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Suppressing Substandard and Falsified Drugs in LMICs[5]

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In low and middle-income countries [LMICs], pharmaceutical products are often of poor quality. In part, this problem derives from inadequate storage conditions or forms of transportation, which increase the likelihood that, by the time drugs are consumed by patients, they have degraded. In part, it derives from unscrupulous behavior by manufacturers and distributors, who deliberately supply drugs that do not contain any (or enough) of the active ingredients they purport to contain.

Defective products of these sorts have come to be known as "substandard and falsified medical products." The World Health Organization [WHO] defines those terms as follows: Falsified medical products are those "that deliberately/fraudulently misrepresent their identity, composition or source"; substandard medical products are "authorized medical products that fail to meet either their quality standards or their specifications, or both."[6] We will follow the emerging convention and refer to them collectively as "SFMPs."

The data concerning the scale of this problem are chilling. In 2017, the WHO, after aggregating many studies, estimated that the 10.5% of the drugs distributed in low-income countries were SFMPs. In middle-income countries, the number was barely lower: 10.4%.[7] An even more recent and comprehensive study found the overall rate in low and middle-income countries to be 13.6% -- and the rate in Africa to be 18.7%.[8]

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[6] See WHO, "A Study of the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products," (2017), 1.

[7] Ibid., 7.

[8] See Sachiko Ozawa et al., "Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-Analysis," *JAMA Network Open* 1, no. 4 (2018).

The rates vary by type of drug. Least likely to be falsified or substandard are the anti-retroviral drugs used to control HIV/AIDS, because most of them are supplied through channels closely monitored by international donors. The rates for tuberculosis drugs and antibiotics are higher – somewhere between 6 and 17%. Most likely to be falsified or substandard are anti-malarial drugs.[9]

One of the most important arenas in which this problem has appeared is the distribution of COVID-19 vaccines. A recent report summarized the situation:

> China has been clamping down on counterfeit versions of its domestically produced vaccines, while Mexico and Poland have reported counterfeits of Pfizer vaccines being given to people for $1000 each. Mexican customs officials have also seized vials of fake Sputnik V vaccine destined for Honduras. An Interpol operation across southern Africa in July and August led to the identification of 179 suspects and the seizure of $3.5m worth of goods, including vaccines, face masks, and fake covid-19 test certificates.
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> "I've never seen such a dynamic situation before," Jürgen Stock, general secretary of Interpol, told *Time* magazine, "The liquid gold in 2021 is the vaccine, and already we are seeing that vaccine supply chains are targeted more and more [by counterfeiters]."[10]

The presence of SFMPs in the pharmaceutical markets of LMICs has several bad effects. First and most obviously, the patients who consume such drugs obtain either zero or reduced therapeutic benefit. The context in which this impact is most severe is the administration of anti-malarial drugs to young children, who are especially vulnerable to the disease. The most comprehensive study estimates that, globally, 122,350 children under the age of five die each year in subSaharan Africa alone as a result of consuming falsified or substandard anti-malarials.[11] As the authors of the study concede, a good deal

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[9] See R. Bate et al., "Substandard and Falsified Anti-Tuberculosis Drugs: A Preliminary Field Analysis," *International Journal of Tuberculoisis and Lung Disease* 17, no. 3 (2013); Theodoros Kelesidis and Matthew E. Falagas, "Substandard/Counterfeit Antimicrobial Drugs," *Clinical Microbiology Reviews* 28, no. 2 (2015): 451; K.F. Laerson et al., "Substandard Tuberculosis Drugs on the Global Market and Their Simple Detection," *The International Journal of Tuberculosis and Lung Disease* 5, no. 5 (2001); O Moses, V Patrick, and N Muhammad, "Substandard Rifampicin Based Anti-Tuberculosis Drugs Common in Ugandan Drug Market," *African Journal of Pharmacy and Pharmacology* 7, no. 34 (2013); UNITAID, "Tuberculosis Medicines: Technology and Market Landscape," (2014), 32; WHO, "Impact of Substandard and Falsified Products," 17.; Ozawa et al., "Prevalence and Burden of Sfmps."

[10] Kanchan Srivastava, "Fake Covid Vaccines Boost the Black Market for Counterfeit Medicines," *BMJ* 2021 (2021), https://www.bmj.com/content/375/bmj.n2754. See also Kerlijn Van Assche, Céline Caillet, and Paul Newton, "Medical Product Quality Report – Covid-19 Issues," (Medicine Quality Research Group, Centre of Tropical Medicine & Global Health, University of Oxford, 2021).; WHO, "Medical Product Alert N°7/2021: Falsified Covid-19 Vaccine Astrazeneca," (2021). (reporting distribution of falsified vaccines in Iran).; Nagesh N. Borse et al., "Responding to the Surge of Substandard and Falsified Health Products Triggered by the Covid-19 Pandemic," (US Pharmacopeia, 2021).

[11] See John P. Renschler et al., "Estimated under-Five Deaths Associated with Poor-Quality Antimalarials in Sub-Saharan Africa," *American Journal of Tropical Medical Hygiene* 92, no. 6 (2015).

of uncertainty surrounds these numbers. But there is little doubt that the number of deaths is appalling.[12]

Second, when patients consume drugs that are supposed to cure them and fail to do so, they (and their neighbors) lose faith in western medicine. In settings where such faith is already shaky, this can diminish their willingness to consult doctors in the future.[13]

Third, consumption of degraded medicines (or a course of treatment in which legitimate and falsified drugs are mixed) accelerates the emergence and spread of drug-resistant strains.[14]

Fourth, the pharmaceutical firms selling authentic versions of the drugs at issue also suffer. Some of their potential sales are displaced by fakes. More importantly, the reputations of the drugs and of the companies from which they purportedly emanate are damaged. Because the firms depend in part on revenue from sales of their products to fund their R&D programs, all of the potential beneficiaries of as-yet undeveloped drugs are hurt.

Finally, in cases in which SFMPs are purchased by public-health services, the result is a waste of the countries' scarce financial resources, which in turn either drains the government's coffers or impairs their ability to address residents' needs.

To be sure, some people benefit: counterfeiters, corrupt government officials, and distributors who violate the guidelines for safe storage of products. Their stake in the practice largely explains its persistence. But their interests plainly do not merit our attention.

Like rats in cities (or endemic viruses), SFMPs (substandard and falsified medical products) are probably impossible to eliminate completely. But we can and should reduce the number. One promising tactic would be to examine drugs periodically during their journeys from manufacturers to patients, thus enabling us to identify the bad versions when they appear and then to purge them. Many systems that would enable surveillance of this sort already exist, and more are in the offing. The challenge is to develop adaptations of one or more of these systems that would work throughout the world.

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[12] Cf. Sarah M. Beargie et al., "The Economic Impact of Substandard and Falsified Antimalarial Medications in Nigeria," *PLoS ONE* 14, no. 8 (2019). (estimating the consumption of poor-quality antimalarials causes 12,300 deaths a year in Nigeria).

[13] See Kelesidis and Falagas, "Substandard/Counterfeit Antimicrobial Drugs," 458.

[14] See Bate et al., "Substandard and Falsified Tb Drugs."; Kelesidis and Falagas, "Substandard/Counterfeit Antimicrobial Drugs," 458 ; WHO, "Global Surveillance and Monitoring System for Substandard and Falsified Medical Products," (2017), 6.; Sachiko Ozawa et al., "Modeling the Economic Impact of Substandard and Falsified Antimalarials in the Democratic Republic of the Congo," *American Journal of Tropical Medical Hygiene* 100, no. 5 (2019). The two factors emphasized in the text – failure to complete courses of treatment, and the presence of falsified and substandard drugs – are the most widely accepted explanations for the emergence of drug resistance in TB. Some scientists, however, contend the causes are more complex. See Keertan Dheda et al., "Global Control of Tuberculosis: From Extensively Drug-Resistant to Untreatable Tuberculosis," *Lancet Respiratory Medicine* 2 (2014): 324ff.

The existing and foreseeable systems fall into two broad categories. Systems of the first type rely on verifying the authenticity of the drugs that, at the end of the chain, are delivered to consumers. In simple variants of this approach, manufacturers embed visible or "scratchable" codes in their packages. The ultimate purchaser of a packet uses his or her cell phone to transmit an image of the code to the manufacturer and receives, in response, a text message indicating whether its contents are authentic. Systems of this sort include Sproxil (developed in Nigeria) and Pharmasecure (developed in Nigeria and India).[15]

Far more complex and effective members of this category are the comprehensive "track and trace" systems that, since the turn of the century, have been established in many jurisdictions. In such regimes, an authorized manufacturer of a properly registered product assigns a unique identifier to every package it produces and sells – a process known as "serialization." Thereafter, every wholesaler, distributor, and dispenser who has custody of the package records when and from whom it was acquired and when and to whom it is transferred. In some track-and-trace systems, those intermediaries also record the conditions under which the package was stored when in their possession. If all goes well, this process ensures that each package finally delivered to a patient is what it purports to be.

The United States is currently in the late stages of deploying a system of this sort. When fully operational, every manufacturer of a pharmaceutical product distributed in the U.S. will be obliged to attach a durable "Product Identifier" (PI) to every unit of the product it sells. Each PI will contain an expiration date, lot number, and "standardized numerical identifier." All intermediaries ("trading partners") will be required to use those PIs to "validate" every shipment they receive. All transactions must be recorded in a standardized electronic format – thereby making it possible to "track" every unit as it moves from manufacturer to customer. Equally important, retention of those records makes it easy to "trace" the series of hands through which any packet has previously passed. Comprehensive "traceability," in turn, will make it possible to identify (and then quarantine) drugs that have entered the chain through illicit channels.[16]

The development of the U.S. system has been onerous and expensive. The 2013 Drug Supply Chain Security Act, which launched the initiative, gave the FDA 10 years to implement it. The deadline was recently pushed back to November 27, 2024. As of this

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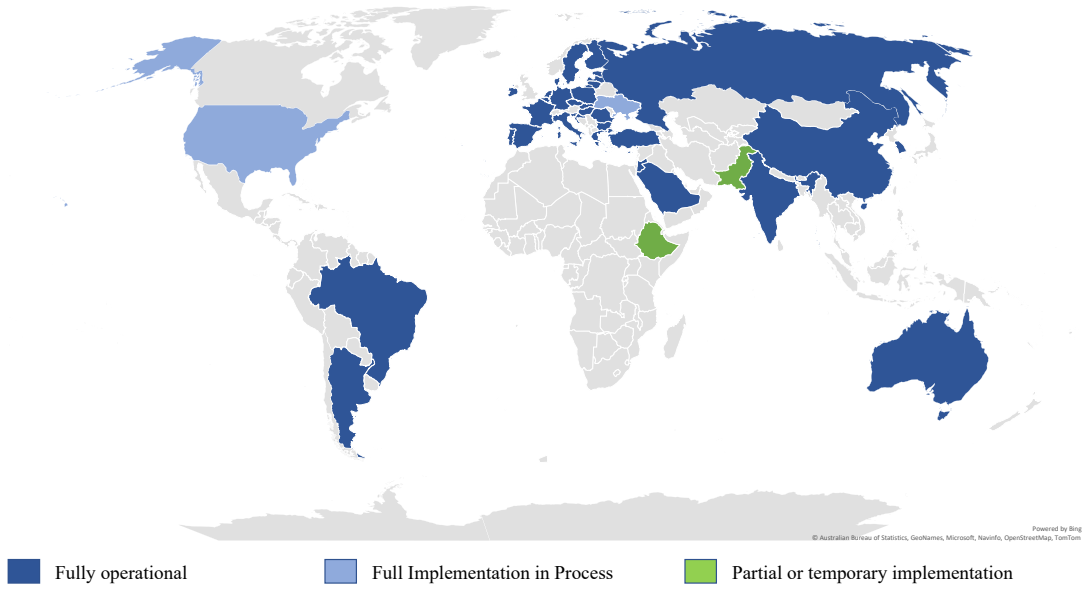
[15] *See* Huma Rasheed, Ludwig Höllein, and Ulrike Holzgrabe, "Future Information Technology Tools for Fighting Substandard and Falsified Medicines in Low- and Middle-Income Countries," *Frontiers in Pharmacology* 9 (2018): 3; Matthew Wall, "Counterfeit Drugs: 'People Are Dying Every Day'," *BBC News*, September 26, 2016 2016.; Jennifer Kite-Powell, "Pharmasecure Uses Mobile Device and Id Codes to Take on Counterfeit Drug Problem," *Forbes*, February 16, 2012.

[16] For a detailed description of the obligations of all of the members of the distribution chain, see U.S. Food and Drug Administration, "Are You Ready for the Drug Supply Chain Security Act," January 19, 2022, available at https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/are-you-ready-drug-supply-chain-security-act. Access to the formal Draft Guidance advising companies of their obligations can be obtained through https://www.federalregister.gov/documents/2022/07/06/2022-14342/drug-supply-chain-security-act-standards-for-the-interoperable-exchange-of-information-for-tracing. Descriptions and assessments of the emerging system include Elona Gjini and Albert I. Wertheimer, "Review of Drug Quality and Security Act of 2013: The Drug Supply Chain Security Act (Dscsa)," *Innovations in Pharmacy* 7, no. 3 (2016).

writing, uncertainty concerning how the new system will mesh with extant licensing requirements and how small-scale dispensers of drugs will be integrated into the system suggest that full deployment is not imminent.[17]

In many other countries and regions, similar track-and-trace systems are either already operational or will soon become so. The map set forth below shows the locations of the principal programs.[18]

Figure 3: "Track and Trace" Systems



Unfortunately, the systems adopted by the various countries and regions differ significantly in both architecture and rules. For example, India, Brazil, China, and the European Union currently use a "Point-of-Dispense Verification" approach, in which intermediaries are not required (at least in the absence of "cause") to record transactions.[19] That approach is less burdensome but also less robust than the comprehensive regimes already in place in Turkey, Russia, and Saudi Arabia and soon to be implemented in the United States and Brazil.[20] Another example: in the Chinese system, inclusion of the expiration date and batch number in the product identification information is optional, not mandatory.[21] With respect to aggregation, again the EU is lenient, requiring serialization

[17] See Joseph T. Kannarkat, Michael W. Denham, and Ameet Sarpatwari, "Improving Drug Supply Chain Security," *JAMA Health Forum* 5 (2024).

[18] The data underlying locations and classifications of the systems were derived from: https://vertassets.blob.core.windows.net/image/d9999998/d9999998-6807-4356-852d-902ef3e9453d/_kztyrworldmap.pdf;

[19] See Joeke Kootstra and Tineke Kleinhout-Vliek, "Implementing Pharmaceutical Track-and-Trace Systems: A Realist Review," *BMJ Global Health* 6 (2021).

[20] See ICMRA, "Recommendations on Common Technical Denominators for Traceability Systems for Medicines to Allow for Interoperability," (2021), 19, 32-34.; Michael Pisa and Denise McCurdy, "Improving Global Health Supply Chains through Traceability," (Washington, D.C.: Center for Global Development, 2019), 15.

[21] See ICMRA, "Recommendations on Common Denominators," 22.

only at the unit level; by contrast, India requires the application of unique ID numbers, not just to individual units, but also to the larger bundles that are typically used to ship products.

Because, for the reasons we have seen, a large percentage of pharmaceutical markets move across national borders, differences of these sorts both increase the costs borne by all parties of complying with the requirements and can undermine the ability of distributors and dispensers in one country to determine the provenances of drugs manufactured in another country.[22]

Efforts are currently underway to increase interoperability among the various systems. For example, a consortium of manufacturers, MNRAs, and NGOs recently released a report outlining a set of features that, if shared by all systems, would augment their compatibility; the World Health Organization issued a similar call.[23] Most likely, the coming decades will witness a process of harmonization of the track-and-trace systems analogous to (and just as slow as) the process described in the preceding section in which the drug-approval processes of individual countries are converging.

Systems of the second type rely, not upon verifications of authenticity, but instead upon testing the chemical composition of medicines at various points in the distribution chain. The most reliable of the technologies employed for this purpose is High-performance liquid chromatography ("HPLC"). Because of its complexity, HPLC testing must be done by trained personnel in laboratories.[24] Somewhat less complex and more portable is the "MiniLab," developed in the 1980s by the Global Pharma Health Fund (and subsequently updated periodically).[25] Some relatively new systems of this type use a combination of portable scanners (relying on Raman, near-infrared, or Fourier-transform Infrared ("FTIR") spectroscopy) and portable digital libraries (containing the spectral profiles of authenticated drugs) to determine, in the field, whether pills contain the

[22] See Pisa and McCurdy, "Improving Health Supply Chains," 16.

[23] See ICMRA, "Recommendations on Common Denominators."; WHO, "Policy Paper on Traceability of Medical Products," (2021).

[24] For a description of HPLC technology and its suitability to poor countries, see Ludwig Hoellein and Ulrike Holzgrabe, "Development of Simplified Hplc Methods for the Detection of Counterfeit Antimalarials in Resource-Restraint Environments," *Journal of Pharmaceutical and Biomedical Analysis* 98 (2014).

[25] *See, e.g.,* Ifeyinwa Fadeyi et al., "Quality of the Antibiotics—Amoxicillin and Co-Trimoxazole from Ghana, Nigeria, and the United Kingdom," *American Journal of Tropical Medical Hygiene* 92 (2015).(comparing HPLC testing and the MiniLab); Gesa Gnegel et al., "Surveillance for Substandard and Falsified Medicines by Local Faith-Based Organizations in 13 Low- and Middle-Income Countries Using the Gphf Minilab," *Scientific Reports* 12 (2022).; Stephanie Kovacs et al., "Technologies for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries," *PLoS ONE* 9, no. 3 (2014): 8-9.; Albert Petersen, Nadja Held, and Lutz Heide, "Surveillance for Falsified and Substandard Medicines in Africa and Asia by Local Organizations Using the Low-Cost Gphf Minilab," *PLOS ONE* 12, no. 9 (2017).

ingredients they purport to contain.[26] Finally, a few portable systems rely on paper chromatography.[27]

Type-1 systems dovetail with intellectual-property law. In other words, they facilitate detection of pills that have been produced or distributed by companies lacking legal rights to do so. Their capacity to ensure that the drugs delivered to patients are up to par are thus dependent upon the quality-control measures that the authorized manufacturers employ. Type-2 systems instead determine whether tested medicines have the right amount of active ingredients (and are uncontaminated by unwanted substances), regardless of whether they have been lawfully manufactured.

In most instances, the two approaches will lead to the same results, but not always. Most importantly, drugs that are safe and efficacious but unauthorized (for example, because they were produced by a generic manufacturer that lacks marketing approval in the jurisdiction in question) are more likely to be detected (and purged) by Type-1 systems, whereas authorized drugs that have degraded (for example, because of improper storage) are more likely to be detected (and purged) by Type-2 systems. Thus, other things being equal, the former is somewhat better for pharmaceutical firms, while the latter is somewhat better for patients.

Comprehensive Type-1 systems have proven to be highly effective. One of the first systems of this sort was launched in Turkey. It has resulted in dramatic declines in the incidence of SFMPs in that country. Additional benefits of Type-1 systems include: curbing reimbursement fraud (the principal objective of the regime in Turkey); enabling rapid recalls of bad batches (using the "tracking" function); and improved inventory management.[28]

Unfortunately, successful implementation of a Type-1 regime requires three things. First, substantial financial resources. The technology required for unit-level serialization is expensive, as are the devices used by intermediaries and dispensers to track those units. Next, the willingness and ability of all intermediaries and dispensers in the jurisdiction to

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[26] See Kovacs et al., "Technologies for Detection," 8.; Lukas Roth et al., "Global Landscape Assessment of Screening Technologies for Medicine Quality Assurance: Stakeholder Perceptions and Practices from Ten Countries," *Globalization and Health* 14 (2018).; Tomoko Kakio et al., "Survey to Identify Substandard and Falsified Tablets in Several Asian Countries with Pharmacopeial Quality Control Tests and Principal Component Analysis of Handheld Raman Spectroscopy," *American Journal of Tropical Medicine and Hygiene* 98, no. 6 (2018). An example of a venture using this approach is RxAll, which currently has preliminary deployments in five other African countries). *See*, *e.g.*, Eillie Anzilotti, "'This Startup Built a Device to Figure out If Prescription Drugs Are Fake," *Fast Company*, https://www.fastcompany.com/90323372/this-startup-built-a-device-to-figure-out-if-prescription-drugs-are-fake.; *Instant Drug Testing*, RXALL, https://www.rxall.net. (last visited Oct. 14, 2021).

[27] See Hui-Han Chen et al., "Cost Savings of Paper Analytical Devices (Pads) to Detect Substandard and Falsified Antibiotics: Kenya Case Study," *Medicine Access @ Point of Care* 5 (2021); Yusuke Hattori et al., "Device-Independent Discrimination of Falsified Amoxicillin Capsules Using Heterogeneous near-Infrared Spectroscopic Devices for Training and Testing of a Support Vector Machine," *Applied Spectroscopy* 75, no. 10 (2021): 1252.

[28] See Parmaksiz, Koray. "Political and Economic Drivers of Medicine Quality: Main Drivers of Success of the Pharmaceutical Track and Trace System in Turkey." July 2018. Thesis, Vrije Universiteit Amsterdam.

participate. Finally, the capacity of the national or regional regulatory authorities to monitor compliance and to enforce the rules of the road. The magnitude of these requirements helps explain why most of the countries shown in Figure 3 in which Type-1 systems are either already operational or under construction are either upper-income countries or upper-middle-income countries.

Type-2 systems have fewer benefits, but are far less expensive and are much easier to deploy incrementally. For the near future, therefore, most LMICs will be obliged to rely on the second approach.

As indicated above, a variety of technologies could be employed to construct a Type-2 system. None is ideal. The most accurate (HPLC) is expensive and slow. The most portable and inexpensive (the paper-based systems) are unreliable.

Our view is that, on balance, the best of the currently available technologies for use as the primary line of defense in low and middle-income countries is near-infrared (NIR) scanning. Each scanner is moderately expensive (roughly 800 USD), but is capable of testing an enormous number of drug samples. (No one knows for sure, but a common estimate is 40,000.) The smartphone that houses the software necessary to drive the system and to store the library of the spectral profiles of authorized drugs costs roughly 200 USD – bringing the total cost of a system to 1000 USD. Testing requires no reagents or other supplies, and can be done without destroying or degrading the samples. Thus, despite the substantial upfront cost, the average cost of a test is very low. Conducting a test requires only a few minutes. Most importantly, if kept up to date, an NIR system is remarkably accurate. Many comparative studies have now been conducted of the various Type-2 technologies. All of them rate the NIR technology highly.[29]

Relying on those studies, we have been collaborating with some other institutions to deploy pilot projects employing NIR technology in two countries: Namibia and Malawi. Our own contributions to this venture have been made under the auspices of Global Access in Action, a research program at Harvard University.[30] The other institutions with whom we have been working are: Global Good (an NGO funded by Bill Gates that originally developed the technology used in the system); the Mission for Essential Drugs and Supplies (MEDS), a faith-based organization in Nairobi that distributes medicines throughout East Africa, which has assumed now responsibility for refining and managing the system); Innospecta, the manufacturer of the scanners; the Ministry of Health and Social Services

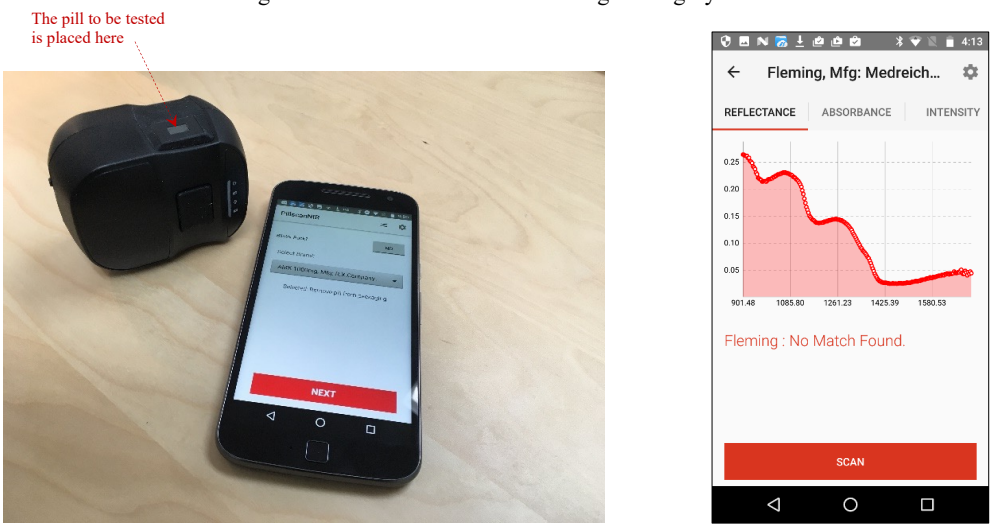
[29] See Nantasit Luangasanatip et al., "Implementation of Field Detection Devices for Antimalarial Quality Screening in Lao Pdr—a Cost-Effectiveness Analysis," *PLOS Neglected Tropical Diseases* 15, no. 9 (2021): 12-13.; P.H. Ciza et al., "Comparing the Qualitative Performances of Handheld Nir and Raman Spectrophotometers for the Detection of Falsified Pharmaceutical Products," *Talanta* 202 (2019): 477.; Wenbo Wang et al., "Evaluating Low-Cost Optical Spectrometers for the Detection of Simulated Substandard and Falsified Medicines," *Applied Spectroscopy* 74, no. 3 (2020): 332.; Stephanie Kovacs et al., "Technologies for Detecting Falsified and Substandard Drugs in Low and Middle-Income Countries," *PLoS ONE* 9, no. 3 (2014): 8, 10.; Moussa Yabré et al., "Detection of Falsified Antimalarial Sulfadoxine-Pyrimethamine and Dihydroartemisinin-Piperaquine Drugs Using a Low-Cost Handheld near-Infrared Spectrometer," *Journal of Analytical Methods in Chemistry* 2022 (2022): 6.

[30] Information concerning Global Access in Action is available at https://globalaccessaction.org.

of Namibia; the Pharmacy, Medicines and Poisons Board of Malawi; the London School of Hygiene and Tropical Medicine; the Infectious Diseases Data Observatory; and most recently the World Health Organization.

A photograph showing one of the scanners used in this system and its associated smartphone appears on the left side of Figure 4, below. To test a pill, the operator removes it from the container (typically a box or jar) in which it was delivered, places it on the small translucent window located on the top of the scanner, uses the software housed in the phone to select from a menu the product that the pill purports to be, and touches a button labelled, "Scan." Less than 10 seconds later, the screen of the smartphone shows the result. If the spectral profile generated by the scan matches the profile (contained in the smartphone's database) of an authenticated version of the product in question (within the tolerances permitted by the software), that result is "Match Found." If not, the screen informs the operator (using a red font): "No match found."

Figure 4: PillScan Near-Infrared Drug Testing System



In either event, the operator then uses the camera of the smartphone to take a photograph of the label on the container from which the pill was taken. A geotagged and time-stamped copy of that photograph is associated with the data generated by the scan and recorded by the phone. To minimize opportunities for corruption, the operator cannot delete or alter any of this data. When the operator returns to a location with access to the Internet, the data is uploaded to a central database.[31]

In 2019, we accompanied government inspectors, first in Namibia and then in Malawi, on unannounced surveillance trips in which they used these devices to conduct

[31] A more detailed description of this procedure in contained in the Operating Manual for the system, which is available at https://ipxcourses.org/GPP/GAiA_Namibia_PillScan_Manual.pdf.

random samples of drugs on the shelves of urban hospitals and rural pharmacies. The devices performed well – and brought to light one batch of degraded cancer drugs.

To be sure, technology of this sort will do little good unless it is deployed as part of a comprehensive testing protocol. At the request of the Namibia Medicines Regulatory Council, we prepared such a protocol. An abridged version is set forth below.[32]

[32] The complete version is available at https://ipxcourses.org/GPP/GAiA_Namibia_PillScan_Protocol.pdf.

Figure 5:

Standard Operating Procedure for Device Use and Data Collection and Management
April 2018

1. Use of the Devices

1.1. The Devices should be deployed at points of maximum supply chain vulnerability to penetration by falsified medicines.

1.1.1. Officials in the NMRC are in the best position to locate those points. Examples may include ports of entry, warehouses that collect significant quantities of medicines, health facilities that obtain medicines from multiple sources, or remote community pharmacies. …

1.2. Devices should be used only by persons ("Users") who have received training from Global Good or the Namibia Medicines Regulatory Council ("NMRC") in their correct use and storage.

1.2.1. Upon successful completion of this training, each User will receive a unique ID number, which he or she should include in all written reports associated with scans that result in "No Match Found" determinations….

2. Management of Suspected Falsified Medicines

2.1. When the scan of a pill results in a "No Match Found" determination, the scanned pill should be placed in a plastic bag along with a completed User Form filled out by the User who performed the scan. The User should then add to the bag an appropriate number of additional pills from the same batch to ensure that the laboratories doing confirmatory testing have a sufficient number of samples. ….

2.2. The NMRC should arrange for additional testing to eliminate user or Device error and confirm that a sample is, in fact, falsified. The optimal sequence of confirmatory testing is as follows:

2.2.1. The sample should be subjected to a second NIRS scan at the NMRC Laboratory to ensure that the scan performed in the field was not an aberration.

2.2.2. If the second NIRS scan also results in a "No Match" determination, then the sample should be subjected to HPLC testing at the NMRC Laboratory.

2.2.3. If the HPLC test indicates that the sample fails to meet the applicable quality standard, then the sample must be forwarded to MEDS for further testing. …

2.2.4. If the third NIRS scan also results in a "No Match" determination, then the sample should be subjected to HPLC testing at MEDS.

2.3. The NMRC should establish, promulgate and periodically review a Quarantine Policy….

2.4. Once a medicine is confirmed to be falsified, its distributors and suppliers should be instructed to cease its distribution and supply. Site inspections should be conducted to ensure compliance with this provision. Individuals who continue to distribute or supply confirmed falsified medicines should be informed of the legal consequences of their actions, and their licenses may be suspended or revoked in accordance with the Medicines and Related Substances Control Act 2003.

2.5. …. If the source of the medicine is a supplier known to the NMRC, this supplier should be removed from national tender lists.

2.6. Confirmed falsified medicines should be reported to the drug regulatory authority of the country of origin stated on the label of the falsified product.

The COVID-19 pandemic forced suspension of the two pilot projects in Namibia and Malawi. We are now in the process of attempting to restart those programs and are currently in discussions with representatives of other subSaharan African countries concerning potential deployments in their jurisdictions. Meanwhile, the World Health Organization determined that the fruits of the initial tests of the system were sufficiently impressive that it commissioned MEDS to conduct training programs in several Schools of Pharmacy in Africa. The result is that many members of the next generation of pharmacists will be ready to deploy it.

The government of an LMIC lacking a "track-and-trace" system would be well advised to adopt a chemical-testing regime of this general sort. The cost of instituting such a regime would of course vary with the size of the country's population, but in any event would be small in proportion to the country's overall public-health budget and could be deployed in a few months. The technology and the software already exist. The only significant hurdles would be training the inspectors and crafting a protocol like the one summarized above.

Such a regime not only would enable the inspectors to detect many SFMPs and prevent them from reaching consumers, but would also facilitate identification of the manufacturers of those products and the channels through which the products are entering the distribution chain – which in turn would help the governments purify the tender process and the networks of distributors. The net result: many lives would be saved and much misery could be avoided.

Originator pharmaceutical firms would also plainly benefit from a systematic chemical-testing regime. Awareness of that potential benefit should prompt them to lend a hand in creating one. They could do so in at least three ways.

First, the pharmaceutical firms could donate to LMICs the modest amounts of money necessary to acquire the NIR scanners and the associated smartphones.

Second, each time a pharmaceutical firm produced a new batch of a drug, it could provide the organization charged with maintaining the library of authenticated spectral profiles (e.g., MEDS in the PillScan system) an authenticated sample of the new batch. That would considerably reduce the logistical burdens borne by the organization and enable more rapid updating of the library.

Third, when licensing other manufacturers to manufacture and distribute generic versions of their products in LMICs, pharmaceutical firms could require the licensees to follow the foregoing procedure – i.e., to provide an authenticated sample of each new batch of drugs they produced to the organization that maintains the library of spectral profiles. If the license in question were negotiated and managed by the Medicines Patent Pool, MPP could not only insert in the license agreement a clause imposing this obligation on the licensees, but perhaps also assume responsibility for maintaining the relevant portion of the spectral library. All parties – licensor, licensees, and (above all) the public at large – would benefit thereby.

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