Mitigating the Public Health Risk of Substandard and Falsified Medical Products Distributed through Informal Markets

Issue:
The United States seeks the support of the Steering Committee for a new prioritized activity to better understand the public health risks posed by distribution of substandard and falsified (SF) medical products through informal markets and develop strategies for national regulatory authorities (NRAs) to mitigate those risks while assuring communities have access to the medicines they need. The United States is prepared to provide support for such activity.

Background:
Many countries around the world have markets where vendors congregate to sell a wide variety of products to their local communities. In many parts of the world, particularly in low to middle income countries, these markets are the main outlet that supply rural and urban communities with locally produced food products, crafts, traditional medicines, clothes, and other useful items. These markets tend to be loosely regulated by local authorities and are not overseen by the NRAs. Some vendors in these markets also provide medicines to the local population who may lack access to an approved pharmacy or medical facility. This is particularly true for rural communities where it may not be economically feasible to open a pharmacy or that may be far from urban centers where pharmacies are prevalent (Wafula et al., 2012).

For some locations, informal drug sellers meet a market demand for convenient and accessible medicines (Goodman et al., 2007). Often these vendors can provide these medications on an as-needed basis and can sell their products by the pill or in small amounts that would be illegal in pharmacies or formal markets with packaging restrictions (Van Der Geest 2013). These vendors usually have a limited supply of products and tend to focus on products needed by their communities (Van Der Geest 2013). Due to lack of oversight, limited pharmacy knowledge, and the questionable supply chains for these products, medical products sold in informal markets may be SF medications that present a public health risk.

While internet sales of medical products may have similar implications, this proposal excludes them since internet sales is already being considered in a working group under the World Health Organization Member State Mechanism for Substandard and Falsified Medical Products (WHO MSM).

Possible activities might include:

1. Exploring existing definitions and developing a consensus definition of informal market as it relates to medical products.
2. Commissioning a study to a) identify the underlying causes, b) assess the public health impacts, and c) assess/evaluate the economic impacts of informal markets for medical products in low- and middle-income countries (1-3 countries).
3. Commissioning a study on the impacts of intervention methods employed by regulatory authorities to control/limit spread of SF medical products through informal markets such as closing illegal pharmacies and tightening control over the supply chain.
4. Developing a survey of member states on the prevalence of medical products distribution through informal markets in their jurisdiction, mitigation efforts used such as

awareness/education campaigns, regulatory action, compliance activities, public-private partnerships, and lessons learned.

5. Convene an open-ended expert session on the issue to hear about current research in this area and raise awareness of the public health and economic trends and emerging/effective approaches to combat the distribution of SF medical products in informal markets.
6. Establishing a working group to gather information on this topic to create a tool kit or guidance document to help regulatory authorities address medical product distribution through informal markets.
7. Developing an awareness/education campaign for consumers about risks medical products sold in informal markets might present to public health.

A Success Story:

An example to illustrate the type of information that would be useful to regulators is the work of the Tanzania Medicines and Medical Devices Authority, formerly the Tanzania Food and Drug Administration. The excerpt below appears in a 2020 National Academies for Sciences, Engineering, and Medicines report entitled, "*Stronger Foods and Drug Regulatory Systems Abroad*" page 171.

> The Accredited Drug Dispensing Outlets in Tanzania
> Informal medicines sellers are often popular in rural areas and other places pharmacies do not reach. Patients may value the convenience of the informal sellers, who are often an important source of health advice for communities. Recognizing the need these sellers meet, especially in underserved areas, the Tanzania Food and Drug Authority began an accreditation program in 2003. Over 9,000 drug stores have since been accredited, making the Accredited Drug Dispensing Outlets (ADDOs) the main medicines chain in Tanzania; 95 percent of Tanzanians live within 5 kilometers of an ADDO. The program has improved the quality and access to medicines, as well as rational use, including a particularly sharp improvement in observation of malaria treatment guidelines.
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> To gain accreditation, store owners and dispensing staff have to complete training in health, communication, and patient counseling, as well as local pharmacy laws, good dispensing practices, and rational use of medicines. The accreditation process also emphasizes business management skills, including record keeping. Review of ADDO records is, in turn, a window into dispensing practices and possible outbreaks for the health authorities. As an incentive to participate, shop owners are authorized to sell a limited list of restricted medicines, and the government promotes the stores through radio, flyers, and other mass media communication. Shop owners are also eligible for business improvement loans, allowing them to improve security or temperature control, for example. The program is also responsible for social benefits beyond those to health; as of 2013, about 90 percent of ADDO dispensing staff and 40 percent of owners are women.
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> One of the biggest advantages of the accreditation process is consolidated procurement. Pooled procurement means the store owners pay less for wholesale inventory; it also puts one qualified district-level officer in charge of wholesale purchases, a notoriously weak link in the drug supply chain. Improved procurement is reflected in the quality of the stock;

over 90 percent of samples collected from ADDOs by secret shoppers passed quality testing. A different secret shopper study found that 90 percent of child pneumonia cases presented to ADDO staff were appropriately referred.

The ADDO model has been duplicated in Liberia and Uganda. Wider implementation is complicated, because the program can be in conflict with professional practice laws in some countries.

SOURCES: Chalker et al., 2015; Embrey et al., 2016; Kaale et al., 2016; Liana, 2014; MSH, 2013; Rutta, 2014.

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