Promoting the
QUALITY OF MEDICINES Plus

Increasing Demand for Quality-Assured Health Products at the Last Mile

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About PQM+

The Promoting the Quality of Medicines Plus (PQM+) Program is a six-year cooperative agreement between USAID and USP to sustainably strengthen medical product quality assurance systems in low- and middle-income countries. The program works to improve medical product quality through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system. By sharing scientific expertise and providing technical support and leadership, PQM+ helps create resilient and robust local health systems that address diseases such as HIV/AIDS, tuberculosis, malaria, and neglected tropical diseases, as well as improve maternal, newborn, and child health.

Suggested Citation

Contents

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Acronyms

ADR	adverse drug reaction
CHW	community health worker
DRC	Democratic Republic of Congo
GPHF	Global Pharma Health Fund
LMIC	low- and middle-income countries
MAS	Mobile Authentication Services
NAFDAC	National Agency for Food and Drug Administration and Control (Nigeria)
NRA	national regulatory authority
PQM+	Promoting the Quality of Medicines Plus
QA	quality assurance
QR	quick response code
ReMeD	Réseau Médicaments et Development
SMS	short message service
SBC	social and behavioral change
SF	substandard and falsified
USAID	U.S. Agency for International Development
USP	U.S. Pharmacopeial Convention
WHO	World Health Organization

Background

Robust health systems are essential in the fight against public health threats, infectious disease outbreaks, pandemics, and other events. In a strong health system, health is a shared responsibility among patients, health care workers, health facilities, and communities (USAID 2022). The U.S. Agency for International Development (USAID) has long partnered with governments in low-and middle-income countries (LMICs) to promote community-based primary health care to achieve the World Health Organization's (WHO) Sustainable Development Goals. This approach recognizes that communities have the power to influence the quality of their health systems and that many important decisions affecting health are made at the community level (USAID 2021).

A**ccess to** and **appropriate use** of quality-assured medical products (medicines, vaccines, devices) is essential for effective health interventions and systems at all levels of the health system. However, the use of substandard and falsified (SF) medical products[1] makes it difficult for health systems to respond effectively to public health needs. Strong national medicines regulatory authorities are critical to ensuring the safety, efficacy, and quality of medical products on the market. Hence, countries with weak regulatory authorities and systems tend to be the most vulnerable when it comes to SF medical products reaching patients (Kusynova 2023). Patient use of SF medical products can lead to treatment failures and antimicrobial resistance, prolong illness, and increase the overall risk of morbidity and death. SF medications waste health care resources and erode consumer confidence in the health care system (WHO 2017). Although the true burden is unknown and very difficult to determine, the WHO estimates that the failure rate of SF medical products in LMICs is at least 10.5 percent, and, in some settings, likely far higher. Studies commissioned by WHO estimated that up to 72,430 global childhood pneumonia deaths can be attributed to the use of falsified antibiotics. Similarly, 72,000–267,000 deaths (Code of Federal Regulations adjusted case: 31,000–116,000 deaths), or 2–5 percent of total malaria deaths in sub-Saharan Africa, can be attributed to SF antimalarials (WHO 2017).

International development partners have traditionally sought to reduce the amount of poor-quality medical products in public health programs and in the private sector by helping national governments address supply-side issues. Supply-side interventions include efforts to improve medical product manufacturing, regulatory oversight, product packaging and labeling, procurement decisions, product distribution and storage, and product surveillance throughout the medical product lifecycle. However, supply-side strategies focused on strengthening medical product supply chains are not enough and must be complemented by **demand generation** for quality-assured medical products by increasing provider and consumer awareness and influencing behavior. Demand-side initiatives include interventions such as mass media campaigns directed at consumer behaviors and preferences (Mayora 2018). Increased demand for quality medical products pushes health systems to ensure that only quality products reach patients, engages more health system actors in identifying SF medical products, and can shift procurement and consumption behaviors.

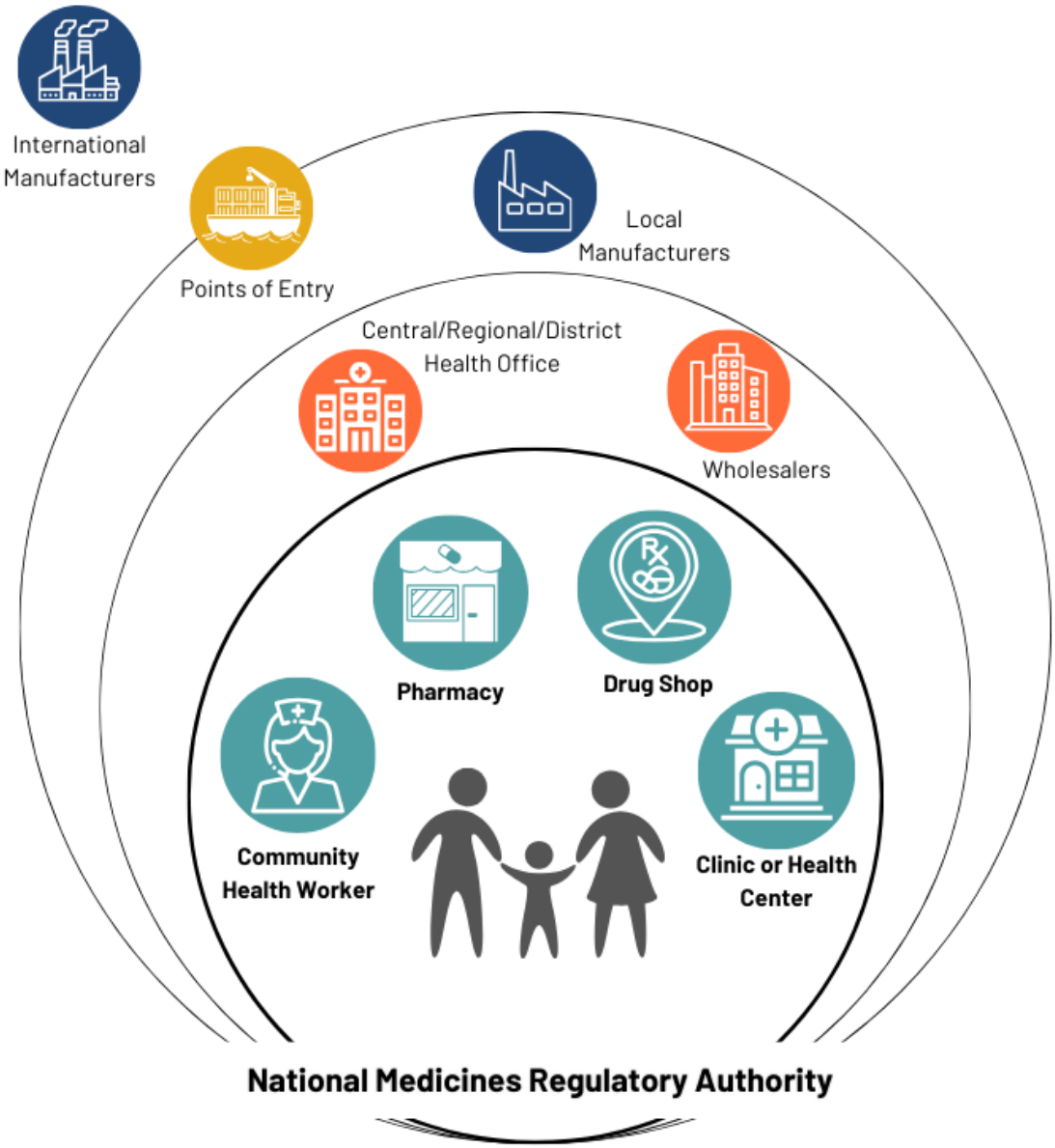
Community-level factors lie at the center of the medical product quality ecosystem (see Figure 1). These factors include individual patients, families, communities, and the social context in which they live.[2] For many patients, the primary points of access to medical products are community health workers (CHWs), drug shops, pharmacies, clinics/health centers, and health care providers. Thus, all these actors and entities should be able to identify SF medical

[1] https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products
[2] Social context can include social norms, religious norms, gender norms, income, geographic location.

products, understand the importance of medical product quality, and demand quality by themselves. Community-level health actors are therefore an important focus of demand generation as part of social and behavioral change (SBC) activities, as highlighted in Figure 1.

Throughout the medical product supply chain (from manufacturing to transport and delivery), there are risks compromising the quality of medical products. Manufacturers (whether international or local), procurement agents (whether national-level central medical stores or local drug retailers), as well as health providers at all levels of the health system have a role to play in assuring the quality of medical products and mitigating the risk of distributing SF medical products. Throughout the system, the national regulatory authority (NRA) must ensure the safety, efficacy, and quality of medical products at every level.

Figure 1. Medical Product Quality Ecosystem



There is not a vast amount of current research on strategies and tools to increase demand for quality-assured medical products at the community level. The most effective interventions identified in the authors' research include a variety of mutually enforcing SBC strategies, approaches, and activities to inform users and community-level providers about quality standards for medical products, provide simple ways to verify quality medicines, and encourage practical actions to ensure they are using only qualified medicines. In addition, CHWs, frontline providers, and authorities at different levels of the health system should have systems and procedures in place for consumers to report SF medical products. Detection and reporting of SF medical products should then trigger regulatory action to remove poor-quality products from the market and prevent reentry. Inattention to quality means that poor and vulnerable populations, with the least ability to pay for better care and products, will be most adversely affected. Over time, balancing both demand and supply interventions can support a culture of quality and responsibility, thus helping to increase access to quality-assured medical products at all levels of the health system.

Purpose and Methods

The purpose of this paper is to provide examples of SBC interventions that can be implemented to raise awareness, identification, and reporting of SF medical products at the consumer and community levels. These interventions are designed to increase demand for quality-assured health products, reduce demand for and consumption of products of uncertain quality, and increase information sharing to effect improvements at higher levels of the medical product quality assurance (QA) ecosystem.

Well-designed SBC programs can:

- Educate users and providers on the existence of SF medical products, their risks, and how to identify and verify SF medical products.
- Create informed and voluntary demand for high-quality medical products.
- Increase reporting of SF medical products, which, in turn, can lead to regulatory and supply chain action to reduce the prevalence of SF medical products.
- Shift social and cultural norms to influence individual and collective behavior related to obtaining medical products from low-quality sources.

The intended audience for this paper is USAID programs that wish to use SBC approaches, which are inclusive of demand generation, to increase demand for quality-assured products. USAID programs will also be able to use the evidence gaps identified in this paper to consider investment and further study.

Methods

The Promoting the Quality of Medicines Plus (PQM+) program partnered with BreakThrough ACTION to review examples of interventions designed to increase demand for quality-assured health products. PQM+ undertook a desk review of peer-reviewed articles, grey literature, and policy and advocacy documents to identify demand generation interventions as part of SBC strategies implemented at the individual and community levels. Although SF medical products are a global challenge with substantial health and economic burdens on health systems,

literature is markedly scarce on interventions and strategies to increase community awareness of SF medical products and create demand for high quality medical products. Available literature specific to SF medical products highlights the scale of the problem, but few studies are evidence-based. Only a few studies have addressed public awareness and knowledge of SF medical products or how to increase demand for quality medicines through proven SBC approaches. Finally, the published literature does not separate medical products from the package of services delivered (i.e., quality products and services) and thereby represents a major gap (Flores 2021). PQM+ consulted with the USAID-funded BreakThrough ACTION program, which reviewed the paper and confirmed that there is little new SBC research on this topic, and current literature reviews continue to largely cite the older literature and research.

Interventions

Despite sparse literature, the PQM+ team identified the following interventions targeting patients, community health care providers, and medicine retailers as potential ways to influence demand:

- Raising awareness of the presence of SF medical products in the market and the risks they pose.
- Building capacity of those in the medical product quality ecosystem to identify SF medical products through:
    - Visual identification
    - Authentication technologies (to identify falsified medicines)
    - Screening technologies (to identify SF medical products)
    - Providing incentives for providers who meet quality standards
- Raising the awareness of actors (i.e., patients, CHWs, medicine retailers) on ways to identify quality sources of medicines to alter their purchasing behavior and promote a shift from poor-quality to quality sources of medicines.
- Contributing data on SF medical products, for example, by reporting medicines that fail to treat or medicines associated with adverse events.

Each of these strategies is examined below in more detail. It is worth noting that the recommended starting point for any demand generation intervention is development of an SBC strategy by stakeholders including national health programs and their partners. The strategy should be based on the specific challenges in any given setting. It should consider audience-specific knowledge and attitudes, community norms, medicine purchasing practices, and decision-making processes of individuals, families, community health providers, medicine retailers, and facility-based health care providers. A comprehensive situation analysis will help intervention planners to better understand the behavior of the audiences mentioned above and the facilitators and barriers to behavioral change. From there, multiple approaches may be used to address the goals and objectives of the SBC strategy and related interventions.

To be most effective, SBC activities, of which demand generation is a part, are complemented by regulatory actions to monitor and ensure the quality of medical products circulating in the market, supply chain system efforts to improve product handling, health service system efforts to increase access to high-quality commodities, and training of providers so that they can meet increased demand for quality products. When developing and implementing demand generation

programs, continued coordination and collaboration with regulatory, supply chain, and health service systems are therefore essential.

Raising Awareness

Ensuring patients' consumption of quality medicines is the ultimate objective of medicine quality demand generation interventions. Patients cannot eliminate SF medical products in their communities. However, patients who consume and health workers who provide medicines can decrease the risk of consumption of poor-quality medicines with increased awareness of the presence of SF medical products, understanding which sources pose the greatest risk, obtaining products from safe sources, and learning how to identify SF medical products. SBC approaches can help raise awareness and change the sourcing practices of patients and health workers—the key audiences.

Several interventions in Africa identified in the literature have sought to raise public awareness of SF medical products.

- The USAID-funded Health Communication Capacity Collaborative project partnered with the Nigerian National Malaria Elimination Program and the National Agency for Food and Drug Administration and Control (NAFDAC) in 2014 to improve awareness of quality-assured antimalarials in Akwa Ibom State. The intervention was a four-month campaign focused primarily on consumers who buy malaria medicines and secondarily on informal medicine vendors. The campaign employed TV and radio spots, posters, stickers, and community volunteer materials to tell consumers how they can ensure that they are buying quality antimalarial medicines (specifically artemisinin-based combination therapies). The campaign's messages included buying from licensed pharmacies, checking for NAFDAC registration and expiration date on the medicine packaging, and verifying the authenticity of the medicine using the Mobile Authentication Service (MAS) (see more on this below). An evaluation of the campaign showed that people exposed to the messages improved their knowledge of good purchasing practices (vis-à-vis quality medicines) (Fordham 2016). However, the evaluation did not measure changed behavior as a result of the awareness.

- In 2003, a public awareness campaign using mainly TV and radio announcements on generic medicines and the dangers of counterfeit medicines[3] was implemented in Cotonou, Benin, by the Ministère de la Santé Benin. This nine-month intervention was designed following a survey of consumers' medicine purchasing practices in Cotonou. Most respondents reported that the campaign announcements increased their awareness; 90 percent understood the messages about the dangers of SF medical products; and respondents named public health facilities and pharmacies (vs. the open market or illicit vendors) as their preferred sources of generic medicines. The evaluators observed decreases in respondents' purchases from illicit vendors as well as the frequency of house calls by illicit vendors (Abdoulaye 2006).

- In 2008, the professional network Réseau Médicaments et Développement (ReMeD) launched an awareness campaign targeting school children and their mothers that placed posters about illegal street medicines in pharmacies in Bamako, Mali, and

[3] Counterfeit medicine as defined by the WHO as "one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with incorrect quantity of active ingredients or with fake packaging." (Mirandah Asia 2007)

> Nouakchott, Mauritania. ReMeD then surveyed 3,182 schoolchildren in those cities about the posters. A majority of the students (61%) reported seeing the posters in pharmacies and telling their parents (school children were the main target of the campaign; mothers were the secondary target). Most (84%) had heard about the dangers associated with illegal street medicines. Researchers noted, however, a gap in their level of perception versus actual knowledge (i.e., only 41% of the students understood the posters) and felt that future campaigns could improve knowledge by using trainers to explain the messages (Cuchet-Chosseler 2011).

Little is known about changing patient/consumer awareness of medicine quality and medicine buying behavior. The few examples cited above reveal the paucity of such campaigns and/or assessments in the literature. They also preceded the widespread availability of mobile phones and social media, which offer other new possibilities for SBC interventions in this area. Still, they demonstrate that public awareness can be increased relatively quickly, at least in the short term. It would be useful to have evidence of impact over the longer term as well. Although evidence of changed behaviors is not well documented and attribution not clearly established in the limited reports available specific to SF medical products, awareness campaigns appear to have affected either the intention to change behavior or in fact have changed behavior. Future efforts would benefit from well-designed research following audiences for longer periods and using qualitative research to understand pathways to self-reported changed intentions or behaviors.

USAID Missions interested in investing in SBC interventions should first develop an evidence-based, country-specific, culturally appropriate, and contextually relevant strategy that raises awareness of SF medical products and helps build capacity to identify SF medical products. From there, advocacy efforts, targeted multimedia campaigns, and other SBC approaches may be utilized accordingly based on well-designed formative research. While less attention has focused on leveraging SBC to address SF medical products to date, based on evidence from other health and technical areas, SBC strategies, tools, and resources have proven impactful and can be used to create demand for quality-assured medical products while complementing efforts to strengthen medical product supply chains.[4] Tools and resources exist to guide SBC approaches at the country level and build capacity for demand creation, although more tools and resources are needed that are specific to SF medical products.[5,6]

Building Capacity to Identify SF Medical Products

Once consumers are aware that poor-quality medicines exist in the market and are threats to health, how does the consumer act on that awareness? They may attempt to identify SF medicines and avoid those medicines or seek to obtain medicines only from trusted sources. The sections below outline interventions identified in the literature in these areas.

Authentication of Medical Products

Interventions that empower community actors to identify SF medical products, including unregistered products, are crucial to building consumer awareness. Such interventions include use of technologies to help consumers visually authenticate falsified or unregistered products and to alert the manufacturer and/or the regulatory authority so that follow-up action can be taken against the falsified product (Fordham 2016). Some approaches that tried in recent years

[4] https://behaviorchangeimpact.org/
[5] https://healthcommcapacity.org/wp-content/uploads/2017/01/Quality-Medicine-I-Kit.pdf
[6] https://learning.breakthroughactionandresearch.org/

to allow authentication at the community level—use of scratch-off codes, holograms, and quick response (QR) codes—are described below.

Scratch-off product authenticity verification at the point of sale has been used with some success, notably in Nigeria.

- In 2010, for example, Nigeria's NAFDAC rolled out the MAS to help consumers verify the identity of SF medical products at the point of purchase. With MAS, pharmaceutical manufacturers place a hidden code under a scratch panel on the medicine packaging. When consumers purchase the medicine, they scratch the panel to reveal a unique, one-time-use alphanumeric code. The consumer texts the code to a dedicated phone number on the medicine pack, then receives a real-time Short Message Service (SMS) text response authenticating the source of the medicine. If the medicine is determined to be falsified, the consumer is given a hotline number to report the falsified drug (NAFDAC 2023, Oyetunde 2019). However, MAS has had mixed effectiveness.

  Following a successful pilot, in 2012 NAFDAC made MAS mandatory on antimalarial and antibiotic medicines imported or manufactured in Nigeria (NAFDAC 2023, Oyetunde 2019). Results were mixed. In a 2013 assessment of MAS, two manufacturers who participated in MAS reported that consumers' use of MAS was low compared to sales of medicines with the scratch panel (18% and 55% of items sold) (Oyetunde 2013). A separate study of 774 respondents from across Nigeria found that more than 70 percent were aware of MAS. Of those, 50 percent had not used MAS at all; 22 percent expressed average utilization; and 28 percent reported high use. Two factors were associated with consumers' use of MAS: 1) awareness raising by pharmacists and 2) feedback received from the MAS system. Whether the pharmacist had spoken to the consumer about MAS influenced consumer knowledge and use of the service. The response consumers received from the MAS system after first use positively influenced ongoing consumer use; the quality of cell phone service and power outages affected whether the consumer received a real-time response and directly impacted uptake and use of MAS (Aisagbonhi 2016).

  A 2021 study found that public awareness, knowledge, and use of MAS was particularly low in rural areas in southeast Nigeria. The major factors affecting the level of public awareness, knowledge, and use of MAS included educational level and location of the respondents. Lack of awareness on the use of MAS in turn led to low utilization of the service in rural locations when compared to higher use in urban centers. Respondents cited poor network services leading to a delayed response to their text at the point of purchase or lack of a code on drug packaging as a deterrent to using MAS. Respondents also felt that messages about MAS were catered to more educated, urban populations. The recommendations for improved use of MAS included creating messages more appropriate to rural audiences, improved network services, and requiring all pharmaceutical manufacturers to use MAS (Chinedu-Okeke, Okoro 2021).

Holograms on medical product packaging have also been used for product authentication. Absence of a hologram when one is expected prompts providers and consumers to report those medicines as being fraudulent. This also helps identify companies or individuals that sell fraudulent products.

- Beginning in 2005, the Government of Malaysia required all registered medicines to include serialized holograms. Almost immediately, Malaysia significantly increased seizure of counterfeit medicines following the introduction of the holograms (from 7,704 products a

year prior to the program to 23,263 products in the first nine months of 2006), which may have been due to the holograms (Mirandah Asia 2007).

It has been difficult to build broad consumer awareness of how the holograms can be used to protect consumer safety. A survey in 2018 (13 years after the program began) of 649 respondents (mostly young, female, and relatively well educated) showed that just more than half (55%) knew that proper registration and labeling of medicines is required in Malaysia, and only a third knew how to recognize a registered medical product in Malaysia through the presence of a hologram. Almost half (46%) responded that they had received medications without holograms. Only a quarter of respondents (26%) knew how to issue a formal complaint about a medicine lacking a hologram (Ong 2020). Thus, even in a middle-income country, among a well-educated segment of the population, consumer use of the authentication technology was limited.

- In 2023, the Government of India began large-scale implementation of consumer authentication of medicines to fight counterfeiting using QR codes. The government has mandated QR codes on the packaging of the 300 most commonly used life-saving pharmaceutical products in the country. As of 2022, 40 percent of the medicines produced in India are exported and already use QR codes in the packaging of these exports. Consumers can scan the QR code to authenticate the medicine they are purchasing (Authentication Solution Providers' Association (ASPA) 2022, Kandregula 2022, QR Code Tiger 2023). This program has just been implemented, and future research will be needed to determine its effectiveness.

Repackaging is a significant challenge for authentication. Use of authentication technologies typically requires use of the original medicine packaging. When a medicine is removed from its original package and repackaged in smaller units (e.g., for sale to people who can afford to buy only a few pills at a time as is common in some LMICs), consumer authentication approaches are rendered ineffective. Several larger LMICs have introduced technologies that enable consumers to authenticate medicines. Although the literature shows evidence of some effectiveness in terms of consumer awareness of SF medical products, authentication technologies have many limitations in LMICs. For authentication technologies to benefit consumers, greater awareness and use of these tools is necessary among consumers.

Most authentication technologies involve product packaging and as such, require the cooperation of manufacturers. That is, manufacturers must incorporate the authentication mark on their packaging and implement other requirements of the system such as a database of codes and medicine information, an online site where they can be accessed, and/or a system to respond to queries. Not all manufacturers will be well positioned to participate in such programs, even if they understand the benefits, due to the added expense of changing product packaging to add authentication technologies. Furthermore, even though the most vulnerable populations possess mobile phones, which would allow them to participate in some authentication programs, illiteracy may hinder use. Health literacy is an important step to consumers managing their own health.[7] An additional option would be for the next level of community-level actors (CHWs, pharmacists, providers) or their medicine sources (medical shops, pharmacies) to use these technologies.

[7] https://knowledgesuccess.org/2020/07/23/a-new-quality-of-care-framework-to-measure-and-respond-to-peoples-experience-with-self-care/?hilite=literacy

Changing Purchasing Behavior Through Licensing and Providing Incentives for Providers Meeting Standards

Ultimately, awareness is useful only if it changes behavior. Checking medicine authenticity will be out of reach for many patients and will likely not be available for many medical products on the market. A more effective and practical approach may be to focus on shifting patient buying behavior from risky to quality-assured sources, such as pharmacies implementing quality practices. For that to happen, the identity of such outlets must be obvious to consumers.

One option for identifying and publicizing the quality of a medicine retailer's product is through government licensing. To use this approach, the NRA must include requirements related to procurement of medicines from quality-assured sources and compliance with good storage, distribution, and dispensing practices in its licensing regulations. The NRA must also inspect medicine retailers or otherwise verify compliance with the regulations prior to issuing a license as well as revoke licenses for non-compliance. Finally, the government must broadly publicize that licensed medicine retailers meet the standards and sell products that can be trusted.

Such an approach requires the appropriate regulatory framework, an NRA able to conduct inspections at an adequate scale, and government willingness to act when needed. With these regulatory requirements in place, a corresponding awareness campaign about the importance of quality-assured medicines and how to identify retailers who sell them (e.g., visual display of licenses) can help generate demand for quality-assured medicines and direct patients to preferred vendors. While this approach is promising, for its ultimate success, medicine retailers' product sources must be considered in licensing or other oversight decisions.

Medicine retailers can face real barriers in procuring medicines from quality sources. In a 2021 study of programs designed to strengthen drug shops in six countries, WHO's Alliance for Health Policy and Systems Research found that interventions connecting drug shops with reliable commercial suppliers (in Nigeria) or directly providing high-quality medicines to drug shops (in Indonesia) helped achieve intended outcomes (such as an in increase in demand for community drug shops and positive relationships between drug shops and their clients) when the medicines were readily available. When major suppliers were stocked-out, medicine retailers sought the product in the open market to satisfy consumer demand (Lamba 2021).

A promising approach is the accredited drug dispensing outlets program in Tanzania, which helps reduce the number of unregistered medicines on the market. This is achieved via a holistic approach to improve capacity by developing an accreditation model, providing training and incentives for accredited drug dispensing outlets providers, improving public awareness through education campaigns, and focusing on regulation and inspection (Rutta 2014).

Consumer Reporting of Adverse Drug Reactions

Consumers can contribute to detection of SF medical products by reporting or suspected adverse drug reactions (ADR) [8] following use of medicines, some of which may be related to product quality issues. If multiple patients report unexpected treatment failures, this might signal the presence of an SF medical product. Adverse drug events, which are reported into the country's pharmacovigilance system for causality analysis and further investigation, may be

[8] Adverse drug reactions can lead to a patient interrupting treatment before completion, and thus contribute to avoidable morbidity, treatment failure, reduced quality of life. So treatment failure is a result of ADR and is not an ADR itself. a-practical-handbook-on-the-pharmacovigilance-of-medicines-used-in-the-treatment-of-tuberculosis.pdf (who.int)

attributed to use of a poor-quality medicine or to other safety issues such as medication error. Patient reporting of problems (i.e., treatment failure or adverse events) directly to the appropriate authority or to the health care provider (who then reports to the authority) is an important step in identifying medicine quality problems. Findings of consumer-reported ADRs include the following:

- A recent review of ADR reports submitted to major pharmacovigilance databases (the European Medicines Agency's EudraVigilance and U.S. Food and Drug Administration's Adverse Event Reporting System) found that the majority of reports originated from consumers rather than health care professionals (Pozsgai 2022).

- A study of patient ADR reporting in Ghana found that two-thirds of respondents who had experienced an ADR had reported the reaction. Of those, 68 percent reported the ADR to their health care professional. Only 3 percent were aware that they could report through the ADR patient reporting system. The study found numerous barriers to patient reporting of ADRs, including the patient not knowing the name of the medicine that led to the ADR (due to the common practice of medicines being dispensed in unlabeled white envelopes from bulk sources); lack of involvement from pharmacies in encouraging reporting of ADRs; and reliance on reporting to health care workers (some respondents were reluctant to do so). The study concluded that there should be multiple and flexible routes for ADR reporting to meet patient needs and that medicine dispensers should share more information about ADRs and ADR reporting with the public (Jacobs 2018).

Increasing patient reporting of treatment failure and suspected ADRs holds promise for detection of SF medical products but will require more countries to have systems for consumer reporting, increased public awareness of the importance of such reporting, and development of multiple easy-to-use avenues for reporting. Use of reporting to identify poor-quality medicines will require regulatory, medical, and pharmacovigilance systems that are able to determine whether medicine quality is the source of the problem.

Helping Actors Identify Quality Sources of Medicines

The sections below identify interventions that help different actors (health care providers, CHWs, medicine retailers, and clinic health centers) identify quality sources of medicines to change their behavior and promote a shift from use of poor-quality to quality sources of medicines.

Health Care Providers/Community Health Workers

Health care providers (at clinics or health centers) and CHWs are on the frontlines of health and medicine services in urban and rural communities across LMICs. In Africa, more than 400,000 million people receive most of their health services from CHWs (Village Reach 2022). In many cases, these actors are also the health care system's final touchpoints with the patient. As they are responsible for diagnosing health problems and prescribing medicines, they can heavily influence demand for quality medicines by educating and raising their clients' awareness and by selling or dispensing only quality-assured medicines. They can also help identify SF medical products by reporting suspicious medicines.

Reporting suspected poor-quality products. Although they provide medicines, health care providers and CHWs tend not to report medicines suspected of being poor quality. WHO has observed that while only 12 percent of the reports on SF medical products in its Global

Surveillance and Monitoring System were initiated by health care providers, they were among the most useful (WHO 2017). Interventions are needed to empower health care providers and CHWs at the point-of-care to proactively identify and report SF medical products.

WHO uncovered numerous factors involved in non-reporting by frontline health workers. These included lack of awareness of medicine quality problems, unfamiliarity with reporting systems, absence of reporting systems, and low response from authorities to reports. WHO further noted that some health care providers were reluctant to report suspected SF medical products due to fears of reprisal or civil action (WHO 2017). WHO has launched interventions to increase health care providers' reporting of suspicious medicines, including piloting a smartphone-based application, where health care providers photograph a suspicious medicine and send it to the regulator. Regulators are expected to respond within 48 hours. This pilot program has been launched in Tanzania and Southeast Asia. If successful, it can be scaled-up around the world (WHO 2017).

Identification of SF medical products. Both formal and informal providers often lack knowledge about medicines, but visual inspection is a simple, feasible technique to use in field screening (WHO 2017, 2020). According to WHO guidelines, the packaging of each collected sample, its labeling, and its package leaflet should be inspected visually for any signs of being an SF product. Checklists for this purpose have been published and may allow the identification of suspicious medicine samples by frontline health workers even before any chemical analysis is performed (WHO 2016).

Several checklists have been developed to help frontline health providers identify SF medical products, such as WHO's 36-question Be Aware Tool and the International Pharmaceutical Federation/USP's 50-question Visual Inspection Tool. Both tools can be used to identify SF medical products; however, the checklists do require greater understanding of technical and regulatory information than most frontline providers have, making them difficult to use (Schiavetti 2020).

- Findings from a cross-sectional survey conducted in the Democratic Republic of Congo (DRC) by the Department of Public Health, Institute of Tropical Medicine in Belgium, with the Direction de la Pharmacie et du Médicament in DRC, suggest that a simplified version of the visual inspection checklist consisting of 26 Yes/No questions and instructions on how to use the checklist were good predictors of SF medical products when compared to full laboratory tests. The questions assess characteristics of medicines that do not require technical expertise or access to regulatory information. The questions are categorized into four sections that deal with packaging, identification, traceability, and physical appearance. Each question corresponds to a level of risk to the patient so that the provider can decide if the medication is safe to dispense, dispense with an explanation to patients, or make a risk-benefit evaluation before dispensing (replace the poor-quality medicine or provide an alternate treatment). Given the burden that frontline workers face in providing care to patients, the simplified checklist can be effectively used at the point of care to identify and take quick action when faced with suspected SF medical products. Digitization and linking with pharmacovigilance programs can also be considered as a next step in the SF medical products reporting feedback loop (Schiavetti 2020). An assessment of the simplified checklist's utility has not yet been reported in the literature.

ADR reporting. Frontline health care workers can identify suspected ADRs that might be linked to SF medical products, although there are barriers to reporting.

- Studies conducted in Denmark and the United Arab Emirates reported that difficulty accessing reporting forms, lack of awareness of the requirements for reporting, insufficient understanding of the purpose of reporting, busy schedules, and uncertainty as to whether the drug caused the ADR led to underreporting (Alnajjar 2019, Sørup 2015).

- In Vietnam, providers who reported ADRs were more likely to have been trained in reporting practices, understood the forms, and had the knowledge required to access reporting forms; underreporting was associated with lack of forms, knowledge about where to access them, and time (Le 2020).

- In South Africa, a study implementing a pharmacovigilance program targeted at pharmacists within a hospital system for in-patient ADR reporting found that knowledge and reporting practices improved, while non-reporting decreased. The study concluded that pharmacists play an important role in improving the safe use of medicines (Terblanche 2018).

Pharmacists and Medicine Retailers

Pharmacists and medicine retailers are another point in the supply chain before medicines are dispensed. Thus, they play an important role in controlling the quality of medicines. Medicine retailers vary tremendously, from pharmacies that are carefully regulated and staffed by trained pharmacists to informal drug shops that, in many countries, are authorized to sell a limited list of medicines. However, retailers are not always well prepared to fulfill these responsibilities. There are gaps in awareness and training related to SF medical products even among pharmacists at the more sophisticated end of the spectrum of medicine retailers.

- In a desk review of the national pharmacy curricula in six sub-Saharan African countries and two Asian countries, researchers found that only one pharmacy curriculum specifically mentioned training in SF medical products (Ferrario 2019).

- A 2021 pilot study designed and implemented by WHO and the International Pharmaceutical Federation at three universities in Cameroon, Senegal, and Tanzania showed that a dedicated course for pharmacy students led to improved knowledge about SF medical products. The course includes detailed information on root causes of SF medical products; the most at-risk products; early signs of the presence of SF medical products in the supply chain; how to avoid, detect, and report SF medical products; and how to advise patients who have been exposed to SF medical products. The study findings suggest that incorporating the course into existing university curricula and empowering pharmacists to intervene and protect communities from SF medical products is a promising strategy (Kusynova 2023, International Pharmaceutical Federation 2021).

Since poor-quality products can easily pass through unregulated borders, those areas are particularly vulnerable to SF medical products. Pharmaceutical outlets in those areas should be made aware of both the availability of such medicines and of reporting mechanisms via national pharmacovigilance alerts.

- Investigating access to and perception of counterfeit medication along transport corridors in East Africa (DRC, Kenya, Tanzania, and Uganda), a study revealed that almost 80 percent of drug shop owners in those areas were aware of the existence of

counterfeit medicines (Fomundam 2014). Most of them learned about counterfeit medicines through mass media; only 19 percent indicated that they had any formal training on how to identify counterfeit medicines. Almost 66 percent reported that they sourced their products from registered wholesalers and distributors; about 34 percent procured medicines from unregistered sales representatives. These interviews with shop owners in a large and high-risk geographic area indicate that training of this population can help protect and inform consumers about SF medical products and quality-assured sources.

- A study in Iraq assessed the effectiveness of national pharmacovigilance alerts to community pharmacies. National alerts about SF medical products were shared with drug stores and community pharmacies through a Facebook page. Study participants agreed that national alerts were helpful in identifying SF medical products in three ways: through medication price sticker, cost, and packaging features (Al-Jumaili 2021).

Other interventions to identify SF medical products include:

- Improved awareness of and training in pharmaceutical authenticity and quality at the retail pharmacy level.
- Dedicated training courses for pharmacy students in identifying SF medical products.
- For pharmacists and other medicines vendors, training and systems to:
  - Confirm medicine registration with the NRA
  - Report SF medicines to the NRA
  - Conduct visual inspection of medicines using the Be Aware Tool or other tool
  - Use scanning technology for verification (barcodes) where available or QR codes with mobile phones
  - Monitor national medical product alerts issued by WHO when SF medical products are found (can be accessed at the WHO Medical Product Alert website)
  - Educate patients on the risks of SF medical products and advise them to report changes in medicine efficacy or appearance of drugs, which will help establish the outlet as a place to obtain quality medicines and build trust with their customers

Clinics and Health Centers

Clinics and health centers play an important role in ensuring the availability of quality-assured medicines *before* medicines reach their end users. All the interventions mentioned above—from raising awareness of the issue of SF medical products to increasing reporting of suspicious medicines, visually inspecting medicines, using authentication technologies, and reporting ADRs to pharmacovigilance systems—are relevant here. Additionally, commercial and faith-based drug-supply organizations (and possibly larger clinics) might be able to utilize available screening technologies to assess medicines quickly and inexpensively. As with most field-based screening technologies, the following technologies likely would be appropriate only for larger clinics or organizations that provide medicines to CHWs.

A 2020 evaluation of 12 medicines screening devices[9] showed that the devices could accurately detect medicines with the wrong or none of the active ingredient (indicating a falsified product). However, it was more difficult for the disposable tests to identify formulations as substandard medicines (i.e., medicines containing reduced amounts of the active ingredient) (Zambrzycki 2021).

Global Pharma Health Fund (GPHF) has developed an inexpensive field test kit to verify drug quality and detect falsified medicines in the field. GPHF-Minilab allows users to conduct physical and chemical screening tests to confirm drug identity and content. It works on more than 100 drug compounds, selected due to their public health interest and reports of falsification. A USP technology review found that trainees with technical and non-technical backgrounds could become advanced users with two weeks of training (GPHF) 2023, (USP 2020). Two studies of local faith-based organizations using the GPHF-Minilab to identify SF medical products in Africa and Asia found that the tool was very helpful in identifying a subgroup of SF medical products at the local level. Reports from these studies resulted in international WHO Medical Product Alerts and several national alerts. Both studies concluded that using the GPHF-Minilab was a cost-effective way to add to the global surveillance of SF medical products (Gnegel 2022, Petersen 2017).

Future Considerations

Over the past few years, there has been a huge global push to tackle SF medical products. In 2019, 50 signatories representing various research and global health organizations released the Oxford Statement and Call to Action to make access to quality medical products an immediate global priority and to encourage research to inform policy and implementation of programs. The statement called for accelerated progress on the adoption of the WHO's "**Prevent, Detect and Respond**" Strategy (WHO 2017). USAID and other global stakeholders have supported comprehensive policies to ensure medicines adhere to quality standards, build regulatory capacity, strengthen surveillance systems and technologies, facilitate global cooperation, and raise global awareness. Focus at the international and national levels should continue, but additional focused attention is also needed at the community level on demand-side interventions to prevent, detect, and respond to SF medical products.

Of the key needs highlighted in the Oxford Statement, evidence gaps remain in areas that specifically address community needs. USAID and other stakeholders should consider these when setting future program priorities.

In the **prevention** field, there are gaps in: (1) education of health workers, policymakers, and the public on the importance and impact of SF medical products, and (2) incorporation of these elements in pharmacy, nursing, and medical curricula. Extra effort is essential in these areas by way of **awareness-raising campaigns as a component of other SBC interventions** to engage facility-based health care workers, CHWs, and individual consumers to empower them to be active participants and part of the solution in addressing SF medical products. Further investments in strategic SBC approaches and accompanying research to measure its impact are sorely needed.

[9] The 12 devices included three near infrared spectrometers (MicroPHAZIR RX, NIR-S-G1, Neospectra 2.5), two Raman spectrometers (Progeny, TruScan RM), one mid-infrared spectrometer (4500a), one disposable colorimetric assay (Paper Analytical Devices, PAD), one disposable immunoassay (Rapid Diagnostic Test, RDT), one portable liquid chromatograph (C-Vue), one microfluidic system (PharmaChk), one mass spectrometer (QDa), and one thin layer chromatography kit (GPHF-Minilab).

NRAs play an important role in communicating information about regulated products to patients and consumers, patients' caregivers, health care professionals, and even the media.[10] Effective communication involves not only the labeling of medicines and medical products, but also communicating the concepts of risk and benefit.[11] Targeted risk communication by regulators with the public including medical product recalls is another important area of work to study and measure for impact in influencing behavior.

In the **detection** field, there are gaps in: (1) pharmacovigilance, and (2) investment in innovative field screening devices for rapid detection of SF medical products. Pharmacovigilance and SF medical product strategies go hand in hand. Safer use of medicines should address ADRs, but also how to identify and **report SF medical products** throughout the supply chain. Furthermore, procedures to identify, evaluate, and report ADRs should include procedures to identify, evaluate, and report SF medical products. Investments in this area are important at the community level, particularly for frontline providers such as CHWs and pharmacists.

Finally, in the **response** field, there are gaps in: (1) mandatory and timely reporting of SF medical products to relevant NRAs and WHO by state and non-state actors, and (2) plans to respond to SF medical products, including ways to engage the public and health workers to ensure an appropriate public health response. At the wholesaler/distributor and pharmacy levels, additional strategies to **incentivize buying from reliable government-approved suppliers** are needed. Awareness of SF medical products at this level may not be enough when profit motives are at play. There is no benefit to wholesalers/distributors if they can purchase cheaper medicines elsewhere and no incentive to report to NRAs and WHO. There is an opportunity for USAID to focus on potential strategies and interventions to address these gaps when setting program priorities, including specific language addressing SF medical products.

Another key area requiring further attention and an opportunity for USAID is **data collection** and interpretation at the global, national, regional, and community levels to support the SF medical products evidence base. Policymakers and regulators need more data on SF medical products, vulnerabilities in the pharmaceutical QA system, and the proportional allocation of appropriate resources to manage them. Through supported risk-based post-marketing surveillance, NRAs can take the lead in gathering this evidence around SF medical products.

Manufacturers, wholesalers, procurers, and supply chain managers play key roles in combatting SF medical projects with supply-side strategies strengthened by demand-side initiatives, such as mass media campaigns directed at consumer behaviors and preferences to ensure that quality products reach patients, engage more parties in identifying SF medical products, and shift procurement and consumption behaviors. This approach should help facilitate self-funded and potentially sustainable QA systems, maximizing country investments, and enabling countries to move away from donor support for regulatory systems strengthening.

There is no one size fits all approach for tackling the problem of SF medical products. Each country must do an in-country assessment of its health system to determine areas most in need of additional resources and support. An effective system must focus on comprehensive policies to combat SF medical products with particular focus at the community level.

[10] https://www.fda.gov/about-fda/reports/strategic-plan-risk-communication#glance
[11] https://www.fda.gov/about-fda/reports/strategic-plan-risk-communication#purpose

Resources

USAID Vision for Health System Strengthening 2030
https://www.usaid.gov/sites/default/files/2022-05/USAID_OHS_VISION_Report_FINAL_single_5082.pdf

USAID Vision for Health System Strengthening 2030-Executive Summary
https://www.usaid.gov/sites/default/files/2022-05/USAID_OHS_VISION_ExecutiveSummary_FINAL_single_508.pdf

Strengthening Primary Health Care through Community Health Workers: Closing the $2 Billion Gap
https://www.usaid.gov/sites/default/files/2022-05/USAID_FAH_Report_digital_version_nov21-508.pdf

Social and Behavior Change and Health System Strengthening
https://www.usaid.gov/sites/default/files/2022-05/SBC_and_HSS_White_Paper_Jan_2022_Final_508_tagged_1.pdf

Health System Strengthening Learning Agenda
https://www.usaid.gov/sites/default/files/2022-05/Final_HSS_Learning_Agenda_.pdf

Health Systems Practice Spotlight Series
https://www.usaid.gov/global-health/health-systems-innovation/health-systems/resources/practice-spotlight-series

USP Global Public Policy Position: Combatting Substandard and Falsified Medicines
https://www.usp.org/sites/default/files/usp/document/about/public-policy/combatting-substandard-and-falsified-medicines-policy-position.pdf

A Framework for Risk-Based Resource Allocation for Pharmaceutical Quality Assurance for Medicines Regulatory Authorities in Low- and Middle-Income Countries
https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based_resource_allocation_framework_june2018.pdf

Guidance for Implementing Risk-based Post-marketing Quality Surveillance in Low- and Middle-Income Countries
https://www.usp-pqm.org/sites/default/files/pqms/article/risk-based_resource_allocation_framework_june2018.pdf

The Medicines Risk Surveillance (MedRS) Tool, https://medrsv2.com

Safe Medicines, https://www.safemedicines.org

Be Aware Tool for Visual Inspection of Medicines
ps://www.whpa.org/sites/default/files/2018-12/Toolkit_BeAware_Inspection.pdf

Tool for Visual Inspection of Medicines
https://www.fip.org/files/fip/counterfeit/VisualInspection/A%20tool%20for%20visual%20inspection%20of%20medicines%20EN.pdf

A simplified checklist for the visual inspection of finished pharmaceutical products: A way to empower frontline health workers in the fight against poor-quality medicines and Instructions for use
https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00211-9/figures/1

https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00211-9/figures/2

GHPF Minilab, https://www.gphf.org/en/minilab/

WHO Expert Committee on Specifications for Pharmaceutical Preparations,
https://www.who.int/medicines/publications/pharmprep/trs_996/en/.

WHO Global Surveillance and Monitoring System for substandard and falsified medical products
https://apps.who.int/iris/bitstream/handle/10665/326708/9789241513425-eng.pdf?sequence=1&isAllowed=y

WHO Medical Product Alerts
https://www.who.int/teams/regulation-prequalification/incidents-and-SF/full-list-of-who-medical-product-alerts

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