

# Stronger Health Advocates Greater Health Impacts

## Markets Matter Advocacy Guide



# Markets Matter Advocacy Guide:

## How advocates can strengthen markets to improve access to essential health products

### About PATH

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at [www.path.org](http://www.path.org).

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# Acronyms

<b>MOH</b>	ministry of health
<b>NEML</b>	National Essential Medicines Lists
<b>NGO</b>	nongovernmental organization
<b>NMP</b>	national medicine policy
<b>NRA</b>	National Regulatory Authority
<b>SRA</b>	Stringent Regulatory Authority
<b>UNFPA</b>	United Nations Population Fund
<b>USAID</b>	US Agency for International Development
<b>WHO</b>	World Health Organization
<b>WHO ERP</b>	World Health Organization Expert Review Panel
<b>WRA</b>	White Ribbon Alliance

# Foreword

**Today, one of global health’s biggest challenges—and opportunities—lies in strengthening the markets that make health products and services available to the most vulnerable women, children, and families in low- and middle-income countries.** The Sustainable Development Goals challenge us to work together to improve the health of all people by 2030. But we won’t reach those ambitious targets—and save the lives of millions of people—without assuring a consistent supply of high-quality, affordable, and appropriate health products to meet demand; and that requires strengthening the markets for these lifesaving products.

To many people working in global health, “market strengthening” sounds complex—a job perhaps best left to economists. However, the reality is that medicines and technologies can only save lives if they reach the people who need them. And the markets that ensure these products are available can only be as strong as the policy environments in which they operate. Governments need to understand how their policies and systems support or hinder health product markets and adapt them to improve access, safeguard citizens, and create market incentives that support affordable products and strengthen the sustainability of supply. And we need citizens to hold their governments accountable to ensure equitable access. Advocates have the power to raise awareness about the costs and consequences of ineffective policies that affect availability and affordability and allow the distribution and provision of poor-quality products that can be harmful, or even deadly.

At PATH, we arm advocates with the evidence they need to demand change in their countries toward better health. We know that informed policy can make a difference in strengthening markets to facilitate access to lifesaving health products. This guide aims to demystify the issue of market strengthening. It offers

critical information and highlights practical opportunities for advocates to identify and strengthen policies that will promote well-functioning markets and ensure greater access to both new and established health products, particularly for those most in need.

Increasing political will and building robust policy environments for healthy markets won’t happen without a strong network of advocates, influencers, and decision-makers joining forces to address the shortcomings in access to health products. We hope this guide will be a useful resource to help grow and support this network, toward the shared goal to bring health innovations within reach of everyone, no matter where they live.

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VP Strategy,  
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# About the guide

**This guide aims to make understanding markets easier and provides information and tools to support advocacy with policymakers and other key decision-makers.** It is designed primarily for experienced health-issue advocates who are new to thinking about markets. Armed with this guide, you will be able to deepen your public health impact by including a market perspective in your advocacy work and ensuring that health equity, choice, and access are effectively reflected and realized.

You are encouraged to read the guide in its entirety and in the order information is presented, as content and concepts build on each other. Wherever possible, the guide links you to actionable resources. The guide also includes annex materials that provide additional background and tools to support development of specific and actionable advocacy for market strengthening strategies.

## Markets matter: Page 6

Background information that explains the fundamentals of markets, why they're so important for health product access, and the characteristics of well-functioning markets. This section also covers the most important actors in a market system and why they matter to advocates.

## Policies and advocacy strategies matter: Page 24

An overview of five specific policies that impact the market for health products and how advocates can influence these policies to strengthen markets.

## Messages matter: Page 46

A set of messages that distill the learnings of the guide into accessible and impactful messages that advocates can deploy to support market strengthening efforts.

## Implementation matters: Page 50

A look ahead at how advocates can pair the guide with existing tools and resources to develop an effective strategy to strengthen market-related policies and support well-functioning markets.

To access this guide along with the full suite of PATH's advocacy capacity tools, please visit <http://sites.path.org/advocacyandpolicy/how-we-do-it/strengthen-advocacy-capacity/>.

### Guide objectives

After reading this guide, you should be able to:

- Explain the role of markets in fostering access to essential health products.
- Describe the basic structure of a market and the key actors involved.
- Understand how policies affect markets for health products.
- Identify opportunities to influence relevant market-related policies for your health issue.

◀ Viewing online? Click the page numbers to navigate to each section.



# Markets matter advocacy guide: Background information



## What happens when markets fall short?

Well-functioning markets are complex global enterprises. They are critical for improving access to health products and strengthening health impact since even the most effective products can't save lives or improve health if they don't reach the people who need them. When markets fall short, the result is that health products are:

- 
- Unavailable** because a manufacturer lacks financial incentives to sell them, because of supply disruptions caused by manufacturing, procurement, distribution, or because of a combination of these challenges.

**Example:** Benzathine penicillin, a low-cost antibiotic, can cure syphilis and prevent mother-to-child transmission when administered early in pregnancy. But because the medicine is only produced by a few manufacturers globally, it is in short supply worldwide.<sup>1</sup> The lack of consistent and available supply means that pregnant women and newborns who test positive for syphilis may not get the lifesaving treatment they need.
  - Unaffordable** for the buyer or consumer, whether it is a government or an individual.

**Example:** Female condoms, the only method available today that provides woman-initiated dual protection from HIV and unintended pregnancy, are often viewed by governments or individuals as too expensive to buy, especially when compared with male condoms. But unlike male condoms, female condoms are a relatively new product with few global manufacturers and low demand, which can increase the price.
  - Of poor or unknown quality,** because of inadequate regulation and oversight that allows products of inferior or unverified quality to be sold or distributed.

**Example:** There are increasing reports of poor-quality antimalarial drugs, including artemisinin-based combination therapies, due in part to inadequate regulation of the private sector. A recent analysis found that up to 36 percent of antimalarial drugs collected in Southeast Asia were falsified, and a third of the drugs in sub-Saharan Africa did not have the correct amount of the active ingredient.<sup>2</sup>



# What is a market?

**While the term “market” is likely not a new term to you, it can be difficult to understand.** Your first thought may be a physical location where local vendors sell food, clothing, and other wares. And you’d be right. A physical marketplace is one type of market, but not the type we’d like to focus on in this guide. We want you to think bigger! In this guide, we’ll focus on markets for health products and show you how advocates can strengthen those markets by improving policies.

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**Before discussing how you can advocate for policies that support markets, you’ll need to understand a few key definitions and concepts:**

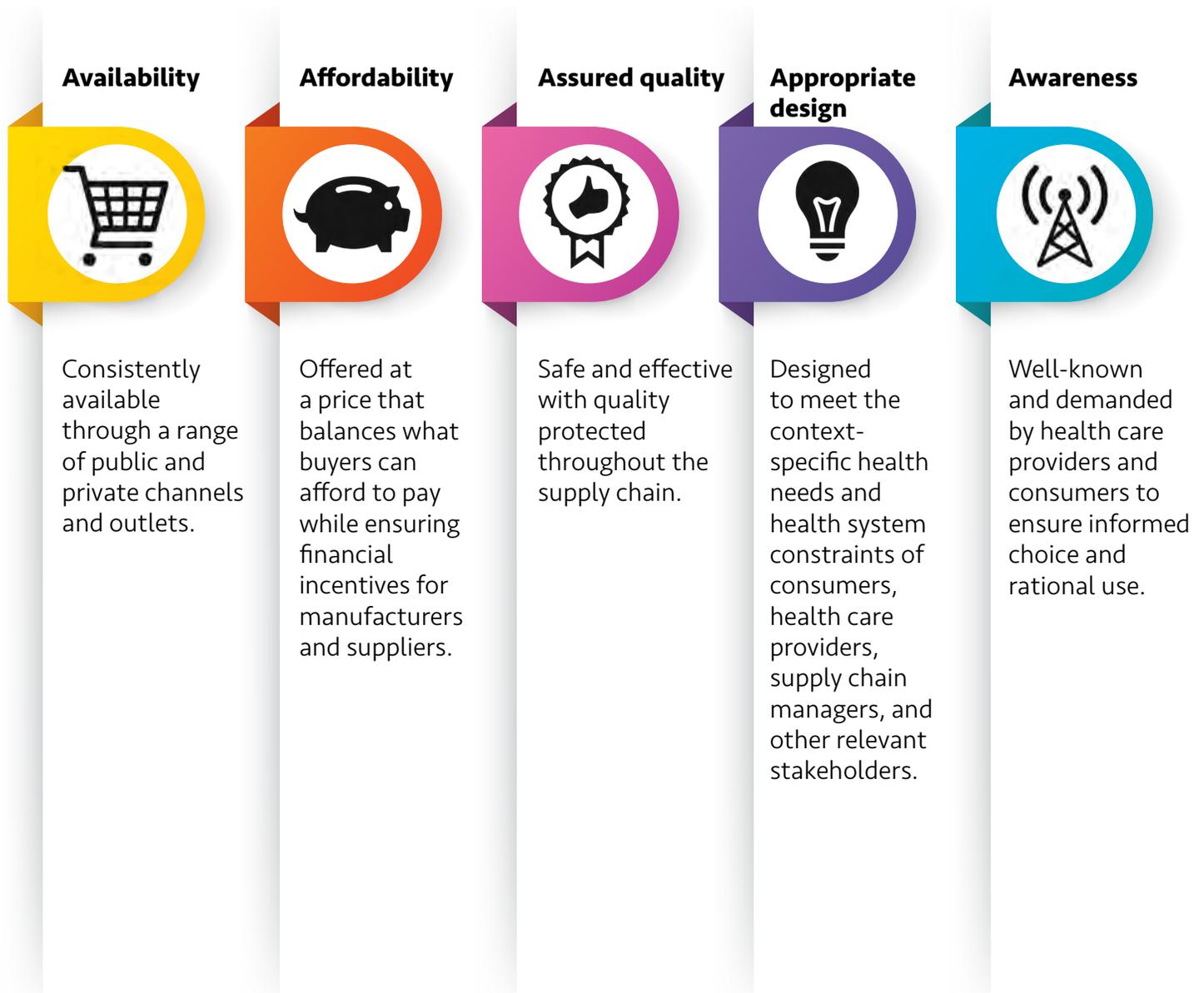
**Markets** are the systems, structures, and institutions that facilitate the buying and selling of goods and services, such as coffee, mobile phones, and of course health products. There are many different types of markets, and they differ by products, consumers targeted, size, geography, stage of market development, and many other factors.

**Market actors** include the individuals, groups, and companies involved in the manufacturing, buying, selling, distributing, and use of products. This includes product developers and manufacturers, suppliers, distributors, procurers (including donor agencies and governments), regulators, health providers, and finally consumers. You’ll learn more about market actors in the next section.

**Market dynamics** describes the range of interactions among market actors that determine how a product is produced, procured, distributed, and delivered. These interactions can be shaped by interventions that seek to reduce long-term demand and supply imbalances to achieve consistent access to affordable, quality-assured products.

## Characteristics of well-functioning health product markets

We've already described what happens when markets don't function well: products are unavailable, unaffordable, of poor quality, or inappropriate—or people simply lack awareness of how to use them. On the other hand, a healthy market is one in which supply meets demand and products are characterized by the “5As”:



Icons and the 5As framework were adapted from Healthy Markets for Global Health: A Market Shaping Primer, USAID, 2014.

## Why the total market matters

For a healthy market, both the public and private sectors must work together. As populations grow and health needs increase, no one sector can support the products and services everyone needs. That's why it's important to focus on the total market for health, which includes both the public and private sectors.

Here's what we mean when we talk about public and private sectors in this guide:

- **Public sector:** Health services and products that are administered by the government, which includes national and subnational government.
- **Private sector:** Health services and products that are provided by nongovernmental entities. These include:
  - For-profit companies (such as manufacturers, drug shops, pharmacies, and private hospitals and private health facilities)—which are often also referred to as the commercial sector.
  - Social marketing organizations that sell or distribute products, often at a subsidized price.
  - Not-for-profit, nongovernmental organizations (NGOs), including faith-based organizations, that run health programs or clinics.

Many people think of the public sector as the part of the market that provides most of a country's essential health products. In some geographies, this is true. However, in many countries, including low- and middle-income countries, the private sector plays an important role in getting health products and services to people, including poor and rural populations—and research shows that this trend is likely to increase over time.

A stronger private sector can help improve the range of health services and products available as countries grapple with increasing and changing health needs, including both communicable and noncommunicable diseases. In addition, an expanded private sector can help relieve overburdened public-sector facilities that suffer from long wait times and thin resources. But potential pitfalls exist, especially if the private sector is not regulated appropriately. This is one reason why strong policy environments are so important. Policies should incentivize and support private-sector investment in health, appropriately regulate products and services, and facilitate equitable access. As an advocate, you can help ensure such policies are developed, implemented, and appropriately resourced—and we'll show you how.

### Fast fact

In Ethiopia, Kenya, Nigeria, and Uganda, nearly half of people in the poorest segment of the population receive health care from private, for-profit health providers. And in the most rural areas of Nigeria and Uganda, more than 50 percent of people reported using private, for-profit health providers.<sup>3</sup>

# Market strengthening interventions versus advocacy for market strengthening

Strengthening markets to better deliver on public health outcomes requires the coordinated efforts of many different stakeholders. Before we get into who these market stakeholders are and why they are important, it helps for advocates to understand the difference between *interventions that directly strengthen the market* (the focus of market specialists, or individuals and organizations with expertise in market dynamics, analytics, and development) and *interventions that strengthen the policy environment for markets* (the focus of advocates).

Typically, when people talk about market strengthening interventions, they mean time-bound actions that are undertaken to reduce supply and demand imbalances. These activities are developed and managed by specialists with expertise in specific products, markets, and market dynamics, working in close coordination with governments, procurers, manufacturers, and key private-sector decision-makers, to improve how products are produced, procured, distributed, and delivered.

Examples of market strengthening interventions include:

- **Volume guarantee:** An agreement between manufacturers of specific products and interested buyers to purchase a set amount of the product over an agreed time period and often in exchange for a set, reduced price.
- **Pooled procurement:** Aggregating orders across geographies to support better value for money, smooth orders for manufacturers, and increase availability.

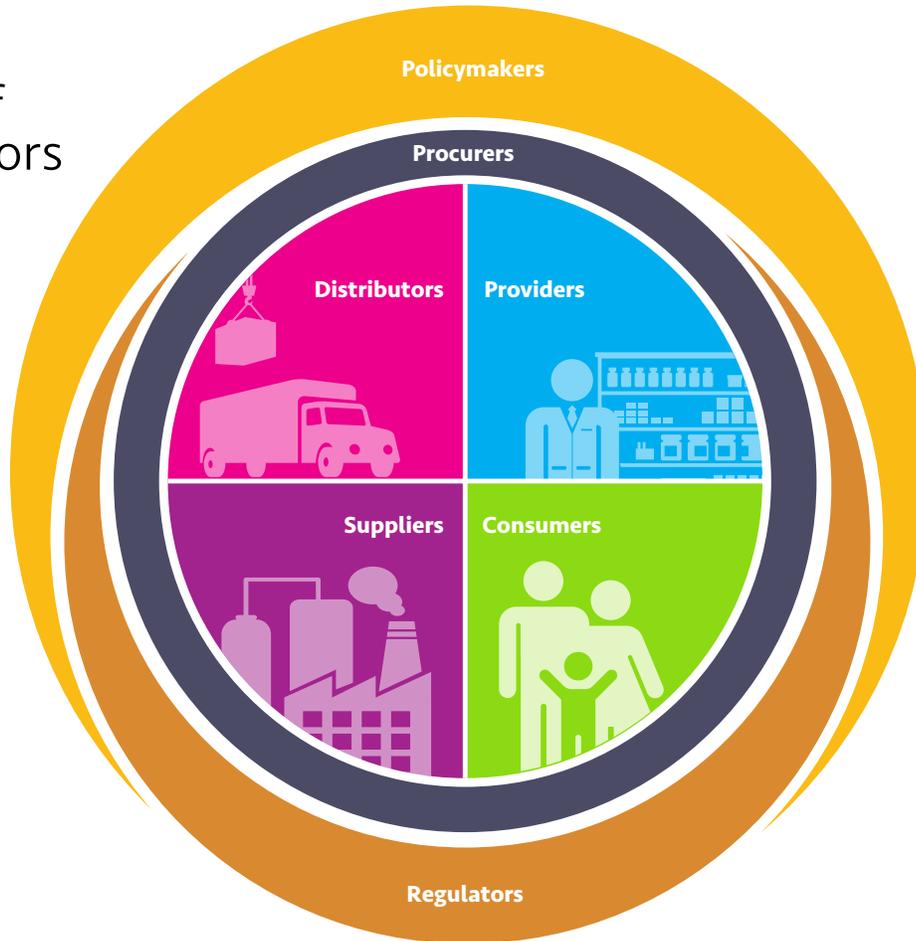
But technical market strengthening interventions are not the only way to make markets stronger.

**Market advocacy** is a relatively new opportunity that focuses on influencing the policy environment to help inform and strengthen the formal rules that guide how markets operate and ensure health products reach those who need them. Market advocacy is an area where civil society can engage and have impact.

When undertaking market shaping of any kind, it's important to abide by the principle of "first do no harm." In both the case of those who engage in market strengthening interventions, and advocates working to create supportive policy environments, a strong understanding of the market dynamics is essential. You must consider the potential impact and tradeoffs any actions may have. For example, an intervention that reduces the price of a product may have the short-term benefit of making the product more affordable. However, it could have the unintended consequence of removing financial incentives for manufacturers to invest in that product, which could limit availability of the product in the long term.

Later in this guide we'll be highlighting specific health policies that affect markets and providing real-life examples of how advocates have affected change to help inform your own advocacy efforts. But first, let's explore some of the groups that will be important to your advocacy efforts.

## Universe of market actors



## Who are market actors?

**Remember, we defined market actors as the individuals, groups, or companies involved in the manufacturing, buying, selling, distributing, and use of products.** Many market actors are probably the same individuals and stakeholders whom you already engage with through other health advocacy efforts.

While there are many different types of market actors, advocates should understand seven of them:

- ▶ **Policymakers**
- ▶ **Regulators**
- ▶ **Suppliers**
- ▶ **Procurers**
- ▶ **Distributors**
- ▶ **Providers**
- ▶ **Consumers**

While suppliers, distributors, providers, and consumers are the central market actors, ultimately, **policymakers and regulators are your primary audience for advocacy.** They determine the policy and regulatory environment that affects markets for health products, including the behavior of other market actors. Most of the time, all other market actors will be a secondary audience for advocacy. Suppliers, procurers, distributors, providers, and/or consumers may be key partners or stakeholders in your policy change effort. Occasionally, they may be the target of your advocacy.

Before you embark on market-related advocacy, we encourage you to get to know each of the seven market actors. Below we explore who they are and what their market-related roles and contributions are. We also show you how each might factor into your advocacy efforts.

**Helpful hint:** Specific individuals or groups may act as different types of market actors. For example, governments can be policymakers and regulators, distributors, providers, and even market influencers.



## Policymakers

Policymakers define the rules that all market actors play by. They impact the entire universe in which markets and market actors exist.

### WHO THEY ARE:

- ▶ **Government**
- ▶ **Global normative bodies**  
(e.g., the World Health Organization [WHO])

Governments have the power to set policy and they have a vested interest in participating in markets to ensure that socially beneficial public goods and services, such as lifesaving and health-promoting supplies, are provided to their populations—particularly those most in need. This might not otherwise occur if left to market forces alone, without government intervention.<sup>4</sup>

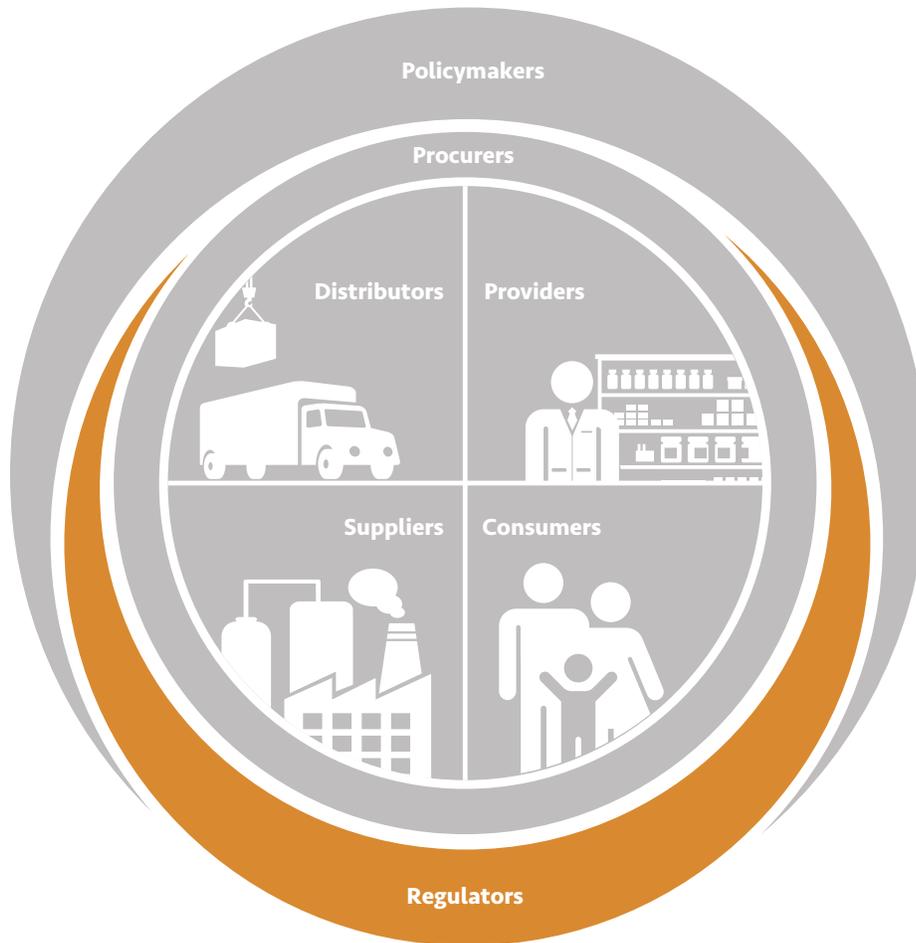
Governments create and maintain the policy environment in which markets function. Government policy defines how products are manufactured, imported, distributed, bought, and sold—including for the private sector. Often, the national policy environment is shaped by global normative bodies. In its role as the directing and coordinating authority

on international health within the United Nations' system, WHO is responsible for setting norms and standards and promoting and monitoring their implementation.

### WHY THEY MATTER FOR ADVOCACY:

For advocates interested in strengthening markets to improve access to health products and services, **policymakers are often a primary target decision-maker**. They set the policy that governs all health markets. Informing and influencing government policies should be central to your market advocacy strategy.

It's important to recognize that sometimes the policy bottleneck occurs beyond the borders of your country. In this case, the target of your advocacy could be a global normative body like WHO and you may be able to partner with other global advocacy allies to enact change.



## Regulators

Regulators set standards and monitor health product quality for all market actors.

### WHO THEY ARE:

- ▶ **National Regulatory Authority (NRA)**
- ▶ **Stringent Regulatory Authority (SRA)**
- ▶ **WHO**

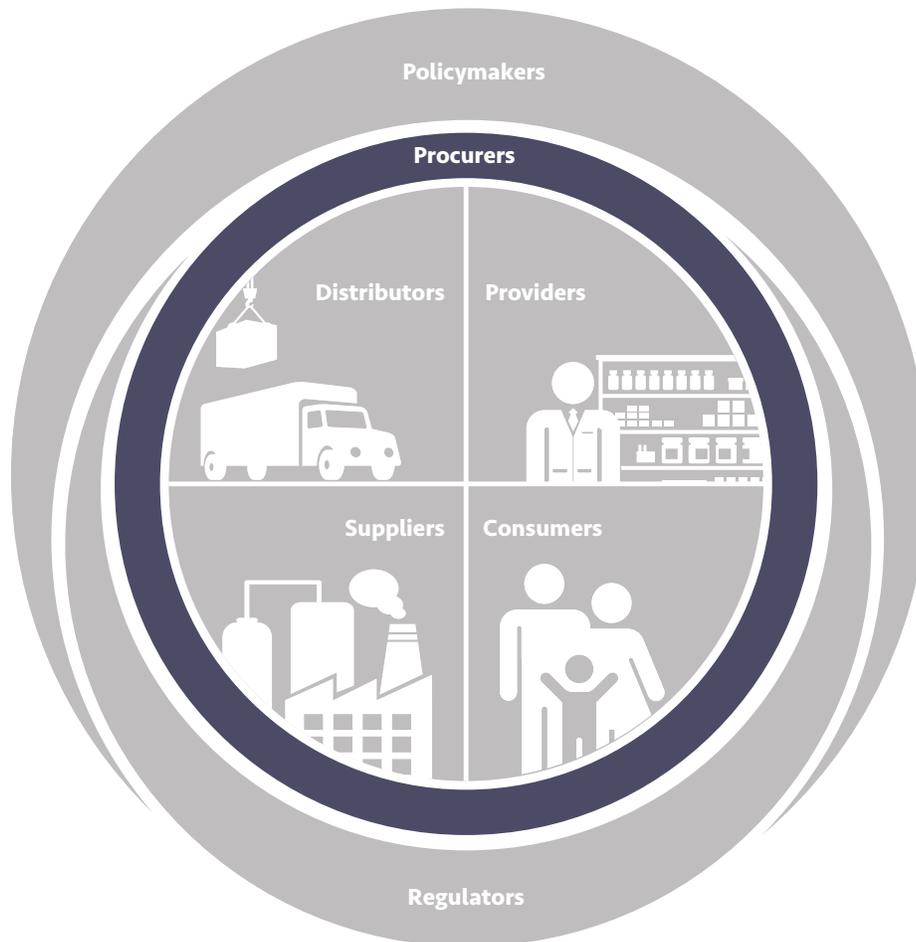
Regulatory authorities, both global and in-country, play a critical role in ensuring that quality health products enter both the public and private markets, and that quality is safeguarded throughout once products enter the market. The guidelines set forth by these agencies are intended to ensure high-quality health products are available to all.

These regulations impact products before they even enter the country since procurement by international agencies is guided by adherence to international quality standards—most often approval by an SRA, WHO prequalification, or WHO Expert Review Panel (ERP). Once a product enters the country, the government, through the NRA, regulates the safety, efficacy, and quality of health products. For

example, governments have the power to remove health products from the market that do not meet minimum quality standards.

### WHY THEY MATTER FOR ADVOCACY:

Like policymakers, regulatory authorities, both national and international, may be a main target for your advocacy since they are responsible for the regulatory frameworks that can improve or hinder the quality, availability, affordability, and/or range of products provided by public- and private-sector facilities.



## Procurers

Procurers are responsible for purchasing health products.

### WHO THEY ARE:

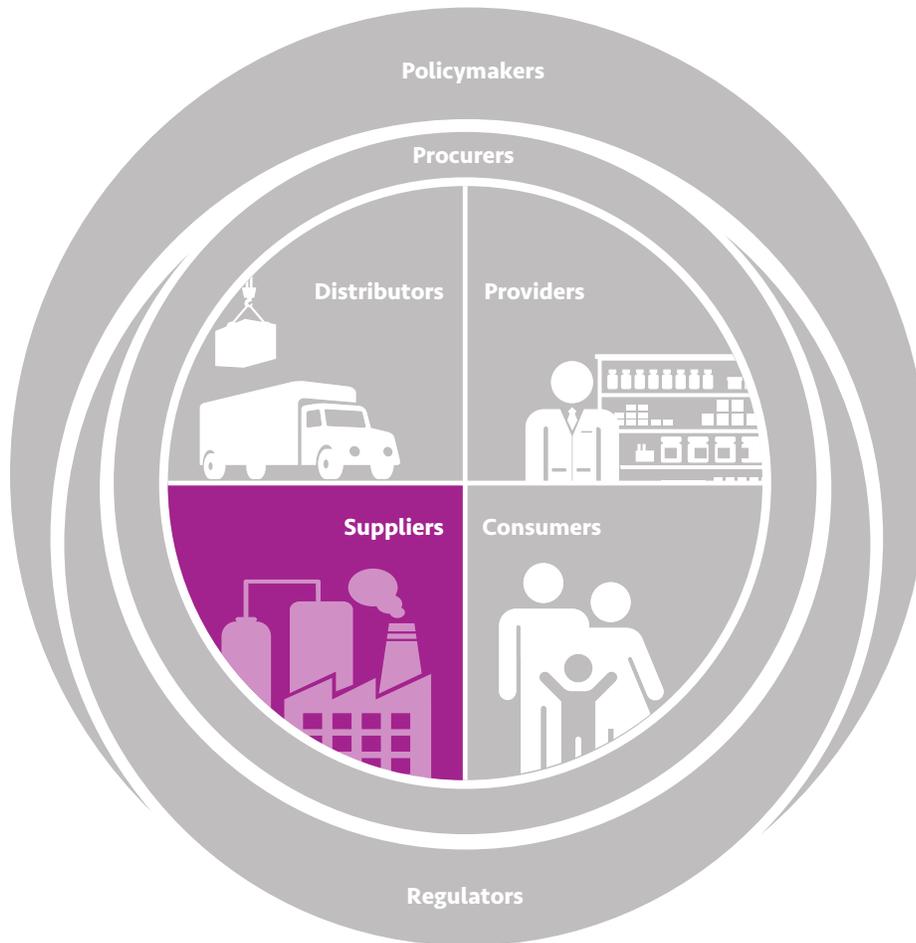
- ▶ **Government** (national and subnational)
- ▶ **Donors** (United Nations Population Fund; US Agency for International Development; United Nations Children’s Fund; the Global Fund to Fight AIDS, Tuberculosis and Malaria; etc.)
- ▶ **Private sector purchasers** (NGOs, private clinics, faith-based organizations)

Procurers seek to purchase high-quality health products at the lowest possible price. This is typically done through a competitive tendering process, awarding contracts, or using other mechanisms to purchase them from suppliers or distributors.

### WHY THEY MATTER FOR ADVOCACY:

Procurers are often the primary decision-makers on issues relating to the quality, availability, affordability, and variety of products offered. A procurer of large volumes of products can leverage its buyer power— which is the pressure or bargaining ability a buyer can exert to get higher-quality products, lower prices, or improved delivery terms—to achieve better value for money through increased competition and innovation.

In the public sector, advocates can inform product selection and forecasting to ensure health products are included in the government’s procurement plan. They can also influence and ensure adherence to operational policies, such as health product specifications, quality assurance policies, and tender documents—which describe the bidding process for suppliers interested in supplying health products—that can have an impact on the quality and price of the products purchased.



## Suppliers

Suppliers source materials, create health products, and make them available to distributors—both public and private.

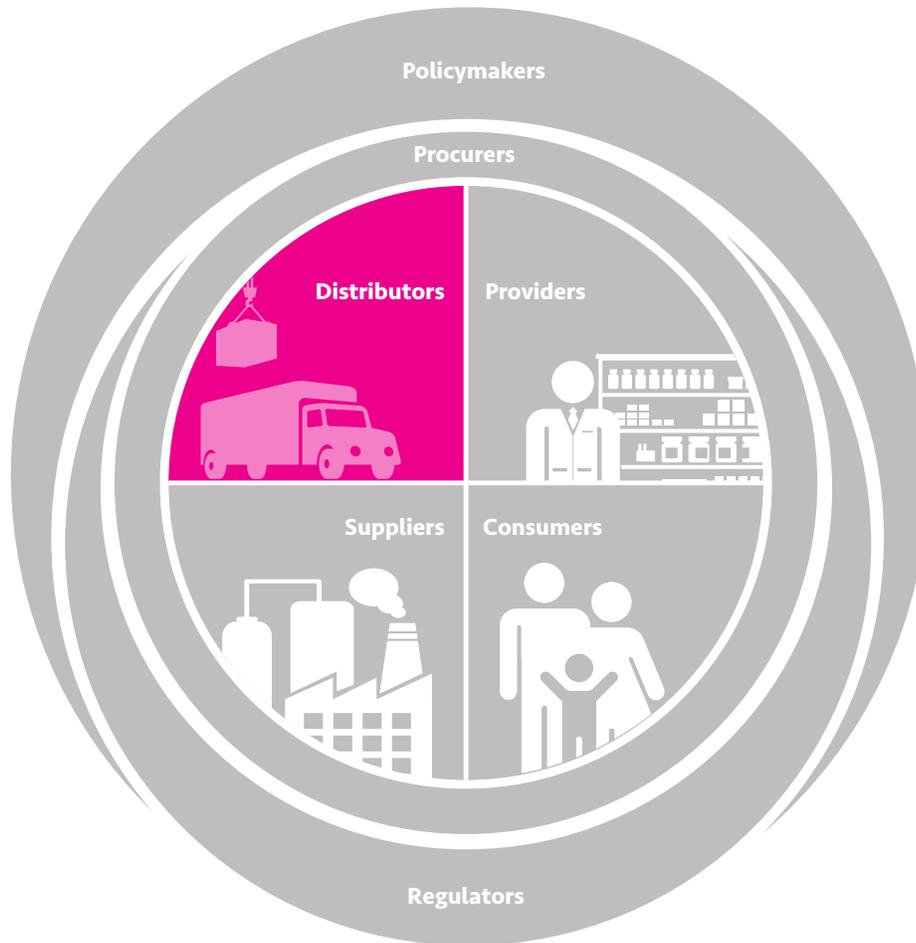
### WHO THEY ARE:

- ▶ **Providers of the raw materials** for the production of health products
- ▶ **Manufacturers** that produce health products

Suppliers play an important role on issues related to the quality, range, and price of products offered in a given market. Suppliers are incentivized to invest in innovation and increase efficiency when governments create enabling environments, for example, by appropriately regulating markets and promoting competition. This results in improved consumer choice and more affordable, higher-quality health products.

### WHY THEY MATTER FOR ADVOCACY:

Suppliers are often a secondary audience when it comes to advocacy. Their willingness to make, introduce, and scale up health products in various countries is influenced in part by a country's policy and regulatory environment. So even though they may not be a direct target for your advocacy efforts relative to the policies discussed later in this guide, you need to consider how policies you are proposing may affect them. In many cases, suppliers can be valuable partners in your advocacy efforts.



## Distributors

Distributors connect suppliers with providers by moving products to health facilities, pharmacies, and drug shops for providers to administer.

### WHO THEY ARE:

- ▶ **Governments**
- ▶ **Private-sector wholesalers, NGOs, faith-based organizations**

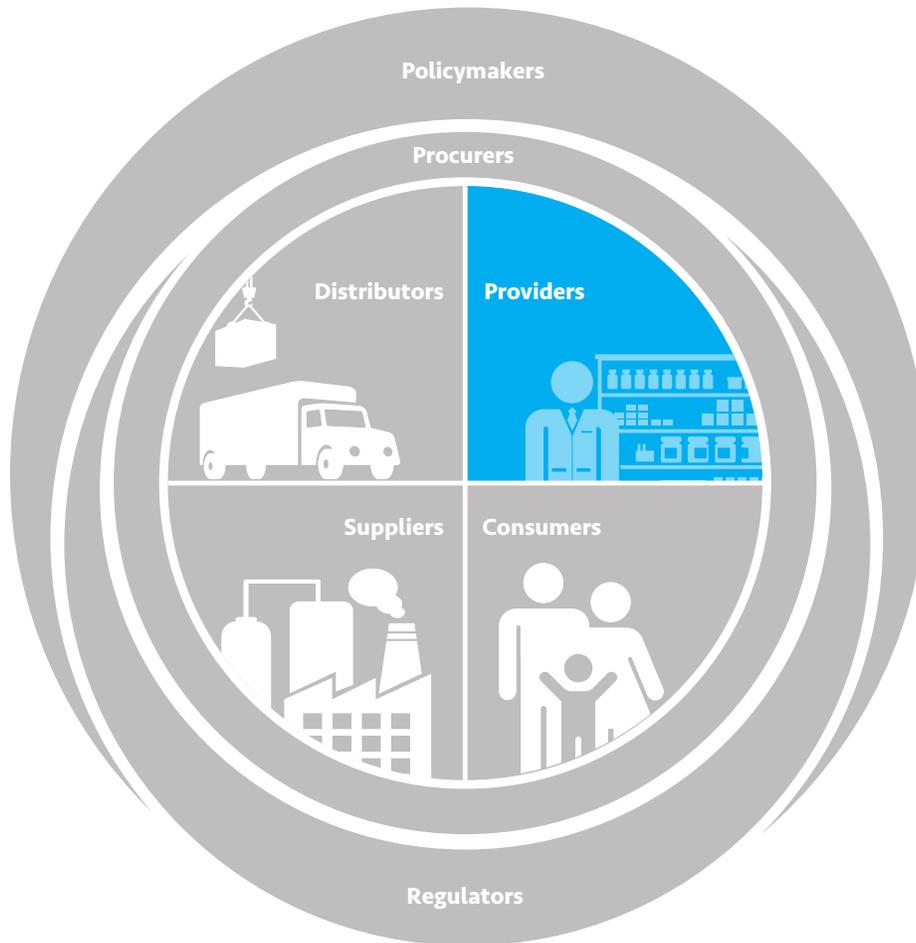
In the public sector, health products purchased by the government or development partners are distributed to health facilities through the public-sector supply chain(s). Often there are multiple supply chains, which are managed by health programs and carry products specific to that health area (e.g., malaria, immunization).

In the private sector, wholesalers, NGOs, and faith-based organizations often act as distributors. They distribute the products to a variety of nongovernmental entities, including for-profit companies (drug shops, pharmacies, private hospitals, and private health facilities), and social marketing organizations. Private-sector distributors often facilitate the in-country regulatory process for suppliers, obtain import

licenses, and provide product service and maintenance, among other functions.

### WHY THEY MATTER FOR ADVOCACY:

Distributors are likely a secondary target for your advocacy. Understanding distribution networks can be key to identifying bottlenecks that hinder access to affordable, quality products. Distributors in both the private and public sectors will be directly affected by policy changes that impact the market, so while not a direct target of your advocacy, it is important to consider how proposed policies changes may affect them.



## Providers

Providers acquire products from distributors and sell or administer health products to consumers.

### WHO THEY ARE:

- ▶ **Health personnel** (doctors, nurses, pharmacists, community health workers) at public- and private-sector health facilities and outlets
- ▶ **Pharmacists and drug shop operators**

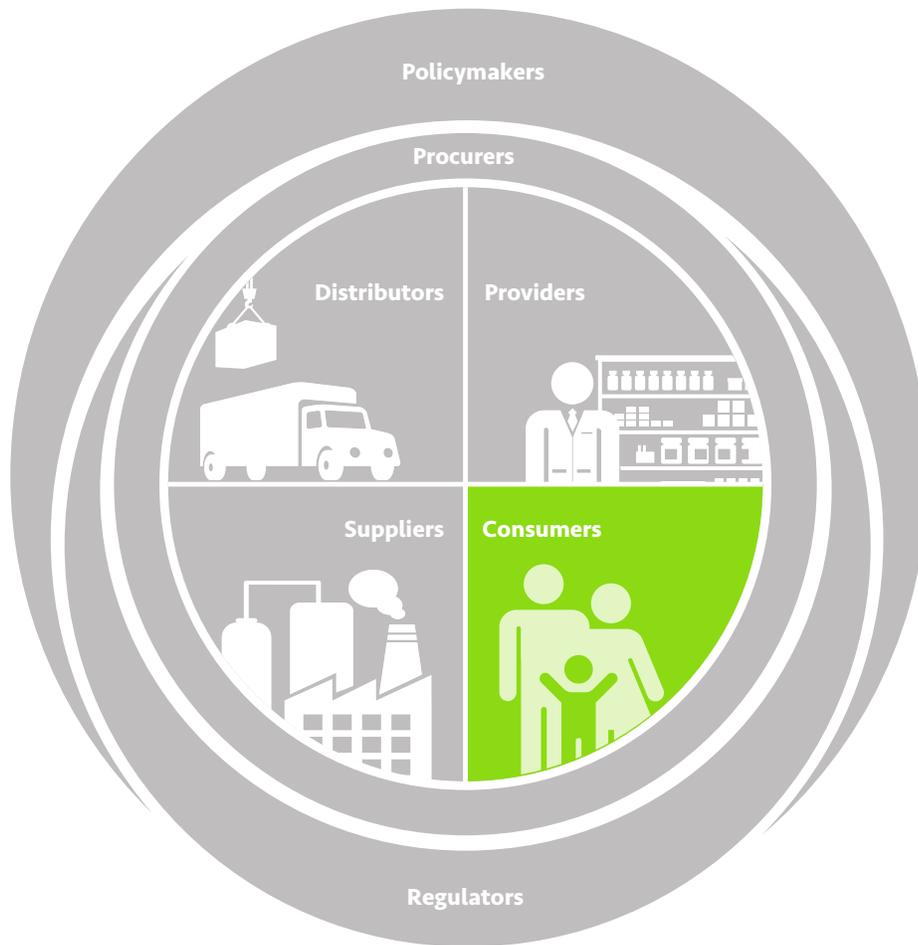
In this guide, providers refer to the individuals who administer health products in either public- or private-sector service delivery outlets. They are responsible for making sure that health products are administered appropriately to and used correctly by consumers.

### WHY THEY MATTER FOR ADVOCACY:

Health providers will typically be a secondary audience for your advocacy. For example, they can be critical allies on a number of issues related to policies and regulation, including:

- Informing development of and advancing implementation of standard treatment guidelines.
- Prescribing, dispensing, and/or administering health products.
- Influencing regulations or policies related to private-sector provision of health care.

In instances where health guidelines are not being fully or correctly implemented, health providers may be a primary target of accountability efforts.



## Consumers

Consumers are the ultimate users of health products.

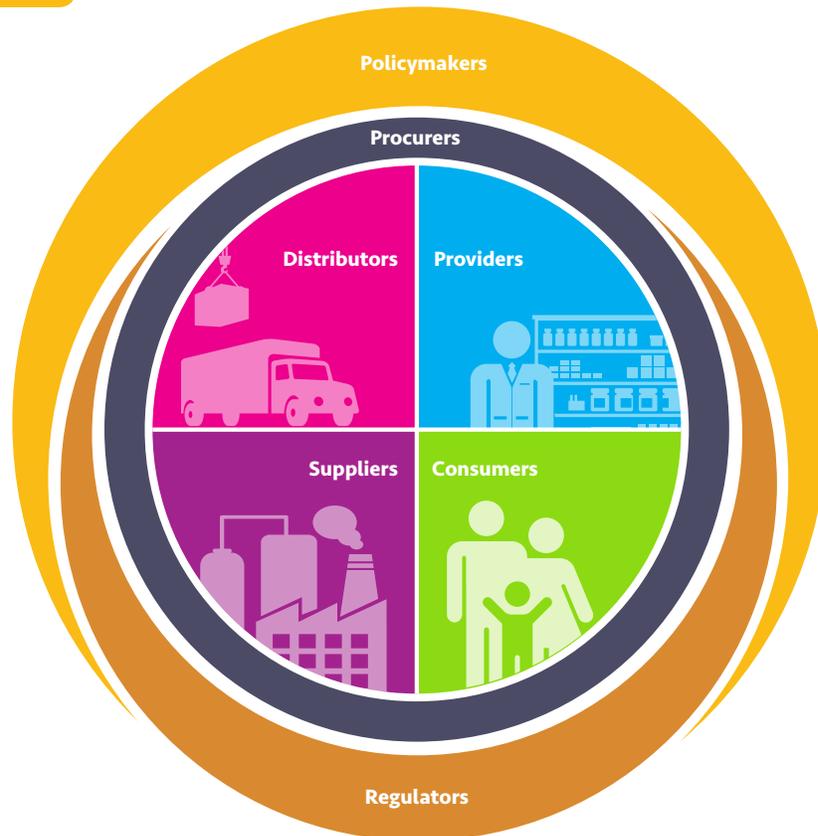
### WHO THEY ARE:

#### ► Individuals that use health products

Individual consumers refer to customers, clients, or patients. They can be powerful health advocates. “Consumer advocacy” describes the actions of individuals or groups advocating on behalf of the general public. Consumer or patient advocacy campaigns often focus on raising public awareness of bad business practices or unaffordable and unsafe products.<sup>5</sup>

### WHY THEY MATTER FOR ADVOCACY:

Consumers can be a key ally in your advocacy effort. Partnering with consumers and consumer groups can be a smart strategy for health advocates wanting to mobilize broad support for their policy goals and reach the key market influencers and decision-makers described above. Consumer and patient groups will also be essential to efforts focused on generating demand for specific health products.



## Market influencers

Market influencers are a broad range of organizations and institutions that play important roles throughout the universe of market actors. They can shape markets and influence the decision-making of market actors, including policymakers and regulators.

### WHO THEY ARE:

Market influencers are a diverse group that may include:

- ▶ **NGOs**
- ▶ **Donors**, such as bilateral or multilateral aid agencies and private foundations
- ▶ **International normative bodies**, such as WHO
- ▶ **Businesses**
- ▶ **Academia and research institutions**
- ▶ **Health provider professional associations**
- ▶ **Media**

Market influencers represent various individuals and organizations working to increase access to health commodities and improve health

outcomes through a wide range of activities.

These organizations directly affect market conditions by filling gaps in financing, information, and technical capacity, which allows market actors to operate more effectively. For example:

- Donors can catalyze or negotiate a volume guarantee, providing assured markets for manufacturers of health products.
- NGOs can coordinate diverse market stakeholders, reducing information asymmetries and improving communication.
- Media outlets can improve awareness about health issues and products, thereby increasing consumer demand.

These organizations can also serve as policy influencers, as they often have important analysis, relationships, or reach with key decision-makers that set the policy and regulatory frameworks for health markets.

### WHY THEY MATTER FOR ADVOCACY:

Market influencers will often be a key partner, ally, messenger, and sometimes even a target in your advocacy efforts, especially those focusing on policymakers and regulators. Often they have data or information that can be used to advance your advocacy. They may also have special relationships, access, credibility, or influence with your key decision-makers that will help accelerate policy change.

## Understanding market shortcomings and advocacy entry points

Advocacy is an important tactic for ensuring a well-functioning health product market. Civil society can use its platforms to highlight policy and financing issues that are preventing health products from being available when and where they are needed.

However, given the range of market actors and functions that must work in concert to ensure a wide range of health products, it cannot be understated that **every market is different**. While the end result of market shortcomings may look the same—stockouts, high prices, uncertain quality—the causes of these failures vary widely. What may be a perfect solution in one context could prove to be a disaster in another. As mentioned earlier in the guide, all market-shaping efforts should be rooted in the principle of “first do no harm.” **Understanding the root causes of a market problem is the critical first step in embarking on market advocacy.**

For example, in many countries, product inclusion on the National Essential Medicines Lists (NEML) is a precursor for public-sector procurement. Many advocates are familiar with, or have themselves participated in, efforts to ensure new products are included on the NEML. While this is an important advocacy effort, it should be noted that inclusion on the NEML alone will not address other market-related issues, such as unaffordability in the private sector or gaps in consumer knowledge. Before deciding to embark on an advocacy strategy, you must fully understand the problem and barriers to product access.

The next section will highlight some specific policies you may be less aware of, along with advocacy entry points to explore. But remember, developing an appropriate advocacy strategy will always require careful observation and assessment of root causes of the market shortcomings.

### Know your funder

Health products such as contraceptives, HIV tests and treatments, and tuberculosis drugs are often funded by donors. Maternal, newborn, and child health products—like medicines to prevent postpartum hemorrhage or antibiotics to treat childhood pneumonia—are often funded by governments. Knowing the funder of the products you care about can help you target your advocacy strategy appropriately.



## **Policies and advocacy strategies matter:**

How to advocate for policies that strengthen the market for health products





## How to advocate for policies that strengthen the market for health products

**Markets cannot function well without strong, supportive, and well-coordinated government policies.** If health markets were left to their own devices, without any government policy intervention or regulation, they would be unlikely to deliver optimal health and social outcomes for countries and populations. For example, without government-mandated product labeling, consumers couldn't determine what ingredients are in health products or when they expire, which would be harmful to consumers.

Governments have the power to develop and implement policy frameworks that impact how health products are manufactured, imported, distributed, bought, and sold. But to ensure that policies are effective and sustainable, officials must understand and address the needs of consumers, buyers, and suppliers, as well as the access and equity concerns of advocates.



## Key policy areas for market strengthening advocacy

Many different types of policies influence how markets function. This section provides an overview of several key public policies that directly affect all health product markets—whether family planning, malaria, HIV, or maternal, newborn, and child health—and should be important to advocates.

While this is not an exhaustive list of the policies that affect markets, it **provides examples of how and where health advocates can have an impact. Even if you've worked on commodity-related advocacy in the past, these areas will likely represent new opportunities.** They include:

- **National medicine policies.**
- **Health product regulation.**
- **Policies affecting provision of health products by private pharmacies and drug shops.**
- **Public-sector procurement policies.**
- **Taxes and duties on essential health products.**

For each of these policies, we provide you with a basic overview of why they are important and what you can do to inform and

influence their development. We also point you to additional resources. And for each policy, we include a spotlight that illustrates how other advocates like you are already positively impacting markets by influencing these policies.

As you learn, **remember that there is no single set of policies that will support access to health products in all settings.**

As always, understanding your country's context is critical when determining policy solutions, and you'll need to consider national priorities, specific population(s) health needs, available resources, level of economic and market development, and broader commitments to health equity and human rights.



## National medicine policies

### WHAT IS THE POLICY?

A national medicine policy (NMP) is a broad framework in which the government commits to coordinate the activities of all market actors across the public and private sectors.<sup>6</sup> Although an NMP is not an enforceable law, it sets the overall tone for medicines in a country and guides further policymaking for all health products. It is not intended to endorse any particular product, medicine, or brand.

The objectives of an NMP are usually expressed in general terms. While they vary by country, most NMP objectives are related to ensuring:

- Essential medicines are available and affordable to those who need them.
- The safety, quality, and efficacy of all medicines provided to the public.
- Appropriate and ethical prescribing and dispensing practices among health providers and the correct use of medicines by health providers and consumers.

These objectives are then realized through the development of specific country policies, laws, and regulations. One example might be regulations that identify the types of service delivery outlets and the cadres of health providers able to sell or administer specific health products. We'll touch on a few of these in a later section.

### Other important goals that may be included in NMPs:

- **Economic** goals related to the role of health care in supporting broader national development, the development of specific sectors such as the pharmaceutical sector, or domestic job creation and promotion in prepackaging, production, or dispensing of health products.
- **Efficiency** goals related to the delivery of the maximum level of services given a specific level of resources.
- **Equity** goals related to achieving and supporting fairness in access to health products and services across populations and consumers.
- **Sustainability** goals related to the country's ability to provide continued basic health benefits without relying on external support.
- **Transparency** goals related to nurturing and supporting accountability per agency and stakeholder group.

**WHAT IS THE ADVOCACY OPPORTUNITY?**

An NMP matters to advocates because it marks the government’s commitment to ensuring equitable access to health products. It is an important tool for keeping governments accountable to achieving health goals. This type of policy also addresses the key characteristics of a healthy market—that essential health products are available in public and private sectors and that they are affordable, quality assured, and appropriate for local populations. You can help make sure that your country has a strong NMP that is implemented effectively.

**WHAT ACTIONS CAN YOU TAKE?**



**Understand the policy environment:**

- Determine whether your country has already adopted an NMP. Knowing this will affect your advocacy goal—whether you are focused on establishing an NMP, updating an existing NMP, or encouraging implementation of an NMP.



**Foster increased coordination:**

- Urge your ministry of health (MOH) to ensure that all relevant stakeholders—including government, private sector, universities, professional associations, and consumer groups—are consulted in the development of an NMP and/or are participating in or monitoring its implementation.



**Inform policies and funding:**

- If your country does not have an NMP, advocate with your MOH to establish one. A good place to start is with WHO’s website, which has resources and guidance for establishing model NMPs and examples of country NMPs.
- If your country already has an NMP, find out whether it is comprehensive or being effectively implemented. Below are some initial questions to ask (if the answer is “no” to any of these questions, consider developing an advocacy strategy to address the issue):
  - Does your country’s NMP include all the components of a comprehensive, model NMP?
  - Do all populations have equitable access to essential health products? Are data collection efforts in place to verify and monitor progress?
  - Do mechanisms exist for transparency and accountability to ensure continued action and commitment by responsible stakeholders in implementation of the NMP?<sup>6</sup>
  - Has sustainable financing been identified and secured to promote implementation of the NMP?

**Components of a national medicine policy:**

- **Legislative and regulatory framework**
- **Choice of essential medicines**
- **Supply**
- **Rational use of medicines**
- **Affordability**
- **Financial strategies for medicines**
- **Human resources development**
- **Monitoring and evaluation**
- **Research**
- **Technical cooperation among countries**



## NMP in action:

### Objectives of Malawi's 2009 National Medicine Policy

#### Broad objective of the NMP

To develop within the available resources the potential that medicines have to control common diseases and alleviate suffering

#### Specific objectives of an NMP:

- To ensure ready and constant availability (universal access) of essential medicines and medical supplies to the community.
- To rationalize use of these essential medicines through the provision of improved medicine utilization information.
- To educate the public on appropriate medicine use and storage.
- To improve supply management, prescribing and dispensing practices, and patient adherence.
- To ensure continuing education and professional development for pharmaceutical and other relevant health workers.
- To institute a sustainable financing mechanism to ensure continuous availability of adequate quantities of the required essential medicines.
- To ensure effective regulation of pharmaceuticals.
- To strengthen partnership at the national, regional, and international levels in ensuring the full implementation of an NMP through utilization of available resources, knowledge, and expertise.

Source: <https://www.msh.org/sites/msh.org/files/mds3-jan2014.pdf>.

#### LEARN MORE! ADDITIONAL RESOURCES ON NATIONAL MEDICINE POLICIES:

- How to develop and implement a national drug policy. Available at <http://apps.who.int/medicinedocs/pdf/s2283e/s2283e.pdf>.
- Essential Medicines and Health Products Information Portal. (Includes existing NMPs by country.) Available at <http://apps.who.int/medicinedocs/en/>.
- Managing Access to Medicines and Health Technologies—Chapter 4: National medicine policy. Available at <https://www.msh.org/sites/msh.org/files/mds3-ch04-national-medicine-plan-mar2012.pdf>.
- National medicine policies: a review of the evolution and development process. (Includes case studies on South Africa, Sri Lanka, Australia, and Macedonia.) Available at <https://jopp.biomedcentral.com/articles/10.1186/2052-3211-6-5>.



## Health product regulation

### WHAT ARE THE POLICIES?

Regulation is a key policy instrument used to ensure the quality, safety, and efficacy of health products on the market. Product regulation is done both by global normative bodies and governments. Government laws and regulations set standards for how products should be manufactured, imported, distributed, marketed, prescribed, labeled, and dispensed. A strong regulatory framework also defines how these standards will be enforced—including the roles and responsibilities of oversight agencies.

Most governments establish a National Regulatory Authority (NRA)—such as the Food and Drug Administration in the United States or the Pharmacy and Poisons Board in Kenya—to interpret, implement, and enforce health product regulations. A strong NRA can ensure that only quality-assured health products are approved for distribution in the public sector and for sale in the private sector and that quality is safeguarded after a product enters the market.

NRAs use a variety of tools and operations to enforce regulations and promote quality, safety, and efficacy of health products. Those of interest to advocates include:

- **Inspecting manufacturing facilities** to ensure compliance with all safety and quality assurance standards, prior to registration.
- **Granting registration** (also known as providing marketing authorization, licensing, or regulatory approval) for health products.
- **Conducting postmarket surveillance** to monitor the continued quality and effectiveness of health products after they have been registered and introduced on the market.



### WHAT IS THE ADVOCACY OPPORTUNITY?

If you are concerned about quality, safety, and efficacy of health products, regulation should be a key issue in your market advocacy efforts.

You can be a strong voice in **making sure your NRA is well resourced** so it can do its job to enforce health product regulations. NRAs need sufficient funds to carry out basic operations in support of product regulation. Depending on context, they can be financed through a number of mechanisms such as general tax income, product registration application and maintenance fees, duties and taxes levied on imported products, and other government funding. Unfortunately, NRAs in low- and middle-income countries are often woefully underresourced and without the staff capacity to ensure timely registration and monitor product quality on the market.

You may also be able to help **improve product quality by advocating for adherence to international quality standards**, especially during the registration process. All health products distributed to consumers must be registered by the NRA—making the registration process a critical point for quality control of products and medicines. Sometimes, however, NRAs are not mandated to apply international quality standards as a condition of product registration, meaning that products of substandard or unknown quality, or even counterfeit medicines, can potentially enter the market. This can endanger patient health, contribute to drug resistance, and undermine consumer trust.

Registration can be a time-consuming process and advocates can help ensure access to key commodities by pushing for prioritized review of key drugs, petitioning for waivers for interim access, or encouraging regional or WHO regulatory harmonization so that new products can reach the market faster.

### What are international quality standards?

Mechanisms that are internationally recognized and used to verify the quality of health products include:

- **Approval by a Stringent Regulatory Authority (SRA), such as the US Food and Drug Administration or European Medicines Agency.**
- **World Health Organization (WHO) Prequalification of Medicines Programme.**
- **A “no objection to procurement” decision for a time-limited period by the WHO Expert Review Panel (ERP).\***

When a product has been judged to meet one of the above quality standards, it is considered quality assured.

\*A WHO ERP “no objection to procurement” decision is time limited, and suppliers are expected to be concurrently pursuing SRA approval or WHO prequalification.



### WHAT ACTIONS CAN YOU TAKE?

#### Understand the policy environment:

- Conduct a policy analysis to understand the strengths and weaknesses of your country's regulatory system, especially when it comes to quality. Some questions you can ask include:
  - Does your NRA have a clearly defined and documented quality policy?
  - Are there requirements that a manufacturer or other entity seeking market authorization demonstrate the quality, safety, and efficacy of a health product in its application?
  - Are there any requirements specifying that only health products that have achieved international quality standards can be legally registered and imported?



#### Mobilize citizen demand:

- Collaborate with civil society organizations and leaders to document concerns regarding the prevalence of counterfeit, substandard, or unknown-quality health products in your community or country. Consider collecting testimonials or writing case studies that capture citizen perspectives on the impact of poor-quality health products, and use these stories in your advocacy for strengthened product regulation.



#### Inform policies and funding:

- Advocate to donors and the government to increase investments in your NRA to build capacity and ensure it can support all aspects of product health regulation.
- Work with government officials to develop or update laws or other requirements to specify that only health products that have achieved international quality standards can be legally registered and marketed.

### LEARN MORE! ADDITIONAL RESOURCES ON PRODUCT REGULATION POLICIES:

- Pharmaceuticals: Drug Regulation in Low and Middle Income Countries. Available at [http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief\\_4.pdf](http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief_4.pdf).
- Managing Access to Medicines and Health Technologies—Chapter 6: Pharmaceutical legislation and regulation. Available at <https://www.msh.org/sites/msh.org/files/mds3-ch06-legislation-mar2012.pdf>.
- Assessing national medicines regulatory systems. Available at [http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/assessment/en/](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/assessment/en/).
- African Union (AU) Model Law on Medical Products Regulation. Available at <http://www.nepad.org/resource/african-union-au-model-law-medical-products-regulation>.
- International Conference of Drug Regulatory Authorities. Available at [http://www.who.int/medicines/areas/quality\\_safety/regulation\\_legislation/icdra/en/](http://www.who.int/medicines/areas/quality_safety/regulation_legislation/icdra/en/).

## Advocacy spotlight:

# Working with the NRA to improve quality of condoms in Vietnam

Over the past decade, Vietnam's MOH has made significant progress in combating new HIV infections through treatment and prevention, including wide distribution of quality-assured condoms. But recently, when external donor support for these efforts began to decline, poor-quality imported condoms and lubricant began to flood the unregulated commercial market. In 2014, an inspection found that 26 percent of commercial condoms sampled in two cities in Vietnam were of substandard quality.

Advocates believed that the country's lack of regulations to guide the production and importation of condoms was an important contributor to the problem. Through the Healthy Markets project, a PATH-led initiative funded by the US Agency for International Development (USAID), advocates focused on decision-makers within the country's NRA—an agency of the MOH—which had the power to strengthen the regulations and technical specifications that could improve the quality of imported condoms available on the market in Vietnam.

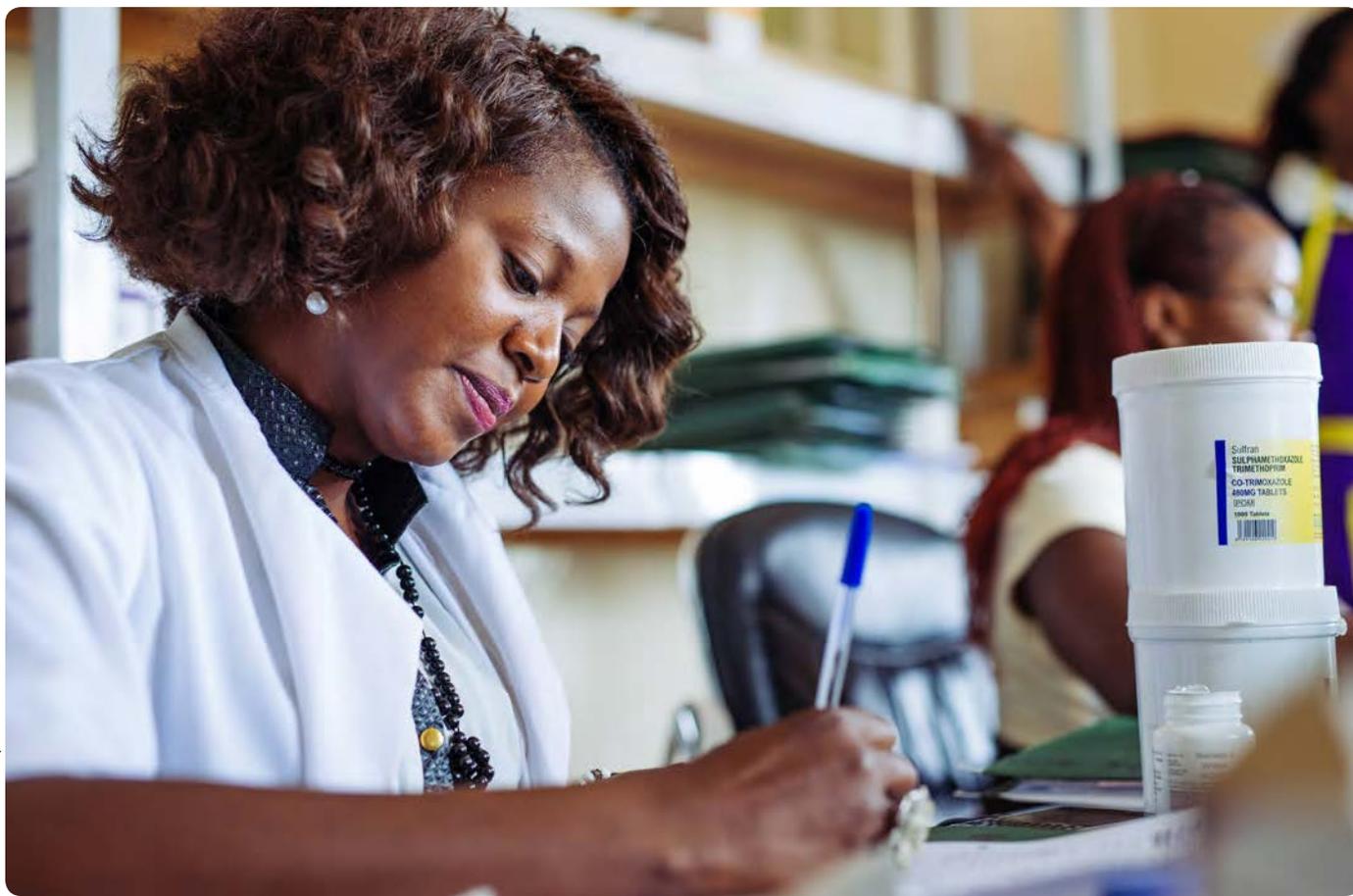
First, advocates conducted a policy analysis that revealed key regulatory barriers related to the growth of the condom market in Vietnam. They also formed



the Healthy Markets project Market Growth Advisory Board, which was composed of public- and private-sector stakeholders and included a strong partnership with the United Nations Population Fund (UNFPA). This group has now worked hand in hand with the NRA, the MOH, and other groups to build awareness regarding condom quality issues and to introduce regulations mandating standard specifications and requirements for market entry.

For example, based on guidance from the MOH, local condom manufacturers, and UNFPA, the Healthy Markets project developed a quality seal program for condoms as a critical step in establishing condom quality assurance in the free market.<sup>8</sup> The quality seal program gives local condom manufacturers a visible way to show that they meet international quality standards. The quality seal program promotes local condom brands, ensures a fairer playing field for domestic condom companies, and provides confidence to consumers.

For more information about the Healthy Markets project, see [Making Markets Work for HIV Prevention: The Total Market Approach for Condom Security in Vietnam](#).



PATH/Gabe Bienczycki

## Policies affecting provision of health products by private pharmacies and drug shops

### WHAT ARE THE POLICIES?

As private pharmacies and drug shops become more prominent in health markets—and more popular places for people to obtain products and services—the laws and regulations that govern provision of health products by these outlets become increasingly important. While laws and regulations can incentivize pharmacy and drug shop participation in health care, sometimes they also place unnecessary restrictions on the engagement of these businesses and providers in health markets. This, in turn, can limit access for consumers and negatively impact the sustainability of commercial markets—and the total market—for health products.

A range of laws and regulations affect pharmacy and drug shop provision of health products and related services. Two of the most important address:

- Whether and which type of business can sell specific health products.
- Whether and which type of private providers can administer specific health products.

### Private-sector service delivery outlets: A critical source of health care products and services

In many countries, private-sector service delivery outlets—including pharmacies and drug shops—play a major role in delivering health care services and products. Pharmacies and drug shops are often the first stop for care and have good presence in both urban and rural areas. The points below illustrate the reach of these service delivery outlets:

- **Malaria:** 40 percent of populations living in malaria-endemic areas seek care and treatment for illness at private-sector outlets.
- **Family planning:** About half of adolescents (15–19 years old) in sub-Saharan Africa, Asia, and Latin America obtain contraception from the private-sector sources.

**WHAT IS THE ADVOCACY OPPORTUNITY?**

In the case where the private sector is unable to provide products under existing laws and regulations, advocates can play an important role. You can help ensure that your country's policy environment supports registered/accredited private pharmacies and drug shops—as well as qualified/licensed pharmacists and drug shop operators who staff them—to sell and administer essential health products.

A country's laws and regulations will often exclude these outlets and providers from selling or administering certain health products. For example, some countries have laws and regulations that do not allow prescription-only medicines to be sold at pharmacies and drug shops. In other cases, the scope of practice for pharmacists and drug shop operators is defined in a way that is medically unwarranted or restrictive. Some countries, for instance, have laws and regulations that do not allow pharmacists to give injections, despite growing experience and evidence that such providers can safely administer products like injectable contraceptives.

**Ensuring quality products and services from the private sector**

While private pharmacies and drug shops can greatly expand access to essential health products and services, ensuring quality through this delivery channel can be a challenge. Pharmacies and drug shops—especially those that operate informally—can potentially sell counterfeits or products of poor quality or employ providers who lack qualification and training to administer products appropriately.

For this reason, your advocacy efforts should focus on increasing access to health products and services through:

- **Private pharmacies and drug shops who are registered/accredited by the MOH to operate.**
- **Pharmacists and drug shop operators that are licensed by the MOH to show that they meet basic medical education requirements.**

Such registration/licensing cannot guarantee that high-quality products and services will always be offered, but it can provide an important basis for the NMRA to enforce standards.

**WHAT ACTIONS CAN YOU TAKE?****Understand the policy environment:**

- To inform your advocacy efforts, you need to better understand the landscape for pharmacy and drug shop provision of health products, including your country's laws and regulations on the matter. Start by researching some key questions:
  - Does your country have a vibrant private retail sector, including pharmacies and drug shops?
  - Does your government include pharmacies and drug shops in public health policy and program planning?
  - What is the process or requirements for a pharmacy or drug shop to become licensed? For pharmacy or drug shop staff to become licensed? What percentage of pharmacies and drug shops are licensed versus unlicensed in your country?
  - Are there any laws or regulations that limit the types of products or services registered pharmacies or drug shops can provide?
  - Are there any laws or regulations that limit the scope of services provided by licensed pharmacists or drug shop operators?
  - Are licensed pharmacists or drug shop operators allowed to dispense drugs without a written prescription from a doctor?

**Collect and package evidence:**

- Compile existing evidence—from your country or other countries—that can help make the case for updating laws and regulations on registered pharmacies and drug shops. For example, look for evidence suggesting that:
  - Pharmacies and drug shops are suitable sales outlets for health products, whether malaria treatment, HIV self-tests, contraceptives, or another priority product.
  - Administration of a given health product by pharmacists or drug shop operators is safe and feasible.



#### Foster increased coordination:

- Encourage your MOH to involve representatives from pharmacies and drug shops in public health policymaking and to consider how these private retail outlets can be leveraged to increase equitable and sustainable access to essential health products.



#### Mobilize citizen demand:

- Conduct policy forums and media advocacy to raise awareness about the importance of registered pharmacies and drug shops, and the pharmacists and druggists who operate them, as key frontline providers that can significantly expand access to prevention, screening, and treatment—with the right training and policy support in place.



#### Inform policies and funding:

- Work with your MOH and parliament to update or change laws and regulations, where evidence exists, to authorize registered pharmacy and/or drug shop provision of priority health products and to expand scopes of practice for qualified pharmacists and drug shop operators.

### LEARN MORE! ADDITIONAL RESOURCES ON POLICIES AFFECTING PHARMACIES AND DRUG SHOPS:

- Private Health Policy Toolkit for Africa. Available at <http://documents.worldbank.org/curated/en/859601478243694324/pdf/109739-WP-hiainstrumentfinal-PUBLIC-ABSTRACT-SENT.pdf>.
- Managing Access to Medicines and Health Technologies—Chapter 32: Drug seller initiatives. Available at <http://apps.who.int/medicinedocs/documents/s19609en/s19609en.pdf>.
- Working with Private Sector Providers for Better Health Care. Available at <http://www.who.int/management/partnerships/private/privatesectorguide.pdf>.
- Drug Shops and Pharmacies: Sources for family planning commodities and information. Available at [https://www.fphighimpactpractices.org/sites/fphips/files/hip\\_pharmacies\\_drug\\_shops\\_brief.pdf](https://www.fphighimpactpractices.org/sites/fphips/files/hip_pharmacies_drug_shops_brief.pdf).
- Navigating Uncharted Waters: A Guide to the Legal and Regulatory Environment for Family Planning Services in the Private Sector. Available at <https://www.shopsplusproject.org/resource-center/navigating-uncharted-waters-guide-legal-and-regulatory-environment-family-planning>.
- Introducing rapid diagnostic tests in drug shops to improve the targeting of malaria treatment. Available at <http://www.actconsortium.org/projects/6/introducing-rapid-diagnostic-tests-in-drug-shops-to-improve-the-targeting-of-malaria-treatment.html>.
- Total Market Approach Advocacy Messaging Framework. Available at <https://www.path.org/publications/detail.php?i=2770>
- Private Pharmacy and Drug Shop Messaging Framework. Available at <http://www.path.org/publications/detail.php?i=2768>



Advocacy spotlight:

## Increasing access to injectable contraceptives through pharmacies and drug shops



**In Uganda, contraception rates among women are low.** Many women face challenges accessing public-sector family planning services due to distance, periodic stockouts, and the shortage of qualified providers in rural areas. Among women who do use contraception, injectable contraception is the most popular.

Across the country, more than 6,000 registered private-sector drug shops and pharmacies provide many kinds of health products. These shops can be an important outlet for women who are unable to access injectables through the public sector. However, no policy authorizes distribution of injectable contraception through drug shops—making current practices technically illegal.

Since 2007, FHI 360 and the MOH have worked alongside a wide range of partners to amend the National Drug Authority Act to allow the safe and legal provision of injectable contraception by registered drug shops. Advocates began by generating evidence through research and assessments that established the suitability of drug shops as distribution points for injectables. They

then packaged and disseminated that evidence during a high-level policy dialogue in 2015 that resulted in the formation of a task force committee that could drive the issue forward. The committee conducted stakeholder mappings, developed an advocacy strategy, and held a range of consultative meetings intended to gather information and involve stakeholders in the process. They then drafted a Justification Paper for the Provision of Injectable Contraception by Drug Shop Operators in Uganda—and in late 2016, the Senior MOH committee provided approval to present the justification paper and seek consensus with the National Drug Authority on the policy change.

With the expected policy change, access to injectable contraception is expected to rise as more women are able to obtain it easily and legally. The recent introduction of subcutaneous DMPA, or Sayana® Press, which increases opportunities for self-injection, is a development that may also make drug shops potentially critical—and sanctioned—sources of information and supplies for women seeking this new type of contraception.

To learn more, please see the related [case study](#) and [advocacy brief](#) from Advancing Partners and Communities.

\* Sayana Press is a registered trademark of Pfizer Inc.



PATH/Minzayar

## Public-sector procurement policies

### WHAT ARE THE POLICIES?

Government purchasing represents a significant portion of the market for health products in many countries. **Procurement** is the process of identifying sources of supply for products and the act of acquiring those products. **Public-sector procurement policies** are the operational policies and practices that govern that process. For the health sector, they dictate how—and which—products are purchased and provided through the public sector. These policies are intended to ensure consistent availability of appropriate, quality-assured products. Procurement of health products by the public sector should be transparent, provide value for money, and prioritize safety and efficacy.<sup>7</sup>

### WHAT IS THE ADVOCACY OPPORTUNITY?

As an advocate, you are best positioned to influence the planning stage of the procurement process, where critical policy decisions are made that affect the availability and quality of health products. For example, you can inform **quantification**, the participatory process many MOHs use to determine the quantities of products to procure and when they should be delivered. After the quantification, you can monitor the supply plan to ensure that sufficient funds are allocated to purchase commodities and that all funders follow through on their commitments. Finally, you can help ensure that other operational policies—such as health product specifications, quality assurance policies, and tender documents that describe the bidding process for interested suppliers—prioritize international quality standards.

### Quantification includes both forecasting and supply planning?

**Forecasting** is the process of estimating the quantities of products that will actually be dispensed or used to meet the health needs of the targeted population during a specific future period of time.

The **supply plan** is the final output of the quantification and details the total product quantities and costs required to fill the supply pipeline to ensure optimal procurement and delivery schedules.



### WHAT ACTIONS CAN YOU TAKE?

#### Understand the policy environment:

- Understand how public-sector quantification is carried out, while paying attention to policies and data sources that may affect this process. Key questions include:
  - How often does quantification take place? At what intervals is the supply plan reviewed?
  - Which government officials are responsible for quantification?
  - Who is invited to participate in quantification and subsequent supply plan reviews? Is there an opportunity for civil society to participate?
  - What role do the National Essential Medicines Lists, standard treatment guidelines, product registration, health technology assessments, and cost-effectiveness analyses play in product selection?
  - Are new policies or programs adequately accounted for when forecasting demand for certain products? For example, policies that mandate universal HIV testing or free maternity services will increase demand for HIV test kits and maternal health products. Policy and program shifts need to be reflected in operational procurement policies and planning.
  - What data is used to forecast future demand?
- Map out the various procurers of health products in your country, including the government and donors, and their funding requirements, restrictions, and cycles.
- Review operational public-sector procurement policies—including health product specifications, quality assurance policies, and tender documents—to determine whether they mandate that products procured must meet international quality standards.



#### Collect and package evidence:

- If existing logistics and health data in your country don't tell you where priority products are being delivered and how they're being used—and quantification and procurement plans suffer as a result—advocate with your government to improve data collection and use. For example, this may include asking for new indicators to be added to your country's health information management system.



#### Foster increased coordination:

- Call for the creation of a multidisciplinary quantification team and encourage quarterly or biannual communication and coordination between agencies responsible for health product forecasting, procurement, and budgeting. The quantification team should include stakeholders from the MOH, ministry of finance, and relevant program, supply chain, and service delivery staff, as well as relevant donors and implementing partners contributing funding or products for the specific health area.



### Inform policies and funding:

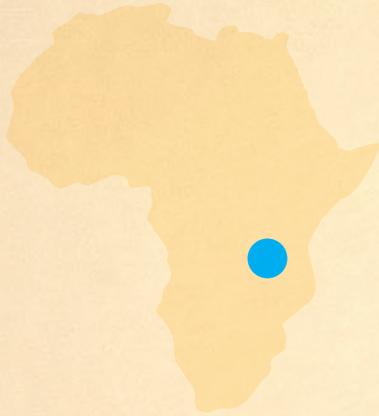
- Ensure programmatic plans (new product introduction, program expansion) and priorities are considered during the quantification to ensure sufficient quantities of products are procured.
- Monitor disbursement of funds toward product procurement and urge all stakeholders to fully fund their commitments.
- Advocate with your MOH and ministry of finance to fully fund health product supply plans:
  - Encourage the MOH to align the quantification process with budget cycles to ensure all procurement needs can be accounted for in budgeting processes.
  - Urge donors and other partners to fulfill their funding commitments to ensure the supply plan can be executed as planned.
- Urge public-sector procurement entities, including governments and donors, to prioritize international quality standards in their health product procurement policies. Note that many international donors already have such policies in place, including the Global Fund to Fight AIDS, Tuberculosis and Malaria; UNITAID; USAID; UNFPA; and the Stop TB Partnership Global Drug Facility.<sup>10</sup>
- Encourage budget officials in decentralized settings to explore pooling of public-sector procurement across subnational levels.

### Procurement in decentralized settings

Countries with decentralized health systems face unique challenges coordinating procurement, both between national and subnational procurement units and among various subnational procurement entities. In places where some or all health product procurement has been devolved to subnational levels, procurements are often fragmented, of smaller quantities, and on different schedules. This weakens subnational procurers' ability to negotiate the best prices, because higher volumes typically lead to lower per-unit costs. It also increases the risk of products of poor or unknown quality being procured, as quality standards may differ among subnational procurers.

### LEARN MORE! ADDITIONAL RESOURCES ON PROCUREMENT POLICIES:

- Addressing Procurement Bottlenecks: A Review of Procurement Bottlenecks in Public Sector Medicine Supply Chains and Practical Approaches Taken to Resolve Them. Available at [http://jsi.com/JSIInternet/Inc/Common/\\_download\\_pub.cfm?id=17426&lid=3](http://jsi.com/JSIInternet/Inc/Common/_download_pub.cfm?id=17426&lid=3).
- UN Commission on Lifesaving Commodities for Women and Children Promising Practices: Procurement Brief. Available at [http://www.lifesavingcommodities.org/wp-content/uploads/2014/08/Copy-of-2\\_Procurement-final.pdf](http://www.lifesavingcommodities.org/wp-content/uploads/2014/08/Copy-of-2_Procurement-final.pdf).
- Quantification of Health Commodities: RMNCH Supplement—Forecasting Consumption of Select Reproductive, Maternal, Newborn, and Child Health Commodities. Available at <http://apps.who.int/medicinedocs/documents/s22288en/s22288en.pdf>.
- Good procurement practices for artemisinin-based antimalarial medicines. Available at [http://apps.who.int/iris/bitstream/10665/44248/1/9789241598927\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/44248/1/9789241598927_eng.pdf).
- Assessing Policies and Practices That Affect Contraceptive Financing and Procurement: A Review Guide. Available at [https://www.k4health.org/sites/default/files/assepoliprac\\_hpi\\_udp\\_2.pdf](https://www.k4health.org/sites/default/files/assepoliprac_hpi_udp_2.pdf).
- Procurement Capacity Toolkit: Tools and Resources for Procurement of Reproductive Health Supplies, Version 2. Available at <http://www.path.org/publications/detail.php?i=1652>.
- Enhancing Contraceptive Security through Better Financial Tracking: A Resource Guide for Analysts and Advocates. Available at [http://pdf.usaid.gov/pdf\\_docs/pa00k7jz.pdf](http://pdf.usaid.gov/pdf_docs/pa00k7jz.pdf).



Advocacy spotlight:

## Saving newborn lives with stronger procurement



PATH/Evelyn Hockstein

**Birth asphyxia, which occurs when newborns fail to breathe at birth, is a leading cause of neonatal mortality in Uganda.** Newborn resuscitation devices, when administered by a trained birth attendant, can decrease neonatal deaths by up to 30 percent. Recently, however, health centers in several districts in Uganda faced a shortage of these devices, threatening the lives of newborns.

The White Ribbon Alliance (WRA), a PATH subgrantee through the United Nations Commission on Life-Saving Commodities for Women and Children, was concerned about the shortage. When it investigated the reasons for constant shortages of the devices throughout the country, it identified two policy weaknesses. First, district health officials could not directly order newborn resuscitation devices because the MOH was responsible for procuring the equipment. Second, there was no

dedicated funding to procure, repair, or replace the devices.

In 2015 WRA successfully advocated to the MOH to transfer its procurement authority of newborn resuscitation devices to the National Medical Stores and include these devices on the National Medical Stores procurement list, making it easier for district officials to access them. The group also identified potential funding opportunities and is advocating for the government to increase budget prioritization for the devices. WRA is now advocating for robust financing for procurement of this essential supply.

For more information, see the full case study by WRA: [Saving Newborn Lives: A Change in Procurement Policy of Resuscitation Devices Is a Matter of Urgency](#).



PATH

## Taxes and duties on essential health products

### WHAT ARE THE POLICIES?

Import duties, or tariffs, are taxes applied to products entering a country. Domestic taxes, such as a value-added tax, are taxes applied to products being bought or sold within the country that increase the price consumers pay. While duties and taxes represent sources of revenue for governments, many public health experts believe they should not be applied to lifesaving health products if those levies negatively affect access for consumers. WHO estimates that high tariffs in select low-income countries increase the price of pharmaceutical ingredients by 23 percent and the price of finished products by 12 percent or more.<sup>6</sup>

Proportionally, poor and sick people pay a higher share of taxes on health products than rich and healthy people. This impacts the health of vulnerable groups, restricting economic opportunities and limiting productivity.<sup>11</sup>

### WHAT IS THE ADVOCACY OPPORTUNITY?

If, after careful analysis, you conclude that taxes and duties are restricting access to essential health products, you can play an important role in their elimination by making the case that taxes and duties negatively impact affordability and undermine public health. While advocating for the elimination or reduction of taxes and duties on essential health products can be challenging, it can also be a productive and rewarding way to bring prices down on the health products you care about.

In addition, it's important to note that sizable increases in the price of health products can occur throughout the supply chain. Advocates should work with governments to identify a range of policy measures, such as competitive pricing policies, to enact in conjunction with the elimination of import duties and taxes to support the affordability of health products.<sup>12</sup>

### Implementation challenges

In 2000, 38 countries in Africa resolved to abolish taxes on drugs and other inputs in health services related to HIV/AIDS, tuberculosis, and malaria. Underscoring the difficulties in meeting this commitment, only four countries had removed taxes and tariffs on all five essential antimalarial commodities ten years after the declaration was signed.<sup>13</sup> Governments forgoing revenue generated by taxes and duties may lose a significant source of income,<sup>14</sup> which makes eliminating these taxes politically difficult. Advocates in these countries can play an important role in holding governments accountable to follow through on commitments.



## WHAT ACTIONS CAN YOU TAKE?

### Understand the policy environment:

- Find out if the health products you care about are subject to import duties/tariffs or domestic taxes. Your country may provide this information publicly—for example, on a website—or you may need to obtain it through stakeholder interviews or a combination of sources. If you find that your government has made a commitment to eliminate such taxes, work with officials to uphold that commitment.



### Collect and package evidence:

- Work with a broad range of stakeholders, including suppliers, providers, consumers, government, and market technical specialists, to understand how reductions or eliminations of duties and taxes would impact prices and access to your priority health product(s). Explore whether modeling the projected health and economic impacts of eliminating or reducing taxes and duties on essential health products is needed.
- Collaborate with technical specialists to identify alternative funding streams for government that offset the impact of reducing or removing duties and taxes. For example:
  - **Duties:** Propose methods to improve customs procedures and make customs revenue collection more efficient. Introducing separate lines in the tariff code for specific products can also help isolate the impact of losing this revenue.<sup>14</sup>
  - **Taxes:** One option may be a “healthy tax.” Healthy tax efforts increase taxes on certain products, such as alcohol and tobacco, which negatively impact public health in an effort to offset revenue lost from taxes on essential health products.<sup>15</sup>



### Foster increased coordination:

- Promote productive dialogue between relevant government agencies, consumer organizations, and global and local industry by convening discussions on proposed policy reforms focused on duties and taxes for essential health products.



### Mobilize citizen demand:

- Host community forums and conduct media advocacy to elevate citizen voices on the harmful impact of duties and taxes on essential health products and to amplify requests for their reduction or removal.



### Inform policies and funding:

- Advocate with key decision-makers—which may include your MOH, ministry of finance, revenue authorities, and other government officials—to reduce or eliminate taxes on products that are essential for the population’s health and well-being. You may need to explain the difference between health products and other types of luxury or everyday commodities that may be more appropriate for taxation, such as cosmetics.



#### LEARN MORE! ADDITIONAL RESOURCES ON TAXES AND DUTIES ON ESSENTIAL HEALTH PRODUCTS:

- Sales Taxes on Medicines. Available at [http://haiweb.org/wp-content/uploads/2015/08/5\\_WHOHAI\\_Policy-Brief\\_Taxes\\_2015.pdf](http://haiweb.org/wp-content/uploads/2015/08/5_WHOHAI_Policy-Brief_Taxes_2015.pdf).
- Taxing Health: The relevance of tariff revenue from anti-malarial commodities. Available at <http://www.intracen.org/Taxing-Health-The-relevance-of-tariff-revenue-from-anti-malarial-commodities/>.
- The Impact of Tariff and Non-Tariff Barriers on Access to Essential Drugs for the Poorest People. Available at <http://apps.who.int/medicinedocs/documents/s16764e/s16764e.pdf>.
- WHO/HAI Project on Medicine Prices and Availability. Available at <http://haiweb.org/wp-content/uploads/2015/08/Taxes-final-May2011a1.pdf>.
- Medicine Prices, Availability, Affordability, and Price Components. Available at <http://www.haiweb.org/medicineprices/manual/documents.html>.
- Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation? Available at <http://www.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf?ua=1>.
- Broken Promise? Taxes and Tariffs on Insecticide Treated Mosquito Nets. Available at <http://www.ajtmh.org/content/journals/10.4269/ajtmh.2007.77.227>.



Advocacy spotlight:

## Eliminating taxes on menstrual hygiene products

**Millions of girls and women in India have difficulty managing menstruation.** In addition to widespread taboos and misinformation on menstruation, few commercially produced menstrual hygiene products are available. Taxes on menstrual hygiene products further create barriers to access and use, especially among poor and marginalized girls and women.

India's recently proposed Goods and Services Tax (GST) schedule taxes sanitary napkins and tampons at 12 percent and reusable menstrual cups at a rate as high as 18 percent. By contrast, other health products like contraceptives are exempted from taxes owing to their public health benefit. Advocates believe that because menstrual hygiene products address a basic biological function, they should be considered a necessity—and not a luxury item—and therefore not subject to taxation.

Momentum has been building in India to eliminate taxes on menstrual hygiene products. Through the Menstrual Hygiene Alliance, PATH and partners have launched an advocacy effort targeting the Ministry of Finance and the Ministry of Health and Family Welfare



PATH/Eric Becker

to ensure that all menstrual hygiene products under the GST fall under a 100 percent tax exemption bracket. To gain traction, advocates—in collaboration with menstrual hygiene management experts—have prepared recommendations to the finance minister laying out their policy asks, leveraged international days like [Menstrual Hygiene Day](#) (May 28) to spark policy dialogue among relevant ministries, and published articles to media outlets to create public awareness. They have also partnered with influencers who have spoken out, including a prominent parliamentarian who circulated her own [petition](#) to remove taxes on sanitary napkins. Finally, to address anticipated concerns from the Ministry of Finance, advocates have been working with the Confederation of Indian Industry to better understand how a complete removal of taxes on menstrual products would influence government revenues in the future.

Although this advocacy initiative is still in its early stages, advocates are hopeful that policy change will be achieved. Removing taxes on all menstrual hygiene products would not only make a wider range of product choices more affordable to girls and women but would also uphold their basic reproductive health and rights.



# Messages matter:

Market messaging  
for advocates



## Market messaging for advocates

**No matter what policy you focus your advocacy efforts on, you will need to communicate about markets.** Markets may be a new topic to your target audiences. This makes it even more important to use simple and clear messages explaining what markets they are, why they are important, and how they can be strengthened. Strong advocacy messaging will help ensure that markets are visible and prioritized in broader discussions about health policy and programming in your country, and they will help advance your specific market-related policy goals.

PATH developed Markets Matter messaging to equip advocates with a way to describe markets and their critical role in driving access to health products. These messages can be used with a variety of target audiences, including policymakers, donors, implementers, and other health advocates. We encourage you to adapt and tailor these messages so that they reflect your country context. Incorporate these messages into your advocacy and communication materials, including relevant policy briefs, fact sheets, newsletters, press releases, and social media.

## What are markets and why do they matter?

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**Even the most effective health products cannot save lives or improve health if they do not reach the people who want and need them. That is why markets—the systems, structures, and institutions that facilitate the buying and selling of health products—matter. When markets function well and are healthy, high quality, well designed, and affordable, health products are consistently available.**

- No matter where we live, we all have the same aspiration—to live a healthy, productive life. Modern science, medical advances, and health products help make this possible. And when people—especially women and children—have access to the products, care, and information they need to be healthy, their families, communities, and countries thrive.
- Healthy markets benefit everyone—manufacturers have the information they need to produce health products and the financial incentives to encourage them to do so, governments and health care providers can buy a sufficient supply of quality-assured products at an affordable price, and people can access and afford products that best fit their needs.
- In order to achieve new global health goals such as the Sustainable Development Goals [**insert global goals/initiatives relevant to your target audience**], markets must be strengthened to improve access to health products. With new, more ambitious targets to reach, no one sector can do it alone. A sustainable approach to delivering health products requires coordination for maximum public health impact.

## How do markets fall short?

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**Too often, markets fall short, and lifesaving, health-improving products do not reach people living in low- and middle-income countries. Products they need may be unavailable, unaffordable, of poor quality, or unsuitable for local needs. For example:**

- Products may be **unavailable** because a manufacturer lacks the financial incentives to sell them in a particular market or setting.
- There may be **disruptions in supply** due to manufacturing, procurement, or distribution challenges.
- The product may be **too expensive** for the buyer or consumer—whether it’s a government or an individual—to afford.
- Limited regulation and oversight might allow **poor-quality products** to be sold or distributed.
- A product may be available but inappropriate for the local context due to **poor design**.
- Individuals may **not have the information** they need to use the product, or health care providers may not be trained to provide the product.

## How can markets be strengthened?

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**Market shortcomings can be addressed through a range of interventions, including direct market interventions and relevant policy changes. Every market is different and will require a tailored market strengthening approach. No single intervention or policy will solve the problems of every market, and not every market needs intervention.**

- Direct market strengthening interventions focus on understanding the dynamics and failings of a particular market and altering them to improve access and ultimately, health outcomes. They involve changing the practices and behavior of market actors.
- Improving the policy environment in which markets operate is another way to strengthen markets and expand access to essential health products. A country's policy environment impacts how products are manufactured, imported, distributed, bought, and sold and is often informed by global policy. To be healthy, markets need supportive policies that encourage competition, spur innovation, safeguard consumers, and improve access to lifesaving health products for all.



# Implementation matters



# Moving forward with advocacy for market strengthening

**Congratulations!** By now, you should have a better understanding of markets: what they are and why they matter, what they look like when they are well-functioning and when they fall short, and who the key actors are. You also know that markets operate within policy frameworks established by governments. You can now recognize key policies that affect health product markets, and you've seen how other advocates have implemented advocacy strategies to strengthen market-related policies and support well-functioning markets. Finally, you have customizable messages about markets at your fingertips that you can use to make your case.

It's time to put all the pieces together and lay the groundwork for advocacy action. As a reminder, the guide is meant to provide a starting point to identify advocacy opportunities for market strengthening. To build out your own advocacy strategy, we encourage you to use the guide alongside PATH's other advocacy tools. **These tools will take you through a ten-part framework to develop a policy advocacy strategy** to support your advocacy for market strengthening efforts, including how to assess policy options and make strategic decisions about policy advocacy goals, activities, and partners.

To access the full suite of PATH's advocacy capacity tools, please visit <http://sites.path.org/advocacyandpolicy/how-we-do-it/strengthen-advocacy-capacity/>.

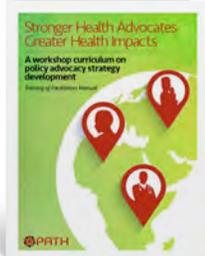
## PATH's ten-part policy advocacy strategy

PATH's ten-part framework can help seasoned global health advocates and newcomers alike develop a policy advocacy strategy that will advance their programmatic health goals.

### The ten parts include:

1. **Advocacy issue.**
2. **Advocacy goal.**
3. **Decision-makers and influencers.**
4. **Decision-makers' key interests.**
5. **Advocacy opposition and obstacles.**
6. **Advocacy assets and gaps.**
7. **Advocacy partners.**
8. **Advocacy tactics.**
9. **Advocacy messages.**
10. **Plan to measure success.**

You can use this strategy to develop your market-focused advocacy strategy. Learn more in the Getting Started section at the end of this guide.



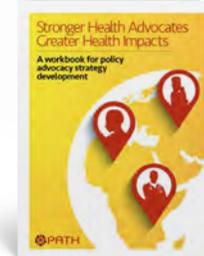
### **Stronger Health Advocates, Greater Health Impacts: E-course**

This tool is ideal for advocates who want to understand the content provided in the workshop curriculum but want to develop their strategy at their own pace.



### **Stronger Health Advocates, Greater Health Impacts: A workshop curriculum on policy advocacy strategy development**

This tool is ideal for advocates who want to design their advocacy strategies through an interactive, three-day workshop.



### **Stronger Health Advocates, Greater Health Impacts: Workbook**

This tool is ideal for advocates who already understand the fundamentals of developing an advocacy strategy and just want to focus on key worksheets that compose an advocacy strategy.

## Select resources on market strengthening

In addition to these resources to help strengthen your advocacy efforts, you may need additional information on market shaping for health. A number of publications and tools that can support your advocacy work and provide important background on market strengthening are provided below. Use these tools to explore the dynamic relationships between global health and market dynamics, which can inspire your own efforts.

### Publications and tools

#### CROSSCUTTING

- ▶ A Market Shaping Primer. Available at [https://www.usaid.gov/sites/default/files/documents/1864/healthymarkets\\_primer.pdf](https://www.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer.pdf).
- ▶ Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations. Available at [https://www.usaid.gov/sites/default/files/documents/1864/Idea-to-Impact\\_Jan-2015-508.pdf](https://www.usaid.gov/sites/default/files/documents/1864/Idea-to-Impact_Jan-2015-508.pdf).
- ▶ Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations. Available at <https://www.usaid.gov/cii/ready-set-launch>.
- ▶ Innovations in applying market systems approaches to the health sector. Available at [https://beamexchange.org/uploads/filer\\_public/6e/a3/6ea34126-a73a-4132-9384-f617f6b45b27/health\\_systems\\_webinar.pdf](https://beamexchange.org/uploads/filer_public/6e/a3/6ea34126-a73a-4132-9384-f617f6b45b27/health_systems_webinar.pdf).

#### ISSUE-SPECIFIC

- ▶ Market Shaping for Family Planning: An analysis of current activities and future opportunities to improve the effectiveness of family planning markets. Available at [http://www.dalberg.com/documents/Market\\_Shaping\\_for\\_Family\\_Planning.pdf](http://www.dalberg.com/documents/Market_Shaping_for_Family_Planning.pdf).
- ▶ Increasing Access to Essential Maternal Health Supplies: A scoping of market-based activities, gaps and opportunities. Available at [https://www.rhsupplies.org/uploads/tx\\_rhscpublications/Increasing\\_Access\\_to\\_Essential\\_Maternal\\_Health\\_Supplies\\_-\\_A\\_scoping\\_of\\_market-based.pdf](https://www.rhsupplies.org/uploads/tx_rhscpublications/Increasing_Access_to_Essential_Maternal_Health_Supplies_-_A_scoping_of_market-based.pdf).
- ▶ Stronger Markets, Increased Access to Maternal Health Supplies [a policy paper series]. Available at <http://www.path.org/publications/detail.php?i=2643>.
- ▶ HIV Preventives Technology and Market Landscape 2nd Edition. Available at [http://unitaid.eu/assets/UNITAID-HIV\\_Preventives\\_Landscape-2nd\\_edition.pdf](http://unitaid.eu/assets/UNITAID-HIV_Preventives_Landscape-2nd_edition.pdf).

#### WEBSITES

- ▶ UN Commission on Life-Saving Commodities. Available at <http://www.lifesavingcommodities.org/about/lifesaving-commodities/>.
- ▶ Beam Exchange: Mapping the System. Available at <https://beamexchange.org/market-systems/what-market-system/mapping-system/>.
- ▶ Markets Matter blog series. Available at <http://blog.path.org/2016/04/markets-matter/>.
- ▶ NextBillion Series: Market Dynamics. Available at <http://nextbillion.net/nextbillion-series/market-dynamics/>.
- ▶ Making Markets Work. Available at <https://pages.devex.com/making-markets-work.html>.

## Annex A:

# Glossary of key terms and icons

**Buyer power:** The pressure or bargaining ability a buyer of large quantities of products can exert to get higher-quality products, lower prices, or improved delivery terms.

**Market:** The systems, structures, and institutions that facilitate the buying and selling of goods and services.

**Market actors:** The groups involved in the manufacturing, buying, selling, distributing, and/or use of products. These include suppliers, distributors, providers, consumers, policymakers and regulators, and market influencers.

**Market dynamics:** The interactions among various market actors that determine how a product is produced, procured, distributed, and delivered.

**Market strengthening interventions:** Actions that are undertaken to directly shape the market.

**Public sector:** Health services and products that are administered by the government, which includes national and subnational government.

**Private sector:** Health services and products that are provided by nongovernmental entities. These include:

- For-profit companies (such as manufacturers, drug shops, pharmacies, and private hospitals and private health facilities)—which are often also referred to as the commercial sector.
- Social marketing organizations that sell or distribute products, often at a subsidized price.
- Not-for-profit, nongovernmental organizations (NGOs) that run health programs or clinics.

### CHARACTERISTICS OF A WELL-FUNCTIONING HEALTH PRODUCT MARKET



Availability



Affordability



Assured  
quality



Appropriate  
design



Awareness

### WHAT ACTIONS CAN YOU TAKE?



Understand  
the policy  
environment



Collect and  
package  
evidence



Foster  
increased  
coordination



Mobilize  
citizen  
demand



Inform  
policies and  
funding

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PATH is an international organization that drives transformative innovation to save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health.

Learn more at [www.path.org](http://www.path.org).