Council of Nigeria Decree 91 of 1992; National Drug Policy of 2003; National Agency for Food and Drug Administration and Control (NAFDAC) Good Distribution Practices Guidelines for Pharmaceutical Products of 2016; Essential Medicines List 2010

Types: Nigeria has two tiers. Retail pharmacies are owned and operated by a trained pharmacist and sell over-the-counter and prescription medicines. Lower-tier patent and proprietary medicine vendors (PPMVs) sell a limited range of over-the-counter medicines, but are prohibited from selling prescription medications.

PPMVs in Nigeria are prohibited from selling prescription medications.

Photo: Vicki MacDonald

Premises, personnel, marketing, and enforcement: Pharmacies must be owned in whole or in part by a registered pharmacist, and pharmacists must have earned a formal degree in pharmacy. PPMVs can be owned by anyone over the age of 21; their owners are not required to have any formal health or pharmacy training—nor a supervisory relationship with a pharmacist—in order to be licensed. Both tiers are required to follow guidelines to promote hygienic practices set out by the NAFDAC. They are also required to keep records related to purchases made, prescriptions dispensed, and disposals of poisons; be licensed by the Pharmacist Council of Nigeria; and pay an annual fee. While retail pharmacists are restricted in how they can advertise themselves, neither pharmacies nor PPMVs are restricted from advertising their product offerings. In addition to licensure duties, the Pharmacist Council of Nigeria is responsible for inspecting both pharmacies and PPMVs and is empowered to close unlicensed outlets if infractions are found. Offending retail pharmacists can also be imprisoned for unprofessional conduct.

Products and services: Pharmacies and outlets abide by similar rules regarding storage and expiration of pharmaceutical products, and sales of counterfeit products. Similarly, neither level faces price regulations. While pharmacists are allowed to repackage products, PPMVs are required to sell all products in the original packaging. PPMVs are also much more limited in the dosage amounts that they are allowed to sell. All pharmaceutical products sold in Nigeria are registered and inspected by NAFDAC. Nigeria's EML includes several family planning methods: OCPs, implants, copper IUDs, DMPA, and condoms. Both retail pharmacies and PPMVs are required to counsel clients when selling contraceptives. In general, both are restricted to providing OCPs and condoms. While injections are generally not allowed at either tier, exemptions have been made for the sale of some injectable contraceptives. OCPs can be provided without a prescription at pharmacies; PPMVs are only allowed to sell refill OCPs and must refer first-time users to a higher-level facility. While ECs are not on the EML, both tiers can provide them.

Senegal

Key documents: Décret n ° 92-1755 Du 22 décembre 1992 réglementant la création et la gérance des dépôts de médicaments; Loi n ° 73-62 Du 19 décembre 1973 portant création de l'Ordre des pharmaciens; Arrêté n ° 1603 du 3 mars 1981, relative à la Libre circulation et directive L'Etablissement de L'Union au Sein de L'Espace UEMOA; n ° 81-039 Décret du 2 Fevrier 1981 portant code de déontologie des pharmaciens; Liste Nationale de Médicaments et Produits Essentiels du Senegal 2008

Types: Senegal has two types of drug retail outlets: pharmacies, which sell prescription and over-the-counter medicines, and private *dépôts* (*dépôts privés* or *dépôts de pharmacie*), which sell a select set of essential medicines and other health goods that have been prepackaged, labeled, and supplied by pharmacists. Both levels must be owned by individuals and not corporations.

Photo: Virginie Combet

Premises, personnel, marketing, and enforcement: Regulations treat both pharmacies and *dépôts* relatively similarly. For example, they institute hygiene practices that must be followed at both levels and establish a minimum distance (20 kilometers) between any two pharmacies or depots. Both pharmacies and *dépôts* require free facility licenses from the Directorate of Pharmacy and Medicine, as well as business licenses. Pharmacies are required to be owned, operated, and supervised by qualified pharmacists on the premises at all times. Depots can be run by a nurse, midwife, medical technician, or pharmacist. Since they are supplied by pharmacies, there is no requirement for a supervising pharmacist to be present for day-to-day operations. Inspections are carried out by the district-level Order of Pharmacists. When an infraction is found, inspectors have to power to censure or close the offending facility.

Products and services: This review found very few rules and regulations for products and services at the pharmacy level. As noted, though, *dépôts* can only stock and sell medicines that have been prepackaged by a trained pharmacist and cannot repackage anything themselves. Counterfeit medicines are outlawed at all levels. Products at both levels are sold under strict limits. Prices are set by inter-ministerial decree, which calculates the price and limits mark-ups at the different levels of the supply chain. All pharmaceutical products sold in Senegal are registered and inspected by the Ministry of Health's Directorate of Pharmacy and Medicine and the National Medicines Control Laboratory. The EML includes condoms, OCPs, ECs, implants, and copper IUDs. While OCPs and ECs are both available without a prescription, auxiliary nurses are the lowest level of health care provider allowed to sell or dispense ECs in the private sector.

Tanzania

Key documents: The Pharmacy Act (2011), The Public Health Act (2009), Guidelines for Establishing and Operating Accredited Drug Dispensing Outlets (2009), the Tanzanian Food, Drug, and Cosmetics Act (2003), Standard Treatment Guidelines and the Essential Medicines List (2007)

Types: Tanzania has two tiers. Retail pharmacies include any premise from which services requiring a trained pharmacist are dispensed, including community, institutional, and wholesale pharmacies. Accredited drug dispensing outlets (ADDOs) are outlets where non-prescription over-the-counter medicines are sold. ADDOs are certified to operate in line with government standards developed in 2009.

Premises, personnel, marketing, and enforcement: Pharmacies must be owned by a pharmacist and operate under rules that dictate hygiene and recordkeeping practices. As dictated by ownership requirements, all pharmacy outlets must have staff with at least a degree in pharmacy who can conduct or supervise sales. Pharmacies must be licensed and are required to pay annual fees. ADDOs can be owned by any Tanzanian citizen older than 18 who has undergone trainings conducted by the Tanzania Food and Drug Authority. Like pharmacies, ADDOs must follow rules pertaining to hygiene, recordkeeping, and licensure. They face additional regulations about their physical size and location to ensure that they are conveniently located in rural, peri-urban, and other underserved areas with limited access to medicines. While ADDOs must be accredited and their staff trained, there is no requirement for supervision of staff by a trained pharmacist. Both levels of facilities face restrictions on advertising medicines. They both receive licenses to operate from and are inspected by the Pharmacy Council. If infractions are found, both pharmacies and ADDOs are subject to loss of licenses, fines, and imprisonment.

Products and services: Pharmacies and outlets abide by similar rules regarding storage and expiration of pharmaceutical products, including sales of counterfeit products. Neither level is governed by rules that regulate prices. All pharmaceutical products sold in Tanzania are registered and inspected by the Tanzanian Food and Drug Authority. The EML in Tanzania includes several family planning methods: OCPs, copper IUDs, male and female condoms, implants, and DMPA. Both retail pharmacies and ADDOs are restricted to providing OCPs and condoms. OCPs can be provided without a prescription, but pharmacies and pharmacies must conduct a screening to assess eligibility. While ECs are not on the EML, both tiers can provide them.

Uganda

Key documents: Pharmacy and Drug Act of 1971; National Drug Policy and Authority Act of 1993; National Drug Policy and Authority Regulations of 2014; Essential Medicines and Health Supplies List (2012)

Types: Uganda has two tiers of retail drug outlets. Pharmacies are owned at least in part by a trained and licensed pharmacist and sell prescription and non-prescription medicines. Drug shops are owned by a medically qualified person (i.e., with at least nurse or midwife training) and are only allowed to sell non-prescription medicines. Initiated by the

donor-funded Sustainable Drug Seller Initiatives program, a subset of drug shops is becoming accredited based on the ADDO model in Tanzania. The initial program included an exemption that would allow accredited drug sellers to sell a limited list of prescription medicines.

Premises, personnel, marketing, and enforcement: In terms of premises, both pharmacies and drug shops are required to have a minimum size, follow rules promoting hygienic practices, keep and maintain records, and pay to receive a facility license from the Uganda National Drug Authority. Drug shops must also list the distance to the nearest pharmacy or drug shop on their licensure applications to encourage their establishment in underserved areas. Pharmacies are required to have someone on staff with a bachelor's degree in pharmacy who has passed a pre-registration exam and is present to supervise operations. Drug shop operators must have at least the level of nursing aide training. These facilities are not required to employ a pharmacist to supervise operations. Both levels are inspected by the Uganda National Drug Authority with district health teams. When infractions are found, inspectors are able to close premises, impound drugs, and issue fines. Offending owners can also face imprisonment.

Products and services: Pharmacies and outlets abide by similar rules regarding storage, repackaging, and expiration of pharmaceutical products. All pharmaceutical products sold in Uganda are registered and inspected by the National Drug Authority. In terms of family planning, the EML includes condoms, injectable methods (DMPA), OCPs, EC, and implants. While OCPs are available without a prescription, both pharmacies and drug shops must conduct a screening before dispensing any. EC, however, requires a prescription in order for pharmacies and drug shops to sell them. Additionally, while regulations indicate that neither pharmacies nor drug shops generally are allowed to inject, a donor-funded project has received an exemption that allows trained drug shop operators to counsel and administer DMPA injections.

An exemption allows accredited drug sellers to sell some prescription medicines in Uganda.

Photo: Saiqa Panjsheri

Discussion and Conclusion

Photo: Jessica Scranton

Discussion

Future research is needed to explore the link between regulatory frameworks and contraceptive prevalence rates.

This scan focused solely on existing drug seller regulations and gaps as one aspect of the enabling environment to inform interventions at the programmatic level. It did not examine other important factors that influence drug outlet products and practices, including consumer demand, reliability of supply, links to clinical services, cultural practices, and level of available technical, human, and financial resources within national health systems. Regulatory reform to improve access and quality would need to take into account those broader systematic factors and the needs of all stakeholders including policy makers, distributors, clinical service providers, consumers, and local governments.

This overview identified some policy trends and outliers within a range of regulatory approaches, from more comprehensive to less prescriptive. We did not examine the impacts of particular provisions on family planning quality, affordability, or access. Regulatory requirements establish boundaries, if enforced, but other powerful forces shape drug seller behaviors as well. These factors include economic constraints inhibiting compliance, market dynamics, business incentives, and social aspirations. Future research is needed to explore the link between regulatory frameworks and contraceptive prevalence rates. Our objective was to document the range of regulatory provisions governing drug shops and pharmacies, particularly as they apply to family planning, to provide some global context, and to serve as a resource for family planning practitioners working within particular country environments. Below are some considerations that surfaced.

Creating a legally recognized tier of non-pharmacy drug retail outlets can be an effective first step in regulating a dynamic pharmacy sector.

We found that a significant number of our focus countries (17 of 32) have codified a second tier of establishments to sell pharmaceutical products without requiring a trained pharmacist on the premises. This trend reflects the change in the pharmaceutical marketplace in which imported medicines have penetrated markets globally, but there has not been a corresponding increase in the availability of professional pharmacists to dispense them. As these medicines (both approved and black market) became available, shops were set up to sell them, though in many cases these enterprises arose outside of regulatory systems. The inclusion of non-pharmacist shops in national policies reflects recognition of the importance of a regulatory response to the growth of this sub-sector and of the shops' role as care providers in the absence of clinical services. By sanctioning the role of lower-tier drugs shops, regulatory frameworks can potentially limit the illicit drug market and expand access to safe and appropriate medicines (Ongolo-Zolo, 2010).

Advocacy to lower regulatory barriers to access of OCPs and ECs at drug retail outlets has been effective.

A basic purpose of pharmaceutical regulation is safety—to prevent harm to consumers from defective products and inappropriate treatments. The widespread inclusion of reproductive health pharmaceuticals on country EMLs reflects the efforts of global stakeholders such as the United Nations

Population Fund and WHO. These and many other organizations supported country policies to expand access with evidence of contraceptive efficacy and safety, in forms which ensure that the quality can be assured, and under storage conditions that will keep products stable. Inclusion on national EMLs demonstrates that contraceptives have gained legitimacy and visibility in our focus countries, which contribute to their availability at private retail outlets. Advocates have also sought to address regulatory barriers that require prescriptions for OCPs and ECs. The high number of countries permitting the sale of OCPs and ECs without prescriptions reflects an assessment of benefits and risks of contraceptive access where no clinicians are available. In those countries that do require prescriptions, there is evidence that as a matter of practice, these requirements are ignored and not enforced (Sabde et al., 2011, Viberg et al., 2009, Mayhew et al., 2001). As noted below, however, liberalizing access through drug shops should address minimum training and screening requirements to ensure safe and appropriate use.

Inclusion on national EMLs demonstrates that contraceptives have gained legitimacy and visibility in our focus countries, which contributes to their availability at private retail outlets.

Use of policy waivers and exemptions to expand drug shop scopes of practice for family planning is appropriate.

Regulations should align with risk to strike the balance between costs and benefits. Rules prescribing minimum entry conditions, quality standards, and operational requirements for both pharmacies and lower-tier drug shops are written to cover all health conditions, but risks of consumer harm vary by the disease and complexity of treatments. Evidence indicates that there are greater consequences from weak regulation and enforcement for acute conditions and life-threatening illnesses than for preventive treatments such as contraception. For example, counterfeit drugs for infectious diseases including malaria, tuberculosis, and HIV/AIDS are widespread, causing thousands of death each year, but evidence of fake contraceptives circulating in markets has been limited (Webb, 2014). There is also evidence that drug sellers cause harm by selling inappropriate treatments for common symptoms and illnesses in children such as pneumonia, diarrhea, and fever (Goodman et al., 2007a; Goodman et al., 2007b). Some products, such as vaccines, require refrigeration and thus require strict adherence to storage standards and requirements to ensure efficacy. These issues suggest a more urgent need for education and monitoring of practices related to curative treatments for these widespread conditions.

A lighter regulatory approach, including exemptions from rules related to premises and personnel, may be appropriate for the provision of family planning. These could include relaxing requirements on minimum shop sizes and on strict pharmaceutical education requirements to allow for alternative training qualifications. A set of layered policies, such as waivers from restrictions on specific practices related to injections or service delivery in underserved rural areas, will best reflect local needs and capacity (Wafula, 2014). Within this family planning context, drug retailers should be required to screen first-time users of hormonal methods for contraindications including cardiovascular

disease. Training on specific methods is also needed to ensure proper counseling for exclusively breastfeeding women and other pre-existing health conditions. As noted in the findings, few countries require pharmacists and drug shop vendors to screen or counsel clients before dispensing OCPs or ECs over the counter.

The popularity and range of injectables has increased in many developing countries, with evidence that DMPA injections are provided by drug retail outlets often in direct violation of licensing laws (EADSI, 2011). Our review indicates that regulatory guidelines have lagged in response to this growing market demand, suggesting the potential need for programmatic responses to monitor risks and ensure quality. Intramuscular injections require proper infection prevention measures, including adequate sharps disposal and disinfection, medical supplies, and training. Options include interventions to promote positive evidence-based practices such as mandatory training and screening by drug sellers for first-time users, distribution of posters to guide clients in self-screening for repeat users, and studies to assess adherence to protocols and track adverse events. Task-shifting programs are building evidence on the conditions necessary to ensure injections performed by cadres with no formal medical training have positive health outcomes (Evidence Project, 2016).

Mandatory, standardized, and cost-effective basic training programs are needed to operationalize regulations.

A priority consideration for expanding a skilled workforce able to provide safe and appropriate methods of family planning is to establish a minimum set of qualifications commensurate with permitted scopes of practice. Our review found wide variation on this topic, including many examples of countries with no language on minimum training requirements. Mandatory basic training programs that are standardized, affordable, and relevant represent a promising approach for improving access through drug shops. Drug sellers' compliance with continuing education requirements can be reinforced through license renewal requirements, supportive supervision, job aids, and opportunities for peer learning. Expert informants from several countries suggest that more collaboration with community health worker training programs should be explored given that drug sellers and community health workers often share similar socio-demographic and educational backgrounds.

Our review indicates that regulatory guidelines have lagged in response to a growing market demand for injectables, suggesting the need for programmatic responses to monitor risks and ensure quality.

Innovative and mixed public-private approaches may enhance enforcement of regulations and expand access.

This regulatory review does not address whether there is compliance with, adequate enforcement of, or effective communication of the rules. Many low- and middle-income countries have weak mechanisms to enforce safety, quality, and efficacy standards, with inadequate systems, resources, or training to inspect or sanction non-compliance (MSH, 2012). The literature is inconclusive about

the effect of government inspections on regulatory compliance, attributed in part to corruption and regulatory capture (Wafula et al., 2014; WHO, 2012; SIAPS, 2015). To address the inadequacies of traditional policing functions of regulators, countries are adopting a range of solutions to reinforce and incentivize compliance (Rutta et al., 2015). These include self-regulation through consensus-based ethical standards, engagement of local stakeholders to monitor quality, and frequent communications (Ensor et al., 2006). This trend is reflected by the guidelines we found in eight countries to promote drug shop education and supervision through fee-based professional associations. Associations can offer potential benefits such as bulk purchasing discounts for supply, access to financing schemes including insurance, voucher, or credit, and business skills training as mechanisms to incentivize group self-regulation.

This review also did not examine regulation of supply-side factors with the potential to impact contraception price and availability. Drug shop access to products through public sector channels could lower prices for critical products due to the bulk purchasing power of central governments. On the other hand, CMS supply may be less efficient than private channels or create competitive distortion of commercial markets. The countries permitting access to CMS supply were located in West Africa, where decades of organization reforms have led to increased privatization, improved accountability, and increased drug quality and affordability (World Bank, 2010). To assess whether CMS access would promote a more secure, cost-effective supply for drug shops, a range of complex contextual factors needs to be considered, including the operational efficiency, funding and cost-recovery policies, and governance structures of the CMS in a country.

Sanctioning and regulating second tier outlets can expand access to safe and appropriate medicines.

Conclusion

The role of pharmacies and drug shops in the provision of modern family planning methods is increasing in low- and middle-income countries. The descriptive summaries of drug shop and pharmacy regulations in 32 countries show wide variation. Some countries have not yet adopted frameworks to establish minimum requirements. Others have many restrictions and requirements with uneven resources for enforcement. This global overview provides a starting point for family planning practitioners to consider the enabling environment in a particular country. In partnership with national governments open to testing options for safe and effective practices, implementers can continue to build the evidence on policy reforms that promote product access, quality, and safety.

Photo: Elizabeth Corley

Annex A. Key Regulations by Country

Afghanistan

- National Medicines Policy 2014
- Competency Framework for Pharmaceutical Services 2012
- National Pharmaceuticals Human Resources Strategic Framework 2013
- National Essential Medicines List 2014

Bangladesh

- The Drugs Act 1940
- The Bengal Drug Rules 1946
- The Drugs Control Ordinance 1982
- National Drug Policy 2005
- The Pharmacy Ordinance, 1976
- Pharmacist Code of Ethics
- List of Essential Drugs 2008

Benin

- Loi n ° 97–020 fixant les conditions de l'exercice en clintele privé du professions medicales
- Loi n ° 90–005 fixant les conditions de l'exercice des activités de commerce
- Politique Pharmaceutique National 2008
- List Nationale des Médicaments Essentiels 2009

Burkina Faso

- Liste Nationale des Médicaments Essentiels 2014
- Liste des Pièces à Fournir par les Postulants à l'Ouverture d'un Dépôt Privé de Médicaments 2015
- Politique Pharmaceutique Nationale 2012
- Recueil de Textes Règlementaires du Pharmacies, du Médicaments et Laboratoires 2014

Côte d'Ivoire

- Classification General du Etablissements Sanitaire Privé 1996
- Création d'une Officine de Pharmacie 2008
- Liste Nationale des Médicaments Essentiels et du Matériel Bio Médical 2013
- Loi n° 2015–533 du 20 juillet 2015 relative à l'exercice de la pharmacie 2015
- Politique Pharmaceutique Nationale 2009

DRC

- Politique Pharmaceutique National 2002
- Liste Nationale des Médicaments Essentiels 2007

Ethiopia

- Assessment of the Pharmaceutical Sector in Ethiopia 2003
- Regulation No 189/2010 Ethiopia Food, Medicine and Healthcare Administration and Control Authority 2010
- Ethiopian Essential Medicines List 2010

Ghana

- Public Health Act, Act 851 2012
- Health Professions Regulatory Bodies Act, Act 857 2013
- National Drugs Policy 2004
- Food and Drug Act of 1992
- Pharmacy Act of 1994
- Essential Medicines List 2010

Guinea

- Law No. 94/012 / CTRN / 22 March 1994 Pharmaceutical Legislation
- Decree No. 94/043 / PRG / SGG of 22 March 1994 Regulatory Provisions Pharmaceutical Activities

Haiti

- Loi de Pharmacie 1955
- Liste Nationale des Médicaments Essentiels 2012

India

- Pharmacy Act of 1948 (Amended up to 1986)
- Pharmacy Practice Regulations of 2015
- Drugs and Cosmetics Act, 1948 (Amended up to 2005)
- National List of Essential Medicines of India 2011

Indonesia

- National List of Essential Medicines 2008
- Pharmaceutical Act 2009

Kenya

- Pharmacy and Poisons Act of 1989
- Public Health Act of 1989
- Guidelines for Good Distribution Practice of Pharmaceuticals of 2006
- Kenya Essential Medicines List 2010

Liberia

- Standards for Accredited Medicine Stores 2012
- National Drug Policy 2001
- Medicines and Health Products Regulatory Authority Act 2010
- National Therapeutic Guidelines and Essential Medicines List 2011

Madagascar

- Decree No. 2015– establishing the powers of the Minister of Public Health and the general organization of the Ministry 2015
- Stratégie Nationale sur la Couverture Santé Universelle 2015
- Plan de Développement du Secteur Santé 2015
- Liste Nationale des Médicaments Essentiels 2008

Malawi

- Pharmacy, Medicines and Poisons Act of 1991
- Malawi Standard Treatment Guideline and Essential Medicines List of 2015

Mali

- Liste Nationale des Médicaments Essentiel 2008
- Arrêté n° 00 – 3476 / Fixant le détail de l'organisation des sections de la Direction de la Pharmacie et du Médicament 2000
- Décret n° 04 — 557 / Instituant l'autorisation de mise sur le marché de médicaments à usage humain et vétérinaire 2004
- Décret n° 07–087 / Fixant les prix des médicaments en dénomination commune internationale de la liste nationale des médicaments essentiels dans le secteur pharmaceutique privé 2007
- La politique pharmaceutique nationale 1998

Mauritania

- Liste Nationale des Médicaments Essentiels 2012
- Loi N° DRAFT / Relative à la Pharmacie (undated draft)

Mozambique

- Formulario Nationale de Medicamentos 2010
- External Evaluation of the Pharmaceutical Sector in Mozambique 2007

Nepal

- National List of Essential Medicines 2011
- Nepal Pharmacy Council Act, 2057 (2000)
- Nepal Health Service Rules, 2055 (1999)
- National Medicines Policy 2007
- Nepal Pharmacy Council Rules, 2059 (2002)

Niger

- Liste Nationale des Médicaments Essentiels 1998

Nigeria

- Pharmacy Council of Nigeria Decree 91 of 1992
- National Drug Policy of 2003
- NAFDAC Good Distribution Practices Guidelines for Pharmaceutical Products of 2016
- Essential Medicines List 2010

Pakistan

- The Drugs Act of 1940 (As modified up to 1967)
- National Essential Medicines List of Pakistan 2007
- Pharmacy Act 1967

Philippines

- Administrative Order No. 2014–0034 – Rules and Regulations on the Licensing of Establishments 2014
- Administrative Order No. 2016–0003– Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration 2016
- Administrative Order No. 2005–0011– Guidelines for the Establishment and Operations of BnBs and PDNs relative to the inclusion of other drugs which are classified as prescription drugs 2005
- Administrative Order No. 2000–0063 Guidelines in the filling of ordinary prescriptions by all drug outlets and drugstore including hospitals 2000
- Republic Act No. 5921 Regulating the Practice of Pharmacy and Setting Standards of Pharmaceutical Education 1969
- Philippine National Drug Formulary– National Essential Medicines List 2008

Rwanda

- Code of Ethics for Pharmacy Profession 2015
- Ministerial Decree N° 20/14 Determining a List of Drugs and Other Pharmaceutical Products which must appear in a Pharmaceutical Point of Sale 2005
- Liste Nationale des Médicaments Essentiels 2015
- National Pharmacy Policy 2016
- Requirements for Authorization to open a Private Health Facilities 2011

Senegal

- Décret n ° 92–1755 Du 22 décembre 1992 réglementant la création et la gérance des dépôts de médicaments
- Loi n ° 73–62 Du 19 décembre 1973 portant création de l'Ordre des pharmaciens
- Arrêté n ° 1603 du 3 mars 1981, relative à la Libre circulation et directive L'Etablissement de L'Union au Sein de L'Espace UEMOA
- n ° 81–039 Décret du 2 Fevrier 1981 portant code de déontologie des pharmaciens
- Liste Nationale de Médicaments et Produits Essentiels du Senegal 2008

South Sudan

- Essential Medicines List 2007
- South Sudan Pharmacy Protocol (No Date)
- Drug and Food Control Authority Act 2012

Tanzania

- The Pharmacy Act 2011
- The Public Health Act 2009
- Guidelines for Establishing and Operating Accredited Drug Dispensing Outlets 2009
- The Tanzanian Food, Drug and Cosmetics Act 2003
- Standard Treatment Guidelines and the Essential Medicines List 2007

Togo

- Loi–cadre de 2001 sur la Pharmacie et le Médicament au Togo 2001
- Loi N° DRAFT Portant Code de la Santé Publique (undated draft)
- Politique Nationale de Santé 2012
- Liste Nationale des Médicaments Essentiels 2012

Uganda

- Pharmacy and Drug Act of 1971
- National Drug Policy and Authority Act of 1993
- National Drug Policy and Authority Regulations of 2014
- Essential Medicines and Health Supplies List 2012

Yemen

- List of Essential Medicines 2009
- Health Sector Reform in the Republic of Yemen 2000

Zambia

- Zambia Essential Medicines List 2013
- Guidelines for Establishment of a Pharmaceutical Retail Business 2015

Annex B. Key Informants Consulted

To contextualize and validate the findings from our multi-country scan, we consulted the following pharmacy and policy experts individually and in consultative meetings:

- Albert Arkoh, Pharmacy Council Ghana
- Jasmine Baleva, USAID/Washington
- Ellen Clancy, Marie Stopes International
- Salisu Ishaku, Population Council Nigeria
- Catherine Goodman, London School of Hygiene and Tropical Medicine (LSH™) Kenya
- Meenakshi Gautum, LSH™ India
- Sanaou Gning, Marie Stopes Senegal
- Timothy Kachule, Independent Consultant Malawi
- Kate MacDonald, Population Services International DRC
- Baker Maggwa, USAID/Washington
- Fatou Mbow, Population Council Senegal
- Maureen Ogada-Ndekana, SHOPS Plus Project Tanzania
- Tracy Orr, FHI 360
- Saiqa Panjsheri, Abt Associates
- Rijalalaina Rasolonofonirina, Marie Stopes Madagascar
- Lois Schaefer, USAID/Washington
- Sarah Shaw, Marie Stopes International
- John Stanback, FHI 360
- Francis Wafule, World Bank Kenya

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