INNOVATIONS IN HEALTHCARE™

How Anti-Counterfeit Innovations Can Improve Global Healthcare Supply Chains

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Introduction

Around the world, inadequate healthcare supply chains result in stock-outs that prevent millions of people from accessing life-saving medicines. According to a 2011 World Health Organization (WHO) report, access to medicines is limited: on average, public sector availability of generic medicines is less than 60 percent of levels required to meet patient need.[1] Chronic medicine shortages disproportionately affect developing countries, where infrastructure is limited and supply chain management is severely under-resourced. Improving medical supply chains can not only increase access to medicines and improve health outcomes, but also reduce costs associated with inventory and product obsolescence, and address growing concerns related to the quality and safety of medicines.[2]

Recent innovation in anti-counterfeiting technology presents a new set of solutions to improve medical supply chains. In both developed and developing countries, experts increasingly identify spurious and counterfeit drugs as a growing public health crisis. In 2010, the Center for Medicine in the Public Interest reported that worldwide sales of counterfeit medicines could top US $75 billion, a 90% increase in five years.[3] The WHO International Medical Products Anti-Counterfeiting Taskforce (IMPACT) estimates that in many developing countries more than 30% of medicines may be counterfeit.[4] This has led to rapid development of new technologies to prevent counterfeit medicines from entering the supply chain and from reaching the end user. While new anti-counterfeit technologies have enabled great improvements in reducing counterfeit medicines, these tools provide solutions to other persistent supply chain challenges in global health.

A review of donor-supported public health programs, with a particular focus on East Africa, and interviews with practitioners from leading global health organizations working in logistics and supply chain management, surfaced several key challenges for global health supply chains. These challenges include inventory information failures leading to stock-outs, broad procurement system failures, product diversion, and demand creation. Of these, information failures and product diversion are problems that anti-counterfeit technologies have clear potential to address. Anti-counterfeit technologies also have potential to improve service delivery challenges, such as medication adherence through increased patient follow-up and engagement.

Using Sproxil®'s Mobile Product Authentication™ (MPA™) as a case study, this paper explores the potential of technology to address these key medicine supply chain and delivery challenges, in addition to its original anti-counterfeiting applications.

1 Alexandra Cameron, Margaret Ewen, Martin Auton, Dele Abegunde, "The World Medicines Situation 2011," World Health Organization (2011). http://www.who.int/medicines/areas/policy/world_medicines_situation/WMS_ch6_wPricing_v6.pdf

2 Thomas Ebel, Katy George, Erik Larsen, Ketan Shah, and Drew Ungerman, "Building New Strengths in the Healthcare Supply Chain," McKinsey & Company (2013).

3 Peter Pitts, "Counterfeit Drugs and China," Center for Medicines in the Public Interest (2006). http://www.cmpi.org/in-the-news/testimony/counterfeit-drugs-and-china-new

4 IMPACT, "Counterfeit Medicines: An Update on Estimates," World Health Organization (2006). http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf

Safeguarding Medicine in Global Health Supply Chains

The public health impact of fake and falsely labeled medicines is significant. In developing countries, problems with medicine safety are particularly acute due to limited resources for supply chain surveillance and enforcement. Among the medicines most often targeted are life-saving drugs such as anti-malarial drugs and antibiotics.[5] Fake and falsely labeled medicines may have sub-therapeutic levels of the active ingredient or incorrect ingredients, which can cause treatment failure and adverse events including death, and may facilitate the spread of drug-resistant pathogens. A 2009 International Policy Network report estimates that fake tuberculosis and malaria drugs alone cause 700,000 deaths annually.[6] Finally, fake medicines incur other costs to the health system, such as loss of patient trust in providers.

Anti-Counterfeiting Technology

Anti-counterfeiting technologies are designed to enable authentication of a product (whether by regulators or by end users) and to deter counterfeiting by increasing the likelihood of detection and, eventually, prosecution.[7] Anti-counterfeit technology is a broad category that can be generally divided into two types: enabling product authentication and enabling product tracking and tracing (TnT) through the supply chain. Authentication technologies include methods such as watermarks or serial product identification that can be verified by the user. TnT systems use machine-readable technology such as radio frequency identification (RFID), electronic product codes (EPCs), and barcodes, combined with a system that enables verification of the product origin and current location.[8]

Common anti-counterfeit solutions include overt and covert insignia, RFID tags, and chemical testing. At the retailer or pharmacy level, chemical testing is the best indicator of authenticity, but it is not usually practical to perform testing comprehensively. The additional costs of equipment, equipment maintenance, training, and ongoing support can further discourage retailers or pharmacies from using chemical testing. Solutions such as insignia, holograms, and watermarks are easily duplicated and thus not reliable indicators of authenticity.

The public and private sector both purchase and implement anti-counterfeit solutions. However, because there is yet to be a unified global set of regulations for anti-counterfeiting, compliance in all relevant and country-specific standards is complex for the private sector, especially for companies and organizations with multinational operations.

In the public sector, creating a unified and feasible anti-counterfeit solution that accommodates the wide variation in each supplier's distribution

5 Paul N. Newton, Michael D. Green, and Facundo M. Fernández, "Impact of poor-quality medicines in the 'developing' world," *Trends in Pharmacological Sciences* 31, no. 3 (2010): 99-101.

6 Julian Harris, Philip Stevens, and Julian Morris, "Keeping it Real: Combating the Spread of Fake Drugs in Poor Countries," International Policy Network (2009).

7 IMPACT, "Anti-counterfeit Technologies for the Protection of Medicines," World Health Organization (n.d.). www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf

8 Ling Li, "Technology Designed to Combat Fakes in the Global Supply Chain," *Business Horizons* 56, no. 2 (2013): 167-177. http://dx.doi.org/10.1016/j.bushor.2012.11.010

network is a significant challenge. Furthermore, policy approaches to the implementation of anti-counterfeit measures are constrained not only by limited resources, but also by a multi-stakeholder environment that creates a complex and fragmented decision-making landscape.

However, government agencies are making efforts to address this problem. One example is Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC), which has established standards such as the requirement that all anti-malarial drugs and antibiotics be protected by a mobile authentication solution (MAS), defined as any NAFDAC-approved mobile-based, consumer-facing product verification solution, such as Sproxil's MPA. Another example is a mandate instituted by India's Director General of Foreign Trade (DGFT), which requires pharmaceutical companies to comply with various barcoding, serialization, and TnT requirements for exports. These policies are being set at national and local levels, however, and there is a growing need for international anti-conterfeit technology standards.[9]

9 Thomas Ebel, Katy George, Erik Larsen, Everett Neal, Ketan Shah, and David Shi, "Strength in Unity: The Promise of Global Standards in Healthcare," McKinsey & Company (2012).

Case Study: Sproxil

Founded	2009
Locations	Ghana, Kenya, Nigeria, India, United States
Focus	Brand protection technology that empowers consumers to avoid counterfeit drugs and reduces these fakes, as well as illegally distributed products, in the market.
Website	www.sproxil.com

Sproxil originally developed the MPA product in response to the single biggest problem with fake and falsely labeled medicines: the consumer often cannot identify them. MPA addresses this problem by enabling end users to verify product authenticity using a security label and a free text message to Sproxil.

The MPA system is a low-cost solution (free to consumers) that increases access to authenticity services for low-technology consumers. At the point of purchase, customers scratch the label to reveal a unique code on the product which they can validate via SMS, voice call, mobile app, or website. The system immediately provides information about whether the purchased product is authentic or suspicious and can provide instructions to the consumer in the case of a suspicious product.

Consumers can also access a 24/7 consumer support hotline to get assistance during the verification process, submit anonymous reports on suspicious counterfeiting activity, and ask product-specific questions.

Originally focused on consumer-level authentication, Sproxil's MPA now includes an optional track and trace (TnT) solution that enables tracing via confirmation of product delivery at each point in the supply chain.

New Applications of Anti-Counterfeiting Technology

The safety and authenticity of medicines is one of many supply chain challenges in developing country public health systems.[10] In a context of weak health systems and limited infrastructure, practitioners struggle with chronic shortfalls in inventory data, an underlying driver of stock-outs and expiring stockpiles (which often occur simultaneously). Another challenge contributing to supply chain inefficiencies is the multi-stakeholder environment, including donors, suppliers, governments, and private providers, which complicates coordination in an already fragmented global health supply chain.

Multilateral organizations such as the WHO and The Global Fund, and bilateral donors including USAID, have invested hundreds of millions of dollars to improve global health supply chains, including initiatives to pool procurement, improve forecasting, enhance inventory management, and verify quality of medications. However, the challenges facing these supply chains are complex and new solutions are needed.

Though developed to meet a need for product authentication, anti-counterfeit technology has relevance for other significant supply chain and delivery challenges faced by emerging market health systems. Sproxil's MPA provides a case example of how anti-counterfeit technology innovations can be used to improve inventory management, reduce product theft and diversion, and increase patient engagement to improve adherence.

1. Improved Inventory Management

A lack of actionable supply chain information is one of the challenges most frequently identified by global health practitioners. Limited or poorly functioning logistics management information systems (LMIS) fail to provide needed data, which causes stock-outs and creates stockpiles, while also limiting awareness about the actual frequency of such problems. Improved supply chain management through effective LMIS can ensure patient access to medications and reduce costs from unnecessary inventory waste due to expired drugs.

However, such systems are inherently complex and require not only appropriate information technology infrastructure, but also training and effective implementation. In resource-poor settings, both limited infrastructure and poorly aligned incentives create barriers to LMIS implementation.

Managers of warehouses and LMIS can often double their salary or more through fraud and theft and may not be incentivized to improve the transparency of supply chain data. Global health program managers, by contrast, need strong supply chains and consistent stocks but do not typically have direct control over the LMIS. Some anti-counterfeit innovations can bolster LMIS, helping to fill information gaps for program managers and address other key challenges in delivering medicines through public health systems.

10 For the purposes of this paper, the term "public sector" includes the significant portion of health products delivered via non-governmental organizations, with donor funding and government support.

The product tracking function of MPA provides actionable information about stock levels that can improve supply chain management and reduce stock-outs. MPA enables product tracking through all levels of the distribution system, which can include service delivery points. When products arrive at a warehouse or service delivery point, product verification via simple SMS, 2D barcodes, or other methods registers secure arrival. This verification can be done at the shipment or pallet level via aggregated codes, without requiring each package to be scanned.

MPA and similar technologies are not a substitute for, but rather a complement to, a complete LMIS, and can feed directly into an LMIS. This stock inflow information, available immediately through web interfaces, can be combined with outflow data from user authentication and can also interface with other LMIS data, providing additional valuable insights into stock levels throughout a health system.

The MPA technology also provides a mechanism for tracking key products that most often experience shortages, or where limited supplies make stock management particularly important. One such example might be malaria commodities, and particularly artemisinin-based combination therapies (ACTs). A recent USAID|DELIVER logistics issue brief discusses the challenges of ACT shortages and recommends additional stock management strategies to reduce the frequency of ACT stock-outs.[11] Such strategies require close monitoring of stock levels, which may require more detailed or more frequent information than that which is typically available from an LMIS.

2. Reducing Product Theft and Diversion

Diversion occurs when products are transferred from one market to another without authorization. Diversion can take various forms, including products smuggled across borders, or theft from one channel, such as a public health system, for resale in private or informal markets. It is difficult to estimate the total cost to health systems and donor-funded programs, but theft and diversion of health commodities is a significant problem around the globe. A 2010 study to assess the diversion of anti-malaria drugs in African markets found that more than 25% of ACTs purchased in private pharmacies had been diverted.[12]

In the public sector, efforts to reduce diversion most often consist of initiatives to improve monitoring and supervision through better management oversight, rather than through technology. The replacement of paper-based tracking with electronic systems, however, facilitates greater management oversight and has been found anecdotally to reduce the incidence of theft and diversion.

Anti-counterfeit technology innovations like MPA can further help protect purchased and donated commodities against product theft and diversion in two primary ways. First, the MPA's track and trace solution enables confirmation of product delivery by authorized, identifiable agents at each step in the supply chain, which can reveal the point in the supply chain at which diversion or fraud occurs. Second, MPA captures information at the point of sale. When consumers attempt to

11 "Addressing In-Country Supply Shortages of Malaria Commodities," USAID | Deliver Project (2012). http://deliver.jsi.com/dlvr_content/resources/allpubs/logisticsbriefs/AddrInCoSuppShor.pdf

12 Roger Bate, Kimberly Hess, and Lorraine Mooney, "Antimalarial Medicine Diversion: Stock-outs and Other Public Health Problems," *Research and Reports in Tropical Medicine* 1 (2010): 19-24.

authenticate a product flagged as diverted, the system generates an immediate alert, facilitating the identification of resellers and the tracing of agents involved in diversion.

3. Increasing Patient Engagement and Adherence

In addition to addressing the risks of counterfeit drugs and product diversion and supporting inventory management, innovative technologies such as MPA have the potential to facilitate engagement with patients after the purchase or disbursement of medicines.

In many developing countries, weak health system infrastructure and scarce resources limit the potential for patient follow-up to ensure appropriate use of medicines. Treatment adherence is a particular concern in the context of rising drug resistance and extended regimens, such as tuberculosis treatment and anti-retroviral therapy. To address these challenges, health outreach programs are incorporating text messaging in various ways, and studies have documented their impact on improving adherence, which directly affects health outcomes.[13, 14] Short-duration treatments such as anti-malaria drugs may also benefit from text message follow-up.[15]

Anti-counterfeit technologies can facilitate follow-up engagement with patients through customized messaging. For example, at the point of purchase or dispensing, when a patient authenticates the product, the MPA system can automatically initiate a protocol for follow-up communications, such as a daily SMS text reminder to take the medication, sent at specific times depending on recommended use. These reminders can be set up automatically, without burdening healthcare workers to record phone numbers in a system. When authenticating a product, the system can also record any relevant voucher or referral data, facilitating integration with other program initiatives.

13 Richard Lester, Paul Ritvo, Edward Mills, Antony Kariri, Sarah Karanja, Michael Chung, William Jack, et al., "Effects of a Mobile Phone Short Message Service on Antiretroviral Treatment Adherence in Kenya (WelTel Kenya1): A Randomised Trial," *The Lancet* 376, no. 9755 (2010): 1838-1845

14 Cristian Pop-Eleches, Harsha Thirumurthy, James P. Habyarimana, Joshua G. Zivin, Markus P. Goldstein, Damien de Walque, Leslie MacKeen, et al., "Mobile Phone Technologies Improve Adherence to Antiretroviral Treatment in a Resource-Limited Setting: A Randomized Controlled Trial of Text Message Reminders," AIDS 25, no. 6 (2011): 825–834.

15 Dejan Zurovac, Ambrose Talisuna, and Robert Snow, "Mobile Phone Text Messaging: Tool for Malaria Control in Africa," *PLoS Medicine* 9, no. 2 (2012).

Challenges to Implementation

As described above, there are significant additional benefits from innovations in anti-counterfeit technology, beyond the primary value of consumer protection from fake medicines. However, there are several key barriers to broad adoption of anti-counterfeit technologies in developing country health systems: high costs, multiple stakeholders with ownership, and a lack of global standards.

The first concern in the developing country context is the cost of anti-counterfeit technologies. While offerings range in price and complexity, a system-wide implementation (across a large portfolio of products) may not be financially feasible. However, there could be significant value to targeted implementation of anti-counterfeit systems for high-value and/or high-priority products. In addition to preventing counterfeit medications from reaching market, this could also generate cost savings for the health system by providing protection from theft and diversion, improving inventory management to reduce stock-outs and expired stockpiles, and increasing patient adherence.

The second challenge is related to decision-making authority and ownership in a complex, multi-stakeholder environment. Producers, distributers, purchasers, and funders may have competing objectives in global health supply chain management and coordination across each stakeholder is difficult to achieve. This context may contribute resistance to the creation of systems that favor specific products (such as HIV products) versus investing in system-wide improvements. This potential tension should be acknowledged when considering investment in a technology such as MPA.

Finally, amidst multiple standards for anti-counterfeit technology, there is growing awareness of the need for a global standard.[16] To date, jurisdictions have enacted policies that endorse different approaches to anti-counterfeiting at the retail level. For example, France and Turkey have enacted national legislation that facilitates authentication at retail pharmacies. In the U.S., the state of California has endorsed a comprehensive "e-Pedigree" system.[17] The emergence of multiple standards within and across countries introduces uncertainty about the policy environment and regulatory requirements. Coordinated national and global standards are needed to support implementation of anti-counterfeit technology.

16 Thomas Ebel, Katy George, Erik Larsen, Everett Neal, Ketan Shah, and David Shi, "Strength in Unity: The Promise of Global Standards in Healthcare," McKinsey & Company (2012).

17 Stephen Barlas, "Track and Trace Drug Verification," *Pharmacy and Therapeutics* 36, no. 4 (2011): 203-204. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3086119/

Implications and Priorities for Further Development

This paper identifies several clear opportunities for anti-counterfeit technologies to not only protect against fake medicines, but also to significantly improve the delivery of global health programs and improve health outcomes. While costs vary, anti-counterfeit technologies can be implemented at a cost of cents per unit and may generate significant net savings to public health systems.[18]

To explore the potential for cost savings, pilot programs should be developed to test the integration of anti-counterfeit technology innovations with TnT technology, such as MPA, with existing supply chains. Donor support may be the most appropriate financing mechanism for initial pilots. However, TnT offerings provide an opportunity to share investment costs by uniting the interests of diverse stakeholders: manufacturers concerned about brand and liability protection, donors concerned about protecting investments against diversion risk, and governments concerned about public health impact. Pilot programs might focus on "lead" products, such as anti-malaria drugs, that currently face high stock-out frequency and elevated counterfeit risk. Evaluation efforts of pilot programs should assess not only the direct benefit for suppliers and users of the focal product (e.g. anti-malaria drugs), but also the broader value for the drug supply chain, such as improving inventory management and identifying points of high diversion risk.

18 It is difficult to estimate net cost savings due to the lack of data about the lost value of diverted and expired products and the public health impact of stock-outs.

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