Promoting the **Quality** of **Medicines** Plus

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

Background

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. 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 that focus on strengthening medical product supply chains are not enough; **demand generation** for quality-assured medical products by increasing provider and consumer awareness and influencing behavior must complement these strategies. Demand-side initiatives include interventions such as mass media campaigns directed at consumer behaviors and preferences. Increased demand for quality medical products pushes health systems to ensure that only quality products reach patients, engages more health system actors in identifying substandard and falsified (SF) medical products,[1] and can shift procurement and consumption behaviors.

An essential component of access is the **appropriate use** of quality-assured medical products (medicines, vaccines, devices). However, the use of SF medical products makes it difficult for health systems to respond effectively to public health needs. Strong national regulatory authorities (NRAs) 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. Patients using SF medical products can lead to treatment failures and antimicrobial resistance, prolonged illness, and an increase in the overall risk of morbidity and death.

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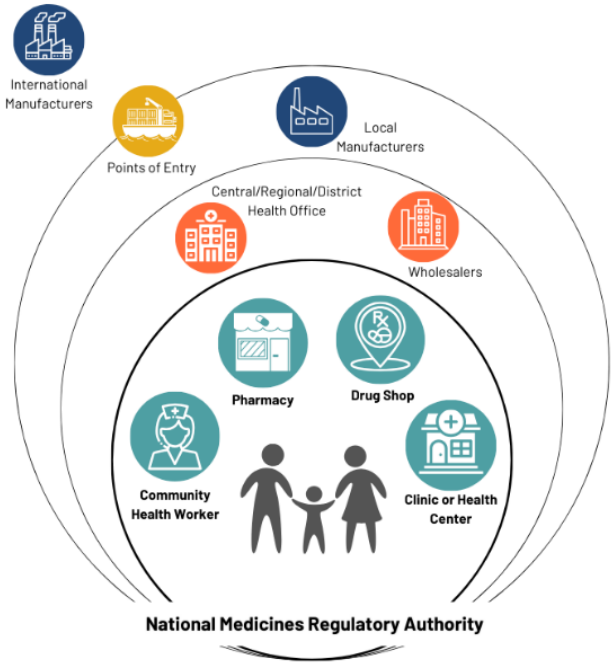
Objective

USAID's 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 and conducted a desk review of peer-reviewed articles, grey literature, and policy and advocacy documents to identify demand generation interventions as part of social and behavior change (SBC) strategies implemented at the individual and community levels. Although SF medical products present a global challenge with a substantial health and economic burden on health systems, the literature on interventions and strategies to increase community awareness of SF medical products to create demand for high-quality medical products is scarce. Available literature specific to SF medical products highlights the scale of the problem, but few studies are evidence-based. Only a handful of 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), thereby representing a major gap.[2] Breakthrough ACTION 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.

Medical Product Quality Ecosystem



Findings and Future Considerations

Despite sparse literature, the following interventions target patients, community health care providers, and medicine retailers and are potential ways to influence demand:

- Raising awareness of the presence of SF medical products in the market and of 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); and
  - Screening technologies (to identify SF medical products).
- Providing incentives for providers who meet quality standards.

- Raising the awareness of actors (i.e., patients, community health workers, medicine retailers) of 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, such as by reporting medicines that fail to treat or medicines associated with adverse events.

Helping Actors Identify Quality Sources of Medication

The sections below identify interventions that help patients, healthcare providers, community health workers (CHWs), medicines 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.

Patients

Patients cannot eliminate SF medical products in their communities. However, patients who consume medicines and the health workers who provide them can decrease the risk of the 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.

Awareness-Raising Campaigns. A few interventions in Africa identified in the literature have sought to raise public awareness of SF medical products.[3,4,5] Though they demonstrate that public awareness can be increased relatively quickly, at least in the short-term, there is a paucity of such campaigns and/or assessments in the literature. 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 is not clearly established in the limited available reports that are specific to SF medical products, awareness campaigns appear to either have affected intentions to change behavior or have in fact 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, other donors, and stakeholders 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 them.

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 the 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.[6] Some approaches in recent years to allow authentication at the community level have included use of scratch-off codes, holograms, and quick response (QR) codes.[7,8,9,10,11,12]

Though 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.

Healthcare Providers/Community Health Workers

Healthcare providers (at the clinic or health center) 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 community health workers.[13] In many cases, these actors are also the healthcare 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 the awareness of their clients and by selling or dispensing only quality-assured medicines. They can also help identify SF medical products by:

- **Reporting suspected poor-quality products.** Interventions are needed to empower healthcare providers and CHWs at the point of care to proactively identify and report SF medical products.
- **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.[14,15]
- **Adverse drug reaction (ADR) reporting.** Frontline healthcare workers can identify suspected ADRs that might be linked to SF medical products.[16,17,18,19]

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.[20,21,22,23,24]

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. This will help establish the outlet as a place to obtain quality medicines and build trust with their customers.

Future Considerations

The past few years have seen a huge global push to tackle SF medical products. USAID and other global stakeholders have supported comprehensive policies that ensure medicines' adherence 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 attention is needed at the community level on demand-side interventions to prevent, detect, and respond to SF medical products.

Evidence gaps remain in areas that specifically address community needs. USAID and other stakeholders should consider these when setting future program priorities.

Opportunities to study gaps in the **prevention** field include:

- Education of health workers, policymakers, and the public on the importance and impact of SF medical products, and
- Incorporation of these elements in pharmacy, nursing, and medical curricula.

Opportunities to study gaps in the **detection** field include:

- Pharmacovigilance, and
- Investment in innovative field screening devices for rapid detection of SF medical products.

Opportunities to study gaps in the **response** field include:

- Mandatory and timely reporting of SF medical products to relevant NRAs and the World Health Organization by state and non-state actors, and
- Plans to respond to SF medical products, including ways to engage the public and health workers to ensure an appropriate public health response.

Another key area requiring further attention and an opportunity for USAID, other donors, and stakeholders is **data collection** and interpretation at the global, national, regional, and community levels to support the SF medical product 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.

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