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Dark Pharma:
Counterfeit and Contraband Pharmaceuticals in Central America

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INTRODUCTION

The trafficking of illicit drugs in Central America has been widely documented in recent years, as the region plays a key role in the trafficking of cocaine from South America to Mexico and the United States, as well as markets further abroad. Nevertheless, the illicit sale of pharmaceuticals in Central America also constitutes a phenomenon that is rapidly evolving, appears to be growing, and has garnered relatively little international attention outside of pharmaceutical, law enforcement, and public health circles.

This paper seeks to fill in critical gaps in the existing knowledge base, and offers a starting point for further inquiry by focusing on two Central American case studies, Costa Rica and Guatemala. It aims to better understand the scope and scale of the trade in counterfeit and black-market pharmaceuticals in Central America as well as the modus operandi of counterfeit and black-market pharmaceutical traffickers, their smuggling routes, and the potential involvement of well-established criminal groups in this burgeoning industry. It seeks to identify the key factors that are driving consumer demand for counterfeit and black-market pharmaceuticals in both Costa Rica and Guatemala, and to better understand government and private sector responses to this growing problem. Additionally, the paper identifies specific areas where government and private sector responses could be more effective, and highlights emerging trends that could shape the counterfeit and black-market pharmaceutical economy in the near and medium term.

To that end, this report is separated into four main sections. Section I offers a global and regional overview of the illicit sale of pharmaceuticals. Sections II and III examine Costa Rica and Guatemala as case studies, with a par-

ticular emphasis on the scale and scope of the problem, the modus operandi of the actors involved, current and future trends in the market, and respective government responses to the phenomenon. Section IV synthesizes the information of both case studies to provide recommendations for stakeholders, and potential opportunities for more effective interventions going forward, which include building off of promising initiatives, leveraging new and emerging technologies, and closing gaps in existing frameworks to better combat the production and sale of counterfeit and contraband pharmaceuticals

Method

This report is based on over forty interviews in Costa Rica and Guatemala with government officials, law enforcement representatives, healthcare providers, private sector actors, consumers of pharmaceuticals, as well as certain actors directly involved in the sale of black-market pharmaceuticals. Fieldwork in both countries was carried out by Peter Tinti, an international consultant from the Global Initiative Against Transnational Organized Crime (Global Initiative), working in partnership with local researchers (Álvaro Murillo in Costa Rica and Louisa Reynolds in Guatemala). Information obtained through interviews with key actors on the ground was further reinforced by a comprehensive desk review of publicly available government and private sector reports, as well as press reports published in local and international media outlets.

Given the sensitive nature of the topic, and the desire to gain a wide array of perspectives and opinions (both official and personal) from a broad range of relevant actors, the Global Initiative granted anonymity to those interviewed for this report. Where possible, the nature of the source of the information (i.e., law enforcement, private sector, black-market vendor, etc.) is disclosed.

1: ILLICIT PHARMA: A GLOBAL AND REGIONAL OVERVIEW

The illicit sale of pharmaceutical drugs is a growing global concern, most particularly in developing countries where the lack of adequate healthcare forces people to seek cheaper drugs. In the absence of effective systems of regulation and access to affordable pharmaceuticals, it is often the case that the demand for cheap medicines drives a criminal market that provides counterfeit, substandard, and diverted drugs to consumers.

The damage caused by such markets relates not only to the quality of the medicines available to consumers but also to the corruption these markets create and reinforce, reducing citizens' confidence in the public health sector and the government more broadly. The most vulnerable people, the sick and poor, are disproportionately drawn to buying counterfeit and contraband medicines in illicit markets. The consequences are manifold, as these substandard and ineffective drugs may worsen the condition of sick individuals, hinder medical professionals' ability to make accurate diagnoses, accelerate the spread of communicable diseases, increase drug resistance, and ultimately kill people. Recent literature suggests that the global market for fake or counterfeit medicines may be as high as $431 billion per year, roughly the same as the illicit drug trade at $435 billion.[1]

While counterfeit medicines are the fake or illegal copies of certain pharmaceuticals, often lacking the correct, or any, active ingredients, contraband medicines are usually licit drugs that are sold through illicit channels. Entering grey or black markets can have an enormous impact on the quality of these licit drugs: when "good drugs" enter the black market, they are often exposed to high temperatures or other suboptimal conditions that reduce their effectiveness or even render them useless.

As with other trafficked goods, the production, transport, and sale of both counterfeit and contraband pharmaceuticals in many ways mirrors the global economy, with technological innovation and increased connectivity enabling the emergence of complex global supply chains. This increased complexity makes tracking and tracing licit pharmaceuticals incredibly difficult, and requires systemic collaboration across an array of international borders, various government and intergovernmental agencies, and cooperation between the private and public sectors.

For legal pharmaceuticals, as the World Health Organization explains, "a tablet taken in Germany may be made in Egypt from ingredients imported from India, Brazil and Spain, packaged in foil that came from China, inserted into a box designed for the United Kingdom of Great Britain and Northern Ireland, and shipped to Liverpool by way of Dubai. A trader in the United Kingdom, taking advantage of fluctuations in the foreign exchange rate, might legally repackage the medicines with information written in German and ship it to Munich."[2]

The increasing complexity of supply chains has led to several public and private sector initiatives in high income countries that emphasize traceability, also known as "track and trace," to ensure supply chain integrity. New regulations such as the Drug Supply Chain Security Act in the US and the Falsified Medicines Directive in the European Union (EU) require producers and distributors to track and trace packages of their products throughout the supply chain.[3] Pharmaceutical companies are increasingly investing in traceability technologies that will enable them to comply with these standards.

A key feature of many track and trace systems is serialization, in which manufacturers assign unique identifiers to every package, enabled by two-dimensional (2D) barcodes that can be scanned every time the product changes hands, thus creating a digital trail throughout the supply chain.[4] Properly implemented, these types

1 Roth, Lucas; Nalim, Ameena; Turessson, Beth; and Krech, Laura. "Global landscape assessment of screening technologies for medicine quality assurance: stakeholder perceptions and practices from ten countries," Global Health. 25 April 2018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5922304/

2 "WHO Global Surveillance Monitoring System for Substandard and Falsified Medical Products," World Health Organization, 2017. http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

3 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

4 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

of traceability systems allow for actors across the supply chain to verify the origin of a given package, enable more accurate and efficient product recalls, and improve forecasting for stock management and commodity needs.[5] Other technologies being explored, particularly by private sector actors, leverage distributed ledgers via blockchain technology to trace products throughout the entire supply chain.

The challenges of tracking and tracing pharmaceuticals are even more daunting when it comes to combatting the sale and distribution of counterfeit and contraband medicines, where those engaged in illegal activity have every incentive to deceive both consumers and regulators. As efforts to combat illicit pharmaceuticals have increased, counterfeiters have responded in kind, becoming increasingly sophisticated in making it harder for retailers and ordinary consumers to distinguish fake products from authentic ones.

After a convincingly packaged counterfeit version of Piersan's Unal injectable contraceptive was found for sale in Guatemala, for example, the company had to make new thermo-shrinkable labels and change the color of the lid in order to make it easier to detect counterfeits.[6] "Very often the owners of small pharmacies accept these products as genuine unless they're very badly packaged, but they (criminal networks that produce counterfeits) almost always produce good packages that look almost identical," explained one pharmaceutical executive in Guatemala.[7] "Organized crime has evolved to such an extent that today it is almost impossible for even the drug manufacturers themselves to determine at first glance if this medication is the original or is the false," said a private sector representative in Costa Rica.[8]

In response to the universal recognition that global supply chains require global monitoring systems to alert to the risks of counterfeit and contraband pharmaceuticals, and that "no country or region working alone could easily collect all the information it needed to respond rapidly to threats," in 2013 the WHO created the Global Surveillance and Monitoring System (GSMS) for illicitly traded medicines, vaccines, and diagnostic tests.[9]

Through GSMS, the WHO aims to improve the quality of reporting instances of counterfeit and contraband pharmaceuticals, as well as to streamline data collection in order to analyze and influence procedures and public health policy at national, regional, and global levels. As of July 2017, the WHO conducted seventeen training workshops, trained 400 regulatory personnel in 126 WHO member states, and sensitized eighteen international procurement agencies on the topic. It also produced some 1,500 product reports, issued more than twenty medical product alerts, created a multilingual portal for access to reporting and database search tools, and launched a mobile application for improving information flows among regulatory authorities.[10]

In addition to the WHO, several other international and regional organizations play an increasingly important role in tackling the problem of counterfeit and contraband pharmaceuticals. These include the International Criminal Police Organization (Interpol), the Permanent Forum on International Pharmaceutical Crime (PFIPC), the World Customs Organization (WCO), the Pharmaceutical Security Institute (PSI), and, in the case of Latin America, the *Red Panamericana para la Armonización de la Reglamentación Farmacéutica* (known in English by the acronym PANDRH), which operates under the auspices of the Pan American Health Organization (PAHO) and the *Alianza Latinoamericana Anticontrabando* (ALAC). The former, PANDRH, is an initiative of national regulatory authorities throughout the region (including North America, Latin America, and the Caribbean) that "supports the processes of pharmaceutical regulatory harmonization in the Americas, within the framework of national and sub-regional health policies and recognizing pre-existing asymmetries."[11] The latter,

5 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

6 Interview in Guatemala City, Guatemala, September 2018.

7 Interview in Guatemala City, Guatemala, September 2018.

8 Interview in San José, Costa Rica, July 2018.

9 "WHO Global Surveillance Monitoring System for Substandard and Falsified Medical Products," World Health Organization, 2017. http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

10 "WHO Global Surveillance Monitoring System for Substandard and Falsified Medical Products," World Health Organization, 2017. http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

11 "PANDRH Network – Pan American Nework for Drug Regulatory Harmonization," PAHO. https://www.paho.org/hq/index.php?option=com_content&view=article&id=11818:acerca-de-la-red-parf&Itemid=41774&lang=en

ALAC, is a private sector initiative launched in 2016 that seeks to collaborate with governments throughout the region to combat range of different types of contraband production and smuggling, including cigarettes, liquors, hydrocarbons, medicine, steel products, ceramics, textiles, clothing, and plastics.[12]

The monitoring and oversight challenges that come with globalized supply chains have been further exacerbated by the emergence of online dispensaries and pharmacies, which allow for consumers to shop for bargains online, and for shady vendors to operate in grey and black markets. The fact that consumers in one country can now order pharmaceuticals online from another, and have them delivered to their doorstep, is a problem for regulators and law enforcement that impacts countries at every income level. Amid rising drug prices in the United States, for example, Americans increasingly began purchasing cheap pharmaceuticals from Canada online, where many of these products receive government subsidies.[13] Global internet penetration, a proliferation in social media and messaging apps, combined with the emergence and mainstreaming of the dark web and cryptocurrencies, has only further empowered both consumers and vendors who seek to purchase and sell pharmaceuticals through illicit markets.

In 2008, Interpol, in partnership with the PFIPC, launched Operation Pangea, which directly targets the online sale of counterfeit and illicit medicines. Held annually, the weeklong operation has grown in participants each year, expanding from just ten countries in 2008 to 116 in 2018. The most recent week of action resulted in 859 arrests and the seizure of $14 million worth of potentially dangerous pharmaceuticals, totaling 500 metric tons of illicit pharmaceuticals seized worldwide. Additionally, Pangea XI, as the most recent operation was called, resulted in the closure of 3,671 web links, including websites and online marketplaces, as well as social media pages advertising the sale of counterfeit or contraband pharmaceuticals.[14]

Pangea has gradually added more actors to its operations as the need for international collaboration across multiple organizations and sectors, as well cooperation between the public and private sectors, becomes more widely recognized. 2018's Pangea XI, for example, was carried out with the additional support of the WCO, PSI, the Heads of Medicines Agencies Working Group of Enforcement Officers as (WGEO), as well as Facebook, Twitter, and payment card companies.[15]

While the GSMS and Pangea are promising initiatives born out of a global recognition that counterfeit and contraband pharmaceuticals represent a growing problem, experts concede that their successes to date are almost certainly outpaced by the exponential growth of illicit pharmaceuticals sales.[16] Efforts to reduce global inequalities in access to healthcare, while a welcome development on the aggregate, inherently expand the pool of potential consumers for counterfeit and contraband pharmaceuticals. Globally, per capita spending on health has more than doubled in the last twenty-five years, but this increase in spending and corresponding expansion of the market for pharmaceuticals and medical products, particularly in middle-income countries, has, as the WHO states, "opened the door not just to quality, safe and effective medicines, but also to medicines, vaccines and other products that do not meet quality standards and that are sometimes positively dangerous."[17]

One particular region where per capita expenditures on health products are increasing, and the problem of counterfeit and contraband pharmaceuticals is expanding, is Central America. In 2017, Central American countries imported $3.171 billion worth of pharmaceutical products, with Costa Rica ($789 million) and Guatemala ($615 million) comprising the top two importers, con-

12 "Se Crea Alac, La Aliana Latinoamericana Anticontrabando," Departamento de Comunicaciones y Relaciones Publicas Fedeccal F.G. http://www.fedeccal.cl/se-crea-alac-la-alianza-latinoamericana-anticontrabando/

13 Shepherd, Marv. "Black Medicine," America's Quarterly. Summer 2010. http://www.americasquarterly.org/node/1698

14 "Illicit online pharmaceuticals: 500 tonnes seized in global operation," Interpol. 23 October 2018. https://www.interpol.int/News-and-media/News/2018/N2018-123

15 "Illicit online pharmaceuticals: 500 tonnes seized in global operation," Interpol. 23 October 2018. https://www.interpol.int/News-and-media/News/2018/N2018-123

16 Mackey, Tim K.; Liang, Brian A.; York, Peter; and Kubic. Thomas. "Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment," The American Journal of Tropical Medicine and Hygiene. 3 June 2015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455087/

17 "WHO Global Surveillance Monitoring System for Substandard and Falsified Medical Products," World Health Organization, 2017. http://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/

stituting 44 percent of imports for the entire region.[18] Within these growing markets, medicinal products like antibiotics, analgesics, multivitamins, and anabolic steroids are sourced from countries where they are cheaply produced or imported and then transported, often in unsuitable conditions, to other countries within the region. These medicines are often sold in open-air markets in highly populated areas, as well as in shopping centers and street-side shops. In some cases, illicit pharmaceuticals are sold at low prices to pharmacies where they are resold at standard market rates, increasing the profit margins for small pharmacy operators who struggle to compete with larger chains.

The challenges posed by illicit pharmaceuticals to Central America are, in many ways, indicative of the challenges faced by Latin America as a whole. A 2015 study, for example, ranked Latin America second, after Asia, as the region with the highest instances of counterfeit and contraband pharmaceuticals.[19] While counterfeit and contraband medicines from China are a global problem, illicit manufacturing and distribution within Latin America is likely to grow and take a greater share of the illicit market as Brazil's pharmaceutical industry continues to expand.[20]

Similarly, Central America is situated between two states, Colombia to the south, and Mexico to the north, where organized crime syndicates are steadily becoming more involved in trafficking counterfeit and contraband pharmaceuticals. In Colombia, believed to be one of the world's largest producers and exporters of illicit pharmaceuticals, the director of the tax and customs police estimated in 2013 that profit margins are between 500 and 1,000 percent for those involved in trafficking fake or stolen medicine.[21] Long established contraband routes along the Colombia-Venezuela border have enabled the production and sale of counterfeit and contraband pharmaceuticals on both sides of the border.[22] In July 2016, Colombian officials dismantled a network operating out of Bogotá, Medellín, and Cúcuta that generated $4 million by selling illegal pharmaceuticals, including "treatments for HIV, cancer, brain tumors and contraceptives." Some of these products were produced in clandestine factories using printing machines to clone legitimate brands. Others were expired goods that were sold by modifying sell-by dates, or medicines smuggled across the Colombia-Venezuela border and stored in inadequate conditions. In addition to selling products through the national healthcare system, authorities said the network would sell medicine to local pharmacies via Facebook and online marketplaces.[23]

In recent years, Mexico, a country long identified as a significant source for counterfeit drugs both in Latin America and the United States, has seen the emergence of "pharma cartels" which sell illegally procured prescription painkillers such as OxyContin and Vicodin to consumers in the United States.[24] As US authorities have cracked down on US-based "pill mills," organized criminal groups in Mexico have stepped in to fill the void, leveraging their connections and expertise to rob factories and pharmacies on both sides of the US-Mexico border, repackage expired pills, and source contraband and counterfeit pills from China.[25] Amid fluctuations in the demand for cocaine in North American markets, as well as variations in cocaine yields produced in South America, cartels whose involvement in illicit pharmaceuticals previously did not go beyond taxing lower level pharma

18 "Pharmaceutical Products: Central American Market Figures," Central America Data. 18 June 2018. https://www.centralamericadata.com/en/article/home/Pharmaceutical_Products_Central_American_Market_Figures

19 Mackey, Tim K.; Liang, Brian A.; York, Peter; and Kubic. Thomas. "Counterfeit Drug Penetration into Global Legitimate Medicine Supply Chains: A Global Assessment," The American Journal of Tropical Medicine and Hygiene. 3 June 2015. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4455087/

20 "How Do Fake Drugs and Chinese Counterfeit Medicine Impact Latin America & Its Pharmaceutical Industry?" Moeller IP Advisors. 10 January 2017. http://www.moellerip.com/how-do-fake-drugs-and-chinese-counterfeit-medicine-impact-latin-america-its-pharmaceutical-industry/

21 Southwick, Natalie. Colombia Pharmaceutical Trafficking 'Has 1,000% Profits Margins'." Insight Crime. 28 October 2013. https://www.insightcrime.org/news/brief/false-pharmaceutical-drug-trade-growing-in-colombia/

22 Crawley, Marguerite. "Desmantelamiento de medicamentos falsos expone lucrativo mercado entre Venezuela y Colombia," Insight Crime. 23 May 2014. https://es.insightcrime.org/noticias/noticias-del-dia/desmantelamiento-medicinas-falsas-expone-lucrativo-mercado-entre-venezuela-y-colombia

23 Yagoub, Mimi. "Colombia Busts Fake Medicine Ring Worth Millions," Insight Crime. 28 July 2016. https://www.insightcrime.org/news/brief/colombia-busts-fake-medicine-ring-worth-millions/

24 Mccleskey, Claire O'Neil. "Mexican Cartels Move into Prescription Pill Market," Insight Crime. 5 October 2012. https://www.insightcrime.org/news/brief/mexican-cartels-prescription-pills/

25 Bosworth, James. "Painkiller Black Market Will Likely Attract Mexico Criminal Groups." Insight Crime. 8 August 2012. https://www.insightcrime.org/news/brief/painkiller-black-market-will-likely-attract-mexico-criminal-groups/

traffickers for operating on their turf, have now moved into the market and are directly involved in the procurement, distribution, and sale of painkillers and opioids, most notably fentanyl sourced from China.[26]

In Central America, no country has been spared from the problem of counterfeit and contraband pharmaceuticals making their way to consumers. In 2017, as part of Pangea X, authorities in Panama, a country where more than one hundred people died in 2006 from poisonings caused by medicines laced with diethylene glycol,[27] seized more than 179 thousand units of pharmaceutical products valued at more than $800,000.[28] In El Salvador, more than 10 tons of pharmaceuticals that were smuggled into the country were found in a storage facility in the capital of San Salvador in 2017.[29] More recently, in November 2018, El Salvador intercepted 5,000 units of counterfeit medicine, valued at $450, at the international airport which were intended for the United States.[30]

Similar cases have been detected in Honduras, where last year authorities shut down a clandestine laboratory that was producing fake medicine to be distributed out of three storefronts.[31] Counterfeit and contraband variants of ibuprofen, amoxicillin, and sertal (an anti-inflammatory) are regularly available at *bodegas* throughout the country, many of which are believed to be sourced from neighboring El Salvador.[32] Also in Honduras, the then vice-president of congress was arrested after she and her family were linked to a pharmaceutical company that "allegedly embezzled and defrauded the government out of $120 million by selling poor-quality medicine at inflated prices" in 2015.[33] For its part, Nicaragua has emerged as a prominent source country for illicit pharma, where counterfeit and contraband pharmaceuticals have been found available in markets and pharmacies, and have been investigated for infiltration into hospitals.[34]

The overview above highlights the extent to which the rapidly evolving challenge posed by counterfeit and contraband pharmaceuticals involve simultaneous and overlapping issues related to technological innovation, global supply chains, global inequality, corruption, and governance. The case studies of Costa Rica and Guatemala, discussed in greater detail below, will highlight the extent to and ways in which counterfeit and contraband pharmaceuticals penetrate health systems is specific to local contexts. Both countries are grappling with the problem, but the grey and black markets that have emerged are uniquely shaped by each country's health systems, regulatory regimes, state capacities, and policy priorities. Thus, the desire to search for broad solutions to a global problem like counterfeit and contraband pharmaceuticals must at the same time be matched with locally calibrated strategies, given that each region, sub-region, and individual country requires solutions tailored to their own political, economic, and social realties. The challenge for international organizations, individual governments, regional and international bodies, as well as private sector actors, therefore, is to develop systems that can address the problem at the macro-level, and at the same time be flexible enough to account for and respond to micro-level imperatives.

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26 Davis, Kristina and Dibble, Sandra. "Fentanyl has taken over America's drug market. Where is it coming from?" San Diego Tribune. 17 June 2018. https://www.sandiegouniontribune.com/news/public-safety/sd-me-fentanyl-pipeline-20180617-story.html

27 "Interpol and Pharmaceutical Industry Launch Global Initiative to Combat Fake Medicines," Medical Xpress. 12 March 2013. https://medicalxpress.com/news/2013-03-interpol-drug-firms-fake-medicines.html

28 "Counterfeit drugs linked to money laundering was seized in Panama," Panamá Today. 26 September 2017. https://www.panamatoday.com/panama/counterfeit-drugs-linked-money-laundering-was-seized-panama-5333

29 Marroquin, David. "FGR y PNC incautan 10 toneladas de medicina illegal," El Diario de Hoy. 1 July 2017. http://www.eldiariodehoy.com/noticias/nacional/56870/fgr-y-pnc-incautan-10-toneladas-de-medicina-ilegal/

30 Rivas, Violeta. "Decomisan casi 5,000 medicinas falsificadas en Aeropuerto Internacional de El Salvador," ElSalvador.com. 14 November 2018. https://www.elsalvador.com/noticias/nacional/539283/direccion-nacional-de-medicamentos-decomisa-casi-5000-medicinas-falsificadas/

31 "El Ministerio Público desbarata un laboratorio de medicinas falsas," El Heraldo. 20 June 2018. https://www.elheraldo.hn/pais/1189890-466/el-ministerio-p%C3%BAblico-desbarata-un-laboratorio-de-medicinas-falsas

32 "Venden medicinas falsas y originales bajo sol y agua," La Prensa. 10 April 2018. https://www.laprensa.hn/actualidad/1171433-410/venden-medicinas-falsas-mercados-ministerio_publico-honduras-el_salvador

33 Pestano, Andrew V. "Honduras court orders corruption arrest of Congress vice president," United Press International. 2 July 2015. https://www.upi.com/Top_News/World-News/2015/07/02/Honduras-court-orders-corruption-arrest-of-Congress-vice-president/9321435848094/

34 "Denuncian más fármacos falsificados," La Prensa. 31 August 2010. https://www.laprensa.com.ni/2010/08/31/nacionales/458351-denuncian-mas-farmacos-falsificados

2: COSTA RICA

Scope and Scale of the Illicit Pharmaceutical Market

Costa Rica has seen a recent surge in contraband pharmaceuticals,[35] with government officials in 2014 stating that the problem of contraband (including non-pharmaceutical consumer goods) is bigger than the problem of drug trafficking, costing the country up to $100 million every year in lost tax revenue.[36]

Interviews with government officials, law enforcement representatives, healthcare providers, and private sector actors involved in the sale and distribution of pharmaceuticals indicated that relatively few counterfeit pharmaceuticals are available in Costa Rica. As one representative from the pharmaceutical industry explained, it is difficult to develop "industrial counterfeiting" in Costa Rica. The reasons cited included relatively strong Costa Rican institutions that monitor the import of precursors and ingredients, relatively low levels of corruption compared to other countries in the region, the comparative lack of organized criminal activity in the country, and higher costs of doing business in Costa Rica compared to its neighbors.[37] This sentiment was echoed regularly over the course of interviews in the field, with several people stating that opportunities for counterfeit pharmaceuticals to enter the broader market were limited due to the fact that the market for pharmaceuticals in Costa Rica is highly regulated. In order to produce and sell pharmaceuticals, vendors need to comply with a long list of requirements and pass laboratory tests from the Ministry of Health.[38]

The fact that approximately 40 percent of the medicinal stock in Costa Rica is supplied through the state-run Costa Rican Social Security Fund (known by its Spanish acronym of CCSS), which is responsible for overseeing the public health sector nationwide, also limits the market for counterfeit or illicit pharmaceuticals within the country. The CCSS, also commonly referred to as the "Caja," has tight controls over the procurement and distribution of pharmaceuticals, which in turn makes it very difficult for counterfeit pharmaceuticals to enter formal supply chains that feed into the CCSS.[39] These regulations also impact the private sector supply chains, which in addition to government controls and regulations (described by one private sector interviewee as effective but "excessive"[40]), are reinforced by the fact that Costa Rica is a small market of approximately five million consumers, with a small pharmaceutical sector in which all of the relevant actors, including regulators, distributors, marketers, and pharmacy owners are known to each other.[41]

This tightly regulated market, however, does come with certain negative consequences. While government officials, private sector actors, and analysts were confident that the system in place protects consumers and ensures high standards, it does reduce competition and causes prices to remain high compared to other countries in the region. According to one government official, the tight controls mean that fewer companies are willing to submit to oversight, "excessive technical barriers," and regulations required by the government, which leads to oligopolies and price distortions.[42]

According to law enforcement officials, the problem of counterfeit medicine is relatively controlled, and, in fact, not as large a problem as they anticipated it would be after a very large counterfeit case in 2015 in which law enforcement authorities broke up a family ring that was selling counterfeit Cofal (a cream used to relieve sore muscles). After a raid in which they confiscated large quantities of Cofal from a warehouse in San Rafael, they

35 Carrillo, Mario. "Costa Rica Registra Explosión de Contrabando de Drogas Farmacéuticas," Insight Crime. 29 May 2013. https://es.insightcrime.org/noticias/noticias-del-dia/costa-rica-registra-explosion-de-cobtrabando-drogas-farmaceuticas/

36 Rojas, Pablo. "País ignora pérdida económica por contrabando de licores, actividad crece como la espuma," CRHoy.com. 11 August 2014. https://www.crhoy.com/archivo/pais-ignora-perdida-economica-por-contrabando-de-licores-actividad-crece-como-la-espuma/

37 Interview in San José, Costa Rica, July 2018.

38 Interviews in San José, Costa Rica, July and August 2018.

39 Interviews in San José, Costa Rica, July 2018.

40 Interview in San José, Costa Rica, July 2018.

41 Interviews in San José, Costa Rica, July 2018.

42 Interview in San José, Costa Rica, August 2018.

Map No. 4430 UNITED NATIONS
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sent the product to a lab where they were able to determine that the Cofal was fake.[43] However, despite this raid, both the law enforcement officials interviewed plus additional fieldwork carried out for this report indicate that the prevalence of fake or counterfeit pharmaceuticals is, at least for the time being, relatively limited in Costa Rica.

There is good reason for caution, however. Higher pharmaceutical costs in Costa Rica compared with other countries in the region, combined with considerably tighter controls and enforcement of the import and sale of pharmaceuticals and precursors, naturally create the conditions for a black market to emerge and criminal entrepreneurs to profit from price discrepancies by moving pharmaceuticals sourced abroad into Costa Rica. Several people interviewed stressed that it is easier to purchase pharmaceuticals without the necessary prescriptions in Nicaragua, and that the quality control of laboratories there is substandard.[44] Due to this wider availability as well as price discrepancies, all manner of pharmaceuticals—from analgesics and anti-inflammatories sold over the counter, to injectable medications used for diabetes

43 Interview in San José, Costa Rica, July 2018.

44 Interviews in San José, Costa Rica, July 2018.

and cancer treatment—have been detected on the black market in Costa Rica.[45]

The overwhelming consensus among government and law enforcement officials, medical professionals, healthcare providers, private sector actors, and people directly engaged in the sale of illicit pharmaceuticals is that Costa Ricans who seek pharmaceuticals on the black market do so because of price. Several people interviewed stressed that Costa Rican, or "Tico" culture, is less accustomed to "informality" than in neighboring countries.

Unlike many of its neighbors, where political and economic turmoil, as well as the collapse of institutions, are in the living memory of much of the population, Costa Rica has largely been spared the civil wars and military rule that has plagued much of Latin America.[46] Relatively stable institutions and lower levels of corruption have inhibited the growth of criminal economies, which combined with comparatively higher levels of income, has translated to Costa Ricans being inclined to trust in and turn to formal institutions when purchasing pharmaceutical products, especially in cities where, to quote one governmental official, "there is a pharmacy every 100 meters."[47]

By comparison, in neighboring Nicaragua, a country with a much more complicated political and economic history, "informality" is woven into the daily lives of many of its citizens. In places like the *Mercado Oriental* in Managua, widely considered the largest market in Latin America, counterfeit or black market products are sold openly, with government regulators and even law enforcement unable to assert control of what one municipal manager in 2016 referred to as a "miniature country" within the city.[48]

One potential growth opportunity for criminal entrepreneurs that may not be receiving sufficient attention is brand falsification. "The consumer only cares if the product is cheap and works," a Costa Rican lawyer specializing in intellectual property explained, "which opens up a great opportunity for counterfeiters" of health products, vitamin supplements, and cosmetics.[49] According to one pharmacist and business person who has experience importing pharmaceuticals and medical equipment and has been a supplier for the CCSS, brand falsification is in part driven by the fact that as generic drugs from India and China become more prevalent, competition with "name brand" pharmaceuticals has created the space for narratives that generics are less effective or of lower quality. As a result, counterfeiters and smugglers may seek to repackage generics in order to sell them on the black market under their "brand name" equivalent.[50] The result may be a burgeoning market in which consumers seek to find brand name pharmaceuticals on the black market (points of sale being through vendors in public parks and shops, or online vendors), rather than purchase the generic equivalent through the CCSS or pharmacies.[51]

According to government officials, there have not been any detected cases of counterfeit or falsified pharmaceuticals entering the CCSS supply chain. There have been cases, however, in which Costa Rican authorities were able to quickly and effectively confiscate and recall products that had been identified as substandard by international alerts. In one such case, the Costa Rican authorities were able to act on an alert put out by the United States Food and Drug Administration to confiscate sexual performance drugs being sold in "sex shops" that contained two to three times the active ingredients that they should have.[52]

While the circumstances outlined above have succeeded in limiting the scale and scope of contraband or counterfeit pharmaceuticals available in Costa Rica, the political crisis in neighboring Nicaragua has invigorated demand for pharmaceuticals on the black market. Nicaraguans who have fled to Costa Rica do not have the same purchasing power as their Costa Rican counterparts, and a large percentage of Nicaraguans in Costa Rica are undocumented and thus cannot access formal healthcare

45 Interview in San José, Costa Rica, July 2018.

46 "Costa Rica Country Profile," Insight Crime. 23 April 2018. https://www.insightcrime.org/costa-rica-organized-crime-news/costa-rica/

47 Interview in San José, Costa Rica, July 2018.

48 Mejia, Brittany. "Seeking bargains, and hope, at the market swallowing Nicaragua's capital bit by bit," Los Angeles Times. 4 2016 May. https://www.latimes.com/world/mexico-americas/la-fg-nicaragua-mercado-20160504-story.html

49 Interview in San José, Costa Rica, July 2018.

50 Interview in San José, Costa Rica, July 2018.

51 Interviews in San José, Costa Rica, July 2018.

52 Interviews in San José, Costa Rica, July 2018.

institutions beyond emergency care. The black market for pharmaceuticals has expanded considerably as a result (Global Initiative researchers had no problem finding black market pharma for sale) and there is concern that this expansion could potentially "pull" more Costa Ricans into the market as more pharmaceuticals become available on the black market.

Similarly, should a more sophisticated smuggling and black-market infrastructure emerge in order to serve the needs of undocumented Nicaraguans, new criminal groups may emerge in order to more efficiently meet the demands of the market. Should this market thrive, existing criminal groups in the region may seek to seize it, and groups engaged in the smuggling and sale of black-market pharmaceuticals may seek to expand the market to include more Costa Rican consumers.

At overland border crossings with Nicaragua and Panama, as well as in airports, contraband pharmaceuticals have been detected, but as officials at border crossings and in San José told the Global Initiative, pills and tablets are easy to hide and are hard to detect. Furthermore, people are allowed to travel with medicine, so they have a greater likelihood of passing through borders undetected compared to other forms of contraband.[53] The porous borders and relatively few official border crossings also provide an opportunity for smuggling into the country.[54]

Reliable estimates regarding quantities of contraband pharmaceuticals in Costa Rica are not available, but numbers provided by Costa Rican law enforcement based on raids carried out since 2015 confirm the prevalence of said contraband. According to law enforcement officials, Costa Rican authorities confiscated 9,266,816 units (a unit being a tablet) of contraband pharmaceuticals in 2015. In 2016, that number fell to 38,162, and rose to 225,000 in 2017. As of July 2018, the number for the year was 100,000-150,000.[55]

Additionally, government officials and local security analysts say there has been a marked increase in online sales in recent years, via social media such as Facebook as well as on the dark web. In the words of one government official, "this has been a hook for many Ticos to choose more to buy online, at least in the last 3 years, the reports of online sales have skyrocketed."[56]

This increase in online sales is attributed to the aforementioned price differences across the region, as well as the higher relative purchasing power of Costa Ricans compared to other nationals in the region, which creates incentives for black market sales. At the same time, consumer purchasing habits are changing. Officials cited the fact that Costa Ricans are increasingly comfortable with purchasing products online and having it delivered to their door. Although the consumer has no real way of verifying the source of the pharmaceuticals or if they have been properly stored and transported, consumers do not necessarily have reason to believe that it is not a quality product[57] In cases where people are seeking medicine for chronic or life-threatening conditions and cannot afford treatment through formal channels, a more affordable option advertised online, replete with a professional looking website and reliable delivery, is particularly appealing.[58]

Several government officials as well as local analysts highlighted an increased prevalence of ketamine, a drug used for anesthesia, but also for recreational abuse, on the black market. The drug is tightly controlled in Costa Rica, and standardized region-wide efforts are harmonizing regulations through *Red Panamericana para la Armonización de la Reglamentación Farmacéutica* should, in theory, mitigate differences in registration and controls processes throughout Central America. Yet, according to officials and analysts in Costa Rica, these controls are not being sufficiently applied or implemented in neighboring Nicaragua, likely due to the volatile political situation there.[59] Although ketamine represents

53 Interviews in San José and Peñas Blancas, Costa Rica, July and August 2018.
54 Interviews in San José, Peñas Blancas, and Los Chiles, Costa Rica, July and August 2018.
55 Interview in San José, Costa Rica, July 2018.
56 Interview in San José, Costa Rica, July 2018.
57 Interview in San José, Costa Rica, July 2018
58 Interview in San José, Costa Rica, July 2018.
59 Interviews in San José, Costa Rica, July 2018.

just one example (benzodiazepines and Diazapam were also mentioned in interviews), continued instability in neighboring Nicaragua could lead to highly controlled substances, such as painkillers, being more readily available on the black market. It also underscores the extent to which harmonized approaches to regulation can only be as effective as their implementation.

Modus Operandi of Groups Involved

Fieldwork carried out for this paper indicates that there is clearly some level of transnational and organized coordination that links black-market pharmaceutical vendors in certain parks and markets in Costa Rica, and possibly online vendors, to source countries in the region from where black-market pharmaceuticals are imported. But the extent to which these linkages constitute a sophisticated network of organized criminals or defined groups of actors is not clear. Although there are certain conditions that could lead to such groups coalescing around a growing demand for black-market pharmaceuticals, there is no such evidence at this time that established organized criminal groups in the region are heavily involved.

Interviews with government officials and law enforcement, for example, did not indicate that those engaged in the sale of pharmaceuticals on the black market were linked to other illicit activities, although there are certainly some actors who, due to the fact that they operate in proximal "illicit spaces," are engaged in overlapping types of criminal activity.[60] The more measured consensus suggests that flows of illicit pharmaceuticals are part of a broader "contraband economy" in which goods from abroad (products such as clothing, beauty supplies, electronics, etc.) enter through ports and land borders.[61] For example, Costa Rican authorities have arrested several people smuggling ethanol from El Salvador, Guatemala, and Nicaragua into the country, which can be used as a precursor to manufacture drugs, but in this case was being used to adulterate liquor.[62] Several government officials and analysts suggested that pharmaceuticals from abroad enter the country by being hidden within larger shipments of legal goods, as well as "drop by drop" in the form of small quantities brought in by individuals acting as couriers.[63]

Although there are no clearly defined networks or groups, fieldwork and interviews did identify two main points of sale, public parks and online, that are useful starting points for trying to better understand how illicit pharmaceuticals are sold in Costa Rica.

Researchers for the Global Initiative, for example, were able to observe the activities of three different vendors at the *Parque de la Merced*, a location where an array of licit and illicit contraband, as well as legal goods, are sold by foreigners, most notably Nicaraguans. As recently as 2015, *Parque de la Merced* was, according to one law enforcement official, a place where people carried pharmacies in their suitcase and sold it "like chewing gum."[64] But after publicized raids and arrests in recent years, the sale of black-market pharmaceuticals has become less overt, with vendors changing up their modus operandi to avoid the attention of police officers in the park.

On one particular day, the Global Initiative observed two women furtively, but with relatively little subtlety, selling pharmaceuticals, including anti-inflammatory and pain-relief pills, as well as beauty products such as skin cream, out of plastic-lined handbags at the *Parque de la Merced*. Prospective clients would ask them for a particular type of medicine, and the vendors would rummage through their respective bags. In the event that they did not have the product, they would often send someone to a similar vendor or send someone to fetch the product.

One of their clients, a Costa Rican national, said he comes to the *Parque de la Merced* for medicines that he would otherwise buy over the counter in supermarkets and pharmacies, because it is cheaper. "I am sure it is real," he said, showing a packet of nasal decongestant pills that were still in their original foil packaging, but removed from the box within which they are sold over the counter. "Even if it is expired it probably still helps," he continued, also suggesting that the risk of purchasing such products on the black market was relatively low because he was only

60 Interviews in San José, Peñas Blancas, and Los Chiles, Costa Rica, July and August 2018.
61 Interviews in San José, Peñas Blancas, and Los Chiles, Costa Rica, July and August 2018.
62 Interview in San José, Costa Rica, July 2018.
63 Interviews in San José, Peñas Blancas, and Los Chiles, Costa Rica, July and August 2018.
64 Interview in San José, Costa Rica, July 2018

trying to treat a minor cold. A taxi driver by profession, he elaborated that if he had a more serious ailment, he would not buy drugs in the park and would be willing to spend more money at pharmacies, but for these "little things," it is not worth paying "full prices."[65]

Notably, the *Parque de la Merced* is within a short walk of several hospitals, including the *Hospital San Juan de Dios*, the *Hospital Metropolitano*, the *Hospital Nacional de Geriatría y Gerontología Raúl Blanco Cervantes*, and the *Hospital Nacional de Niños*, as well as several pharmacies and shops that sell non-prescription pharmaceuticals. The proximity, one government official highlighted, further underscores the extent to which black-market pharmaceuticals are readily available.[66]

The vendors at the *Parque de la Merced* on this day were reticent about being interviewed, but did confirm that their products came from Nicaragua, and that when a customer comes to them looking for a product they do not have, they contact other vendors in order to try to find it for them.[67]

One vendor at the *Parque de la Merced* did agree to go into more detail a week later. She said she came to Costa Rica from Nicaragua with her husband two years ago looking for work, and is undocumented. When she first came to Costa Rica, her brother-in-law in Managua (Nicaragua) asked them to bring a small shipment of medicine that could fit inside a pair of shoes. When she arrived in San José (Costa Rica), she delivered the medicine to a Nicaraguan woman at *Parque de la Merced*. She began working with the woman in the park, selling mostly anti-inflammatory pills, and was surprised at the amount of people who came to purchase medicine at the park, as well as the amount of people who worked together to supply the pills that clients were asking for.

She insisted that she only sells real pharmaceuticals that are produced in "good laboratories" in Nicaragua, sourced from a friend in Managua who sends her medicines via couriers on buses. She said she knows other people who sell drugs that are expired or "damaged," or are "only sugar," but she does not because many people know her and she would be easily identified by clients if she were to sell fake or substandard medicine. That is why, according to her, she does not sell injectable pharmaceuticals—she would need to keep them properly refrigerated.

According to this vendor, the police have confiscated her merchandise three times in the last two years, but most of the time, the police pass in front of her and do not even check her bag. She says she even once sold pills to a police officer to help him with a headache and that he came by to thank her the next morning.

In terms of sourcing her product, the woman said that she has only had her merchandise confiscated at the border once, when the person who was smuggling the pills was rounded up in a police operation targeting people believed to be involved in migrant smuggling. Other than that incident, she has always received her orders, which she pays for in San José by making deposits of about $500 per month via Western Union. Her profit, she said, is also about $500 per month.[68]

As previously mentioned, interviews with government officials and analysts suggested a dramatic increase in the sale of black-market pharmaceuticals online in recent years, with several different techniques being used by online vendors.[69] Social media, particularly Facebook pages, are increasingly used to advertise contraband pharmaceuticals at rates cheaper than available through formal hospitals and pharmacies. It is not clear how these vendors source their drugs, but in addition to contraband brought in from outside of the country, several sources suggested that these types of pages are often used to sell "loose pharma" that is sourced in Costa Rica. That is, these drugs are excess prescription medicine sourced from people who have recovered and have pills or tablets remaining, or family members of people who have passed away from chronic or life-threatening diseases.[70] The fact that some of these social media vendors, who start new pages as soon as authorities shut

65 Interview in San José, Costa Rica, July 2018.
66 Interview in San José, Costa Rica, July 2018.
67 Interviews in San José, Costa Rica, July 2018.
68 Interview in San José, Costa Rica, August 2018.
69 Interviews in San José, Costa Rica, July 2018.
70 Interviews in San José, Costa Rica, July 2018.

them down, are capable of providing high-value drugs at a discount and without prescriptions, and with a degree of professionalism, makes them appealing in the eyes of consumers who might otherwise be reticent to purchase medicine on the black market.[71]

Another burgeoning point of sale, and one that is much more difficult to combat, although less easy to access, is markets on the dark web. Black-market pharmaceuticals are only a fraction of what is being sold on sites on the dark web, which may also sell everything from narcotics to weapons to trafficked women and hitmen for hire. But, as one private sector actor who follows the contraband economy in Costa Rica explained, the professionalization of the dark web has reached a level where, "it works just like Amazon," with sellers receiving ratings and reviews and products being delivered at people's doorsteps in a matter of days.[72]

While Facebook pages and other forms of social media tend to be run by local actors catering to local markets, websites operating on the dark web are believed to be more global in scope, and allow for drugs sourced in places such as China, India, or Brazil to be shipped via mail directly to Costa Rica. The nature of these websites allows for anonymity for both the buyer and seller to be maintained through encryption, and for payments to be made via cryptocurrencies which are also encrypted. As a result, pinning down where vendors using these market places are based, where they source their products, and the extent to which they are connected to established organized crime groups is a literal and "virtual" unknown.

Another trend of note, according to security analysts, is that smuggling routes of all sorts of contraband from Nicaragua into Costa Rica may continue to grow, not only as more Nicaraguans seek refuge in Costa Rica but also as the Nicaraguan police and military grow more preoccupied with the political crisis, turning their attention away from criminal activity. Criminal networks may seek to profit from this insecurity and instability in a myriad of ways, including moving pharmaceutical smuggling away from an "artisanal" activity toward a more "sophisticated industry" operated by organized crime.[73]

There is a growing concern that although Costa Rica has largely been spared the corruption and violence perpetrated by organized crime groups in Latin and Central America (although the country has been a transshipment zone for cocaine from Colombia for years), an increase in drug consumption and a recent rise in violence could indicate that these networks are penetrating Costa Rican society in new ways.[74] Local analysts and government officials expressed concern that organized crime networks could expand in Costa Rica in a way that starts to stress and stretch institutions, thus creating pathways of corruption. As one government official involved in drug enforcement warned, the logistics will be built on other criminal activity, and counterfeit or smuggled pharmaceuticals will enter via that infrastructure.[75]

Government Responses

The Costa Rican government has identified the problem of contraband and counterfeit pharmaceuticals and has responded with several concrete measures. In addition to law enforcement measures carried out in the form of raids, and participation in PANGEA in conjunction with Interpol, the government established the *Comisión Nacional contra Productos Ilícitos Falsificados* (CoNaPIF). CoNaPIF is a working group that brings in relevant actors from throughout the government, including, but not limited to, the Ministry of Health, law enforcement, intelligence officials, Interpol, CCSS, border and airport control, and fiscal authorities, to better tackle the problem of contraband and counterfeit products, including medicine.

There have been several instances in which illicit, substandard, or falsified pharmaceuticals have been detected in Costa Rica on the black market, or in private phar-

71 Interview in San José, Costa Rica, July 2018.

72 Interview in San José, Costa Rica, July 2018.

73 Interview in San José, Costa Rica, July 2018.

74 Dennis, Claire. "Consumo local de drogas en Costa Rica agudiza tasa de homicidios," Insight Crime. 20 July 2017. https://es.insightcrime.org/noticias/noticias-del-dia/consumo-local-drogas-costa-rica-agudiza-tasa-homicidios/; Asmann, Parker. "Arrestos en Costa Rica apuntan a mayores nexos de fuerzas de seguridad en narcotráfico," Insight Crime. 24 May 2018 https://es.insightcrime.org/noticias/noticias-del-dia/arrestos-en-costa-rica-apuntan-a-mayores-nexos-de-fuerzas-de-seguridad-en-narcotrafico/; and Kjelstad, Bjorn. "¿Cuál es la causa de la creciente violencia en Costa Rica?" Insight Crime. 16 August 2018. https://es.insightcrime.org/noticias/analisis/causa-creciente-violencia-costa-rica/

75 Interview in San José, Costa Rica, August 2018.

macies, but there have not, to date, been detected cases of fraudulent or falsified medicine infiltrating government pharmacies or hospitals, which is widely cited as a testament to the procedures and regulations in place.[76] Costa Rica has clear policies and procedures to respond to these cases of counterfeit and contraband pharmaceuticals, and any entity that wishes to sell pharmaceuticals must have operating permits and agree to regular oversight, which to date has succeeded in ensuring that the CCSS supply chain has not been compromised. Costa Rica's existing procedures and institutions, combined with its cooperation with international institutions and the private sector, have so far succeeded in mitigating and responding to the risks posed by counterfeit and contraband pharmaceuticals.[77]

Government representatives, for example, were able to cite several success stories in which various institutions collaborated to detect, identify, and tackle problems related to contraband pharmaceuticals. In one such example, the Ministry of Health had received a general complaint that a bus company providing transportation between Nicaragua and Costa Rica was smuggling medicine amidst its licit cargo. The only information the Ministry of Health had to go on was a name, but thanks to recently developed relationships and lines of communications across agencies they were able to act quickly and coordinate with law enforcement, which had the capacity and authority to request a vehicle review. After fifteen days of monitoring, they were able to intercept one of the buses, on which they discovered a compartment hidden under the driver that had four boxes full of pharmaceuticals that were not registered in Costa Rica, and had been manufactured in El Salvador, Nicaragua, Guatemala, and Mexico.[78]

Government officials also said that CoNaPIF has enabled them to reach a level of inter-institutional coordination and establish protocols that did not exist before, and to help sensitize relevant actors as to the nature of the problem. According to one government official, several years ago, border police may have detected someone with four boxes of medicine, and might not have considered it to be suspicious, let alone thought to call the Ministry of Health or even have the contact information of the relevant liaison. Now, the border police know to confiscate the pharmaceuticals and alert the Ministry of Health so that they can confirm that the product is legal.[79]

76 Interviews in San José, Costa Rica, July 2018.
77 Interviews in San José, Costa Rica, July 2018.
78 Interview in San José, Costa Rica, July 2018.
79 Interview in San José, Costa Rica, July 2018.

3: GUATEMALA

Scope and Scale of the Illicit Pharmaceutical Market

The existence and expanding market for illicit pharmaceuticals in Guatemala is a reflection of the huge challenges the country faces in terms of ensuring Guatemalans' right to high quality, universal healthcare. The health indicators of poor and indigenous Guatemalans, who comprise almost 50 percent of the total population, continues to be among the worst in the Western Hemisphere. According to the United States Agency for International Development, 65.9 percent of indigenous children suffer from chronic malnutrition, and the infant mortality rate for the indigenous population is 40 per 1,000 live births.[80]

Guatemala, according to the Pan American Health Organization (PAHO), has a chronic shortage of healthcare practitioners, and medical resources tend to be centralized and concentrated in urban areas. The country has an average of 9.92 doctors per 10,000 inhabitants and 71 percent of healthcare practitioners can be found in the country's central department. As a result, there is one doctor per 332 inhabitants in Guatemala City and surrounding municipalities, but only one doctor per 9,064 inhabitants in the highland department of Quiche, where the majority of the population is rural and indigenous.[81]

Under Guatemalan law, public and private sector workers have the right to receive healthcare from the Social Security Institute (known by its Spanish acronym of IGSS), which is funded through monthly quotas paid by employees and employers. However, less than 20 percent of the workforce is affiliated with the IGSS, which is a reflection of the growth of the informal economy and the prevalence of temporary contracts that do not offer these benefits. In 2014, various pharmaceutical companies decided not to participate in tenders for medicines or supply drugs to the state due to unpaid debts owed by the government. The public healthcare system reached a critical juncture in 2015, when patients went on a hunger strike to protest against the lack of medication, food, and basic supplies such as bed sheets and cleaning products in the country's forty-four public hospitals.[82]

The situation in hospitals run by the IGSS has continued to deteriorate in recent years, with a chronic shortage of medication becoming the norm. In March of 2018, for example, a group of IGSS patients held a protest at the institute's headquarters and said their lives were at risk due to a shortage of medication to treat chronic illnesses such as kidney failure.[83]

Underfunding for public hospitals has been compounded by corruption. In May 2015, the International Commission Against Impunity in Guatemala (known by its Spanish acronym of CICIG), a UN-funded anti-graft body that Guatemalan President Jimmy Morales is currently seeking to disband, arrested a number of high level IGSS officials including the institute's former president, Juan de Dios Rodríguez, for anomalies in a contract signed with the PISA pharmaceutical company, which was linked to deaths of a number of kidney patients who received deficient treatment and sub-standard medication.[84]

Although the dismantling of this corruption network was an important step towards stamping out corruption within the healthcare sector and led to the approval of a stricter procurement law (*Ley de Contrataciones del Estado*), it has also made procurement procedures slow, as public officials are wary of approving purchases within a system that is still rife with corruption, for fear they will blamed for any anomalies further down the line.[85] As a result, a shortage of medication in IGSS hospitals continues to be a major problem.

80 "Health and Nutrition: Situation Analysis," USAID-Guatemala. https://www.usaid.gov/guatemala/health-nutrition

81 "Guatemala: Overall Context," Pan American Health Organization. https://www.paho.org/salud-en-las-americas-2017/?p=3338

82 "Guatemala: Pharmaceutical Companies Not Selling Medicines to State." Central America Data. 4 November 2014. https://www.centralamericadata.com/en/article/home/Guatemala_Pharmaceutical_Companies_Not_Offering_Medicines_to_State

83 Orozco, Andrea. "Falta de medicinas causa inconformidad," Prensa Libre. 27 March 2018. https://www.prensalibre.com/guatemala/comunitario/igss-faltan-medicinas-pacientes-con-enfermedades-cronicas-catastroficas-derechos-humanos-camip/

84 Gagne, David. "Reciente escándalo de corrupción en Guatemala podría terminar por derrocar al presidente," 22 May 2015. https://es.insightcrime.org/noticias/analisis/reciente-escandalo-corrupcion-guatemala-terminar-derrocar-presidente/

85 Interviews in Guatemala City, September 2018.

Map No. 3834 Rev. 3 UNITED NATIONS
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Department of Peacekeeping Operations
Cartographic Section

The criminal market for illicit pharmaceuticals in Guatemala can be divided into two main categories. First, contraband medicines sourced internationally or domestically, for sale in black and grey markets; and second, counterfeit pharmaceuticals produced illegally in registered laboratories and clandestine laboratories in Guatemala.

Concerning the first category, our fieldwork identified three main categories of illicit pharmaceuticals being sold within Guatemala.

The first consists largely of medicines smuggled into the country from abroad, brought into Guatemala from neighboring Mexico and El Salvador. These products either enter through illegal border crossings known as *puntos ciegos*, or are brought in at legal crossings, in small amounts by people who repeatedly cross the border. Although these medicines are not counterfeit, they are not legally registered with the Guatemalan Ministry of Health (*registro sanitario*) and those bringing them into the country have not paid import duties.[86]

In June 2018, for example, Guatemalan police arrested individuals who were smuggling pharmaceuticals from Mexico and using fake rubber stamps from Mexican and Guatemalan doctors in order to print fake prescriptions and obtain prescription-only medication. In August 2018, Guatemalan authorities raided two distributors (*droguerías*), selling contraband medicine brought to the country from Mexico and El Salvador. Some of the medicine had passed its expiration date.[87]

According to interviews with government officials, individuals engaged in these types of activities usually work in small groups, often as small as two or three people. Their target clients are small pharmacies in poor neighborhoods in Guatemala City and in rural areas, as well as markets such as *La Terminal*, *El Guarda,* and *La Florida*; in Guatemala City; small markets in rural towns (*mercados cantonales*); and small grocery stores (*tiendas de barrio*). The contraband pharmaceuticals are usually stored in houses or in clandestine warehouses and distributed to pharmacies or to the black-market points of sale using motorbikes and minivans.[88]

Sometimes these individuals sell both contraband and legally imported medicine in an attempt to avoid detection by the authorities. In July 2018, for example, the police raided the home of an individual in the highland department of Quetzaltenango who had a basement full of food supplies, medication, and sexual performance pills, all from Mexico. The police checked the individual's import documents and discovered that around 45 percent of the merchandise was contraband and the rest had been legally imported. According to government officials, the contraband medicine was being sold in small, independent pharmacies in various towns in Quetzaltenango and San Marcos.[89]

The second main category of illicit pharmaceuticals available in Guatemala are medicines that are prescribed to patients from the IGSS, and then sold on the black market. According to government officials, these schemes typically involved small groups of individuals, in which taxi drivers who loiter in the vicinity of IGSS hospitals seek to purchase medication from prescription holders as they leave. Prescription medicine procured in this way has been found in small pharmacies in poor neighborhoods in Guatemala City, small grocery stores (*tiendas de barrio*) or used clothes stores known as *pacas*. This medication is clearly marked as "government property" and therefore not placed on shelves but sold directly to customers that request it (*venta por encargo*).[90]

The sale of medicine belonging to IGSS hospitals represents an obvious health hazard to the patients who choose to sell their medication on the black market, as well as to consumers who cannot be sure that the products have been properly stored or that they have not been tampered with. According to government officials, one criminal network that was selling medication purchased from IGSS prescription holders, arrested by the police in 2015, was selling expired medicine.[91] In August 2018, the Guatemalan police raided two distributors in Guatemala City, named Fardeco and Chic, that were

86 Interviews in Guatemala City, September 2018.

87 Monzón, Kenneth. "Droguerías comercializaban medicinas adulteradas, vencidas y sin registro," Prensa Libre. 21 August 2018. https://www.prensalibre.com/guatemala/justicia/ministerio-publico-detecta-medicamentos-sin-registro-sanitario-en-la-ciudad

88 Interviews in Guatemala City, September 2018.

89 Interviews in Guatemala City, September 2018.

90 Interview in Guatemala City, Guatemala, September 2018.

91 Interview in Guatemala City, Guatemala, September 2018.

selling contraband pharmaceutical products. One of the products available was an anti-fungal cream produced by Selecfarma that had been taken off the market five years ago and contained a quantity of steroids higher than recommended by health professionals.[92]

In addition to medication brought in from outside Guatemala, or purchased from prescription-holders for resale on the black market, a third source of illicit pharmaceuticals available in Guatemala is medication stolen from public hospitals. According to government officials, this problem is particularly acute in hospitals in Guatemala City.[93]

As previously mentioned, the second main category of the illegal pharmaceutical market in Guatemala is counterfeit pharmaceuticals produced within Guatemala. In recent years, Guatemala identified several "legal" laboratories that were producing products for which they did not have proper authorization, as well as clandestine laboratories that are completely illegal.

According to government officials, the "legal" laboratories usually have a license from the Mercantile Registry and a license from the Ministry of Health, but produce medicines or supplements for which they do not have a patent. These products are distributed to small pharmacies in rural areas, mainly in the Northern departments of San Marcos and Huehuetenango, as well as to markets in poor neighborhoods in Guatemala City.[94]

In 2012, police raided a clandestine laboratory that was producing counterfeit Neurobion (a vitamin B supplement produced by Merck) and Ensure (a nutritional powder produced by Abbott). The people running the laboratory were apparently exporting these counterfeit products to Mexico.[95] Counterfeit versions of Unal, a contraceptive made by Piersan, contained nothing but common painkillers. In addition to producing fake or substandard products, clandestine laboratories often operate in unsanitary conditions, further compounding the risks they pose to public health. According to prosecutors, counterfeit Neurobion and Ensure supplements produced in the clandestine laboratory raided by police in 2012 were contaminated with fecal matter.[96]

Sample list of contraband products found in Guatemala:

Neurobion (vitamin B)

Virogrip (anti-flu medication)

Vicks Vaporub

Clotriplex (anti-fungal cream containing betamethasone and clotrimazole)

Neobol (a cream containing Clostebol used to treat burns, dermatosis and other skin conditions)

Hemorrhoid cream

Chinese Viagra

Ambroxol (a drug that breaks up phlegm)

Metronidazole (an antibiotic used to treat pelvic inflammatory disease)

Ceftriaxone (antibiotic)

Oxolvan syrup

Dexamethasone (a corticosteroid medication)

Neo-melubrina (An antipyretic drug banned in the US due to its association with agranulocytosis but available in Mexico)

Metamizole (painkiller)

Rowatinex (used to help dissolve and help prevent the reformation of kidney stones. Contains pinine, camphene and other ingredients)

Eye cream

Cream to treat athlete's foot

Slimming tablets

Diclofenac (non-steroidal anti-inflammatory drug)

Cyanocobalamin (synthetic form of vitamin B)

Testosterone

Supplements for osteoarthritis

Levonogestrel (birth control)

92 Monzón, Kenneth. "Droguerías comercializaban medicinas adulteradas, vencidas y sin registro," Prensa Libre, 21 August 2018. https://www.prensalibre.com/guatemala/justicia/ministerio-publico-detecta-medicamentos-sin-registro-sanitario-en-la-ciudad

93 Interview in Guatemala City, Guatemala, September 2018.

94 Interview in Guatemala City, Guatemala, September 2018.

95 Interview in Guatemala City, Guatemala, September 2018.

96 Interview in Guatemala City, Guatemala, September 2018.

According to one drug company executive, criminal organizations prefer to produce counterfeit versions of popular, widely-purchased consumer products rather than specialty medicines. "Counterfeit production occurs with products sold in large volumes because if a product is very specific, counterfeits are a lot easier to detect," he explained.[97]

Despite the fact that contraband and counterfeit pharmaceuticals have been found in smaller, independently run pharmacies, there have been no recorded cases of their sale in large, chain operated pharmacies such as Batres, Galeno, Cruz Verde, and Meykos. According to government officials and industry representatives, the gradual consolidation of the pharmacy industry has forced many smaller pharmacies out of business. As a result, some small pharmacies struggling to stay open may be willing to procure and sell contraband pharmaceuticals in order to survive.

"[Illicit pharmaceuticals] are sold in small pharmacies in rural villages or working-class neighborhoods because when chain pharmacies arrived they brought the prices down because they purchased medicine in bulk and the smaller pharmacies couldn't compete with them," explained one pharmaceutical executive. "When someone offers them a cheaper product they are going to buy it because that's how they can compete with the pharmacy chains. That's how *falsificados* came to exist because there were a lot of smaller clients that couldn't compete with the chains," he continued. "Initially, the chains used to purchase medicine from distributors or *droguerías*, as they're known here. After some time, they started to compete against each other by offering discounts and the chains began to purchase medicine directly from the pharmaceutical companies so that they could use the percentage of the price that was paid to distributors to compete against each other, which meant that distributors were also pushed out of the market."[98]

There are no reliable estimates regarding what percentage of contraband or counterfeit pharmaceuticals in Guatemala end up being sold in legally established and licensed businesses such as independently run pharmacies, versus those sold on the street. Public officials and pharmaceutical companies provided estimates as varied as 20 and 40 percent.[99]

Contraband and counterfeit pharmaceuticals are usually purchased by low-income individuals in poor neighborhoods in Guatemala City or in rural areas who are desperate to obtain low-cost medication. The popularization of generic brands has also caused confusion among consumers. Clients who are unlikely to know the active ingredients in medicine may confuse contraband and counterfeit pharmaceuticals with cheaper, generic brands. According to government officials and healthcare experts, many of the rural and urban poor in Guatemala are not aware of the fact that pharmaceutical companies need permits from the Ministry of Health (*registro sanitario*) and must have a registration number.[100]

"The (Guatemalan) healthcare system is based on maternal and child healthcare, meaning that unless you're a pregnant woman you won't have access to public healthcare services. This leaves diabetes patients, patients with renal diseases or who need HIV medication in a difficult predicament because they don't receive any help from the state," explained a former high-level public health official. "Public hospitals will give you medication while you're there, but after you're discharged from hospital you have to buy your own medication. So, what do you do? You buy it on the black market. And logically you'll go for the cheapest option. You'll do what you have to do in order to survive."[101]

According to government officials and private sector actors, people who purchase contraband and counterfeit pharmaceuticals often have little awareness of the health risks involved. Both those consuming and selling medicine, for example, often mistakenly believe that there is minimal to no danger in consuming expired medicine. "These people (the people selling social security medication on the black market) didn't have the necessary permits and none of them were responsible for ensuring the medication hadn't expired or met the necessary quality standards," said one government official. "We asked one individual why they kept huge amounts of

97 Interview in Guatemala City, Guatemala, September 2018.
98 Interviews in Guatemala City, Guatemala, September 2018.
99 Interviews in Guatemala City, Guatemala, September 2018.
100 Interview in Guatemala City, Guatemala, September 2018.
101 Interview in Guatemala City, Guatemala, September 2018.

Some Examples of Counterfeit Drugs Produced in Guatemala		
Neurobion, an injection containing B vitamins.	Made by Merck	Clandestine laboratory in Guatemala City, zone 8
Ensure, a nutrition powder	Made by Abbott	Clandestine laboratory in Guatemala City, zone 8
Foly Tonic, a vitamin supplement for children and adolescents	Made by Phara	Found in a local pharmacy in Mazatenango, southern coast
Unal, an injectable contraceptive	Made by Laboratorios Piersan, a Guatemalan pharmaceutical company	Found in two small pharmacies in Guatemala City

medication that had passed its use by date and she said: 'We know it can still be taken 10 months after the expiry date.'"[102]

"They (the network selling IGSS medicine) sought people who were very sick because the Social Security Institute gives them a greater amount of medication," said one government official. "When we raided the location where they kept the medicine we noticed that one of the individuals involved was diabetic and was about to have his leg amputated. We realized that these people prefer to sell their medication on the black market rather than taking their medication."[103]

Due to the fact that abortion is illegal in Guatemala with the exception of when a woman's life is at risk, there is a considerable black market for abortion pills or medicines that can be used to abort a pregnancy.[104] One widely cited example is Misoprostol, sold under the brand name Cytotec, which is used to induce labor and treat stomach ulcers, but can be used for abortions. Since the sale of these pills without a prescription is illegal, they are commonly sold on the Internet.[105]

Modus Operandi of Groups Involved

Whereas Guatemala's criminal organizations "are among the most sophisticated and dangerous in Central America," with entrenched, widespread collusion and coordination between government authorities and organized crime,[106] when it comes to the procurement, production, and sale of contraband and counterfeit pharmaceuticals in Guatemala, our research indicated that there is no real evidence that state actors are heavily involved. That said, these activities do take place within a broader ecosystem of corruption and criminality that allows for a range of illicit activities to take place, often due to government complicity.

As stated above, contraband and counterfeit pharmaceuticals are typically sold in small, independent pharmacies in poor neighborhoods in Guatemala City or in rural areas, particularly in the northern departments of San Marcos and Huehuetenango, near the Mexican border, as well as the highland department of Quetzaltenango and the southern department of Suchitepéquez. Although these departments are also part of the drug corridor in Guatemala that links South America with North Ameri-

102 Interview in Guatemala City, Guatemala, September 2018.

103 Interview in Guatemala City, Guatemala, September 2018.

104 "La verdad detrás del comercio de las pastillas abortivas en Guatemala," Soy502, 20 March 2017, https://www.soy502.com/articulo/negocio-pastillas-abortivas-guatemala-71746

105 See, for example, this advertisement for Cytotec online: http://ventadecytotecenguatemala.com/

106 "Guatemala Profile," Insight Crime. 29 November 2017. https://www.insightcrime.org/guatemala-organized-crime-news/guatemala/

ca, there is no evidence that the groups involved in the production and sale of illicit pharma are also involved in drug trafficking, and vice versa.[107]

Government officials said that those arrested for offenses related to counterfeit or contraband pharma are typically individuals who did not have a criminal record. To the extent that these individuals were part of a criminal organization, their groups were usually small (less than ten people according to government sources) and often consisting of family members. [108]

These groups might also include drivers and delivery men who distribute the product to the small, independent pharmacies where it is sold (these individuals are known as *mochileros* or backpackers as they go from pharmacy to pharmacy with a small backpack full of medicine). Much of this medicine is then distributed by street peddlers known as *merolicos* who sell their products on buses or in rural plantations where they have access to a large number of workers and where there is little or no oversight from the Ministry of Health.[109]

There is limited evidence that these organizations are involved in other types of organized crime such as drug trafficking, trafficking of persons, migrant smuggling, or money laundering.[110] There are, however, some instances of overlap, such as in July 2018, when police found that a small criminal organization in the municipality of San José Pinula (18 kilometers from Guatemala City), may have also been involved in migrant smuggling and human trafficking. In addition to contraband medicine and liquor, authorities found a large amount of cash and small amounts of currency from various Asian countries in a home that they raided. Private security guards in the residential area where the home was located said they had seen "Chinese" and "African" individuals enter and exit the house at night, implying that some sort of human trafficking or migrant smuggling might have been taking place.[111]

Of those interviewed, the only person who said it was "very likely" that criminal organizations are involved in the production of illegal drugs also produce counterfeit medicine was a member of the private sector and a representative of the pharmaceutical lobby.[112] Prosecutors, however, have found no concrete evidence of this in the clandestine laboratories raided by the police.[113]

Barriers to entry into the sale of counterfeit and contraband pharmaceuticals are relatively low, requiring minimal capital inputs or criminal connections for anyone seeking to enter the market. "They (criminals involved in the production and sale of counterfeits) make tablets or capsules in a garage or a house without the necessary hygiene conditions so they don't have to invest in infrastructure. All they have to buy is a machine and their profit margin is 100 to 200 percent," explained one executive for a pharmaceutical company. "They purchase a cheap neurotropic vitamin from India, for Q5 ($.65), for example, and they just re-label and re-box it and sell it for Q15([$2) or Q20 ($2.60)."[114]

While barriers to entry into the illicit pharma market are relatively low, it is unclear to what extent it is a lucrative enough enterprise to attract the attention of organized crime syndicates engaged in other, more profitable activities such as narcotics trafficking. The amounts of cash found in the properties raided are relatively small in comparison with other forms of organized crime.[115] "People who sell [illicit pharma] are poor. Those who produce counterfeit medication will sell it to 20 people, who start to make money and will eventually be able to purchase a second-hand car brought from the US and later their own home. But I don't know anyone who's made millions from this," said one pharmaceutical executive.[116]

The procurement, movement, and sale of illicit pharmaceuticals in Guatemala functions within a broader system of informality as well as black and gray markets that thrive within a context of limited state capacity. Goods

107 Interviews in Guatemala City, Guatemala, September 2018.
108 Interviews in Guatemala City, Guatemala, September 2018.
109 Interviews in Guatemala City, Guatemala, September 2018.
110 Interviews in Guatemala City, Guatemala, September 2018.
111 Interviews in Guatemala City, Guatemala, September 2018.
112 Interview in Guatemala City, Guatemala, September 2018.
113 Interviews in Guatemala City, Guatemala, September 2018.
114 Interview in Guatemala City, Guatemala, September 2018.
115 Interviews in Guatemala City, Guatemala, September 2018.
116 Interview in Guatemala City, Guatemala, September 2018.

and people regularly flow in all directions, with formal checkpoints often bypassed, customs and taxes unpaid, and registration and paperwork ignored altogether.

One particularly illustrative example of how clandestine laboratories and the sale of illicit pharmaceuticals may operate within a broader criminal economy, even if they are not directly tied to organized criminal groups, is *La Terminal*. A large market located in Guatemala City's Zone 9, *La Terminal* is primarily a fruit and vegetable market but is also a major hub for "chicken buses" arriving from rural areas and is a notoriously dangerous area where all sorts of contraband and counterfeit goods, including pharmaceuticals, are sold.

According to one former official at the Ministry of Health, his office received several reports about the existence of a clandestine laboratory operating in and around *La Terminal* but failed to take action because officials were afraid of reprisals. "I received several anonymous telephone calls saying there were several places in *La Terminal* where counterfeit pharma was being produced. Obviously, ministry officials are afraid because when those places are inspected they have no support from law enforcement agents. The people in charge of carrying out those inspections are afraid of being lynched," the official said.[117]

Another government official said that prosecutors received threatening calls from *Los Angeles Justicieros* (The Avenging Angels), a group of enforcers which patrols *La Terminal* protecting vendors from extortion gangs and law enforcement. "*La Terminal* is the market where all sorts of counterfeits are produced. We have a lot of information on that place. A leader of *Los Angeles Justicieros* came to see us. They've killed a lot of people," the government official explained. "He said: Is it true that your office has received a legal complaint against us? Don't you dare set foot here because you'll get beheaded."[118]

Similarly, a pharmaceutical executive said that he reported to the government ten years ago that a counterfeit injectable contraceptive was being sold in two locations in Guatemala City: *La Terminal* and another notorious street market called *El Guarda*. After he accompanied the prosecutors to the two locations, he received threatening phone calls from unknown individuals, who in addition to identifying him and finding his phone number, knew the whereabouts of his wife and daughters.[119]

Government Responses

In 2011, the Guatemalan Congress approved a bill that establishes prison sentences of up to ten years for the production, storage, and sale of contraband or counterfeit medicine. Under this law, establishments caught selling contraband or counterfeit pharmaceuticals lose their license, and penalties are harsher for public officials and medical professionals.[120]

Prosecutors say that the approval of this law has been useful for prosecuting the production and sale of counterfeit pharmaceuticals. For example, individuals arrested in 2012 during a raid on a clandestine laboratory in Guatemala City's Zone 8 that was producing counterfeit Neurobion and Ensure were given a ten-year prison sentence under Law 28-2011 (six years for the production of the counterfeit drugs under Law 28-2011 and four years for the violation of intellectual property laws).[121]

According to one government official, it is not the current legal and regulatory framework so much as it is resources and implementation that represents the largest

117 Interview in Guatemala City, Guatemala, September 2018.

118 Interview in Guatemala City, Guatemala, September 2018.

119 Interview in Guatemala City, Guatemala, September 2018.

120 For the full text of the law, "(Ley 28-2011 para combatir la producción y comercialización de medicamentos falsificados, productos farmacéuticos falsificados, medicamentos adulterados, dispositivos médicos y material quirúrgico falsificado," see: http://ww2.oj.gob.gt/es/QueEsOJ/EstructuraOJ/UnidadesAdministrativas/CentroAnalisisDocumentacionJudicial/cds/CDs%20leyes/2011/pdfs/decretos/D28-2011.pdf

121 Interview in Guatemala City, Guatemala, September 2018.

challenge in combatting counterfeit and contraband medicine. The Ministry of Health only has twenty-five inspectors to cover thousands of pharmacies and stores all over the country, and government officials said it would require at least two hundred personnel for inspections to be done adequately. Pharmacies in upscale neighborhoods in Guatemala City claim they are regularly and thoroughly inspected by the Ministry of Health on a quarterly basis but oversight in rural areas is very limited and in some cases, there is only one inspector for the entire department.[122]

Similarly, the public prosecutor's office only investigates the production and sale of counterfeit pharmaceuticals when a legal complaint is filed. A legal complaint must provide an exact address and if possible, a name. Most of these legal complaints are made by pharmaceutical companies or are filed anonymously, and may not provide sufficient information to warrant an investigation.[123] Additionally, different bureaus within the public prosecutor's office are tasked with dealing with the sale of medicine supplied by the IGSS or stolen from public hospitals (contraband) and the production of counterfeit medicine. As a result, files and knowledge are scattered across the institution and there is limited communication and information-sharing between prosecutors.[124]

In an effort to crack down on contraband, the Guatemalan government created an inter-institutional taskforce known as Coincon that includes the Police, attorney general's office, the Internal Revenue Service, customs officials, and the Ministry of Health, which should, in theory, lead to better coordination. By all indications, however, the initiative has had a negligible impact on contraband pharmaceutical flows, as the majority of products seized by customs agents in 2017 were reportedly dairy products, vegetable oil, cigarettes, beverages, liquor, and poultry products.[125]

There are still other significant gaps in coordination and collaboration. When the public prosecutor's office carries out a raid and individuals are arrested, investigating the financial assets of the actors involved is often hampered by bureaucratic hurdles and the need to obtain court orders.[126] The fact that officials from both the Ministry of Health and public prosecutor's office said they were too afraid to investigate the alleged existence of clandestine laboratories in *La Terminal* illustrates the weakness of Guatemalan law-enforcement bodies. Even in cases where raids on clandestine laboratories did take place, such as in 2012, there were no subsequent efforts to investigate the source of the raw materials and precursors used to produce counterfeit Neurobion and Ensure. "In theory, these raw materials cannot be sold to a company that does not have a license from the Ministry of Health. So where do these clandestine laboratories obtain their ingredients from? The Attorney General's Office hasn't been able to answer this," explained one government official.[127] A member from the attorney general's office confirmed this, saying that how ingredients were obtained was never a line of enquiry in its investigation.[128]

Interviews with government officials also indicated that there have been limited efforts to work with other countries in the region to tackle the problem of contraband and counterfeit pharmaceuticals, despite acknowledgement that the problem is regional.[129]

122 Interview in Guatemala City, Guatemala, September 2018.

123 Interviews in Guatemala City, Guatemala, September 2018.

124 Interviews in Guatemala City, Guatemala, September 2018.

125 Martinez, Allan. "Coincon presenta resultados por lucha al contraband," Republica. 2 August 2017. https://republica.gt/2017/08/02/coincon-presenta-resultados-por-lucha-al-contrabando/

126 Interview in Guatemala City, Guatemala, September 2018.

127 Interview in Guatemala City, Guatemala, September 2018.

128 Interview in Guatemala City, Guatemala, September 2018.

129 Interview in Guatemala City, Guatemala, September 2018.

4: RECOMMENDATIONS GOING FORWARD

As the two case studies above highlight, the criminal markets for counterfeit and contraband pharmaceuticals in both Costa Rica and Guatemala are heavily shaped by concentric trends at the local, regional, and global level. As a result, tackling the problem of counterfeit and contraband pharmaceuticals requires concurrent responses at each level, and implementing systems that can provide for local solutions to local problems and at the same time scale upward regionally and globally.

While the government of Costa Rica has taken several steps to respond to the growing threat of illicit pharmaceuticals, and has by and large succeeded in mitigating the negative impacts of the growing phenomenon, there are several concrete measures that could be taken in the near and medium term to combat the sale of counterfeit and contraband pharmaceuticals.

There is clearly a need to develop information sharing and reporting procedures that would allow for systematic data collection so as to better understand the scope and scale of the counterfeit and contraband pharmaceutical market as well as the modus operandi of the actors involved. Investing in such data collection and investigative capacities would also enhance authorities' ability to identify and anticipate future trends. Similarly, improved coordination between the various government and private sector actors involved, building off of CoNaPIF should be made a priority.

Given that demand for illicit pharmaceuticals is driven by consumer preferences for more competitive price points, information and sensitization campaigns which warn consumers of the risks of black market pharma could go a long way to helping reduce demand, but more importantly, the government should consider measures that would enable Nicaraguans, especially those who are undocumented, to access formal healthcare institutions so that they are less reliant on the black market to meet their healthcare needs.

In Guatemala, addressing the challenge of combatting counterfeit and contraband pharmaceuticals is as much a matter of improving the overall healthcare system and state capacity across an array of sectors as it is about tackling the specific problems of illicit medicines. The fact that there are certain areas where the state is unable or unwilling to intervene, for example, is indicative of problems of governance that reach far beyond the scope of illicit pharmaceuticals. In order to address the underlying conditions that allow the contraband and counterfeit pharmaceutical market to expand and flourish in Guatemala, the government should redouble efforts to improve overall access to healthcare, especially for the rural poor. It is hardly surprising that the poor, especially in areas where healthcare services are notoriously absent, turn to the black market to purchase medicine. Thus, meeting the needs of these segments of the population would reduce demand for black market pharmaceuticals, which is driven by a general lack of access to healthcare and affordable medication.

Similarly, the government should also invest more resources into the Ministry of Health so that it can fulfill its mandate to provide proper oversight of pharmacies, distributors and pharmaceutical laboratories. Given that there is considerable demand for contraceptives, abortifacients, and consumer drugs that can be used to induce abortions, the Guatemalan government could put a dent in the black market were it to increase access to contraceptives for Guatemalan women. Under the 2005 Family Planning Law, contraceptives are supposed to be free of charge in public facilities, however, access to contraceptives in rural areas continues to be a problem.

Guatemalan authorities, along with civil society and the private sector, should develop public awareness campaigns in order to better inform consumers of the risks and dangers of contraband and counterfeit pharmaceuticals. The government should also develop culturally appropriate information campaigns in the country's Mayan languages, as well as Spanish, with an emphasis on the municipalities in border areas where contraband pharmaceuticals are most prevalent, in order to improve access to information about the dangers of counterfeit and contraband pharmaceuticals.

Lastly, the Guatemalan government should build off of the inter-institutional collaboration and communication being established through Coincon in order to develop an inter-agency government approach to combatting counterfeit and contraband pharmaceuticals specifically.

At the regional level, the governments of Central America should examine region-wide market demands and price discrepancies in order to better understand the black-market and smuggling networks they incentivize.

Political realities and differences in healthcare systems will preclude levels of harmonization that would remove smuggling incentives altogether, but finding areas where harmonization would be possible, should be pursued. Similarly, it is hard to overstate how valuable better data collection and information sharing on a regional level would be in understanding the scope and scale of the problem, crafting policies to combat it, and developing predictive capacities to anticipate future trends. Countries in the region could also partake in a legal gap analysis so as to harmonize laws against counterfeit and contraband pharmaceuticals across the region. Forums such as the *Red Panamericana para la Armonización de la Reglamentación Farmacéutica* and PAHO are well-positioned to foster this type of collaboration and coordination.

Many of these regional recommendations also apply to the global level. A recent Organisation for Economic Co-operation and Development (OECD) report which offers a comprehensive overview of the illicit trade in counterfeit medincines notes that while evidence suggests that "counterfeit pharmaceuticals are increasingly prevalent and increasingly profitable," a great deal remains "unknown and unmeasurable." There is an urgent need for investments in mechanisms and methodologies that would allow for better data collection. As the OECD report states, "the greatest victories in the battle against counterfeiting come with successful co-operation and the largest failures may frequently be traced to its absence."[130]

Due to the globe-spanning challenge that counterfeit and contraband pharmaceuticals pose to global public health, the possibility of leveraging new technologies to improve supply chain integrity has received considerable attention in recent years. As mentioned earlier in this report, many of these technologies center around traceability and authentication. Applying labels with security features that can provide assurance that the medicine is from a legitimate producer could go a long way in distinguishing authentic pharmaceutical products from counterfeits, as well as to detect packaging that has been tampered with. For instance, utilizing serialization efforts which apply 2D barcodes and store information in a database for track and trace systems.

Within track and trace systems, there are two basic models being pursued within the pharmaceutical sector. The first, known as the "point-of-dispense verification model," consists of two phases. During the first phase, pharmaceutical manufactures use a serialized ID in a barcode for each outgoing package and record each outgoing event in their database. During the second phase, the pharmacy, hospital, clinic, or healthcare provider can scan the product in order to verify the authenticity of the product before giving it to consumers.[131] The strength of this model is that it is relatively straight forward, requires minimal technological inputs, and is the most cost-effective approach to improving supply chain integrity. [132]

A key weakness of the "point-of-dispense verification model," however, is that actors cannot trace the movement of products throughout the supply chain. Full traceability models, on the other hand, allow for real-time updates throughout the supply chain, with the product being scanned and recorded every time the product moves between the dizzying array of actors that comprise global pharmaceutical supply chains.[133]

Implementing full traceability systems, however, requires installing a complex data architecture that can capture, share, and make use of the data among an array of actors across the entire global supply chain.[134] Among proponents of full traceability systems, blockchain technology has garnered significant attention in recent years. Although normally associated cryptocurrencies such as Bitcoin and Ethereum, blockchain technology, which makes cryptocurrencies possible through bypassing a central authority by creating a shared database or ledg-

130 Lybecker, Kristina (2016), "Illicit trade in counterfeit medicines", in OECD, Illicit Trade: Converging Criminal Networks, OECD Publishing, Paris.

131 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

132 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

133 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

134 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

er that records all transactions in real-time, has moved outside its initial application within financial services.[135]

While blockchain technology has now been applied for contracts, real estate, shipping, medical records, insurance, and even voting, it has shown particular promise in industries that rely on "non-linear" supply chains.

Walmart, for example, recently announced that after an eighteen-month pilot program in which it used a blockchain ledger to keep tabs on its network of fresh produce, it will be using a blockchain database developed by IBM (which nine other companies are also using) to "keep track of every bag of spinach and head of lettuce."[136] The technology, Walmart claims, is likely to save the company money and assure consumers of the quality of its fresh produce. During an E. coli outbreak affecting romaine lettuce last year that killed five people in the United States, Walmart was forced to throw out every bag until it located the source.[137] Last year, however, the company conducted an experiment to trace the source of sliced mangos. According to Walmart, it took seven days for its employees to pinpoint the farm in Mexico where the mangos were grown, while the blockchain software located the farm in a matter of seconds.[138] As of January 31 of this year, Walmart is requiring direct suppliers of lettuce, spinach, and various other greens to have joined its blockchain database, with other farmers, logistics firms, and business partners mandated to join by the end of September 2019.[139]

Another emerging use case for blockchain technology, and one that may be more analogous to the pharmaceutical industry given the complexity of the supply chains, is its adoption by the diamond and jewelry industry. Several companies are now using blockchain technologies to track diamonds, precious metals, and gemstones around the globe. In April 2018, IBM launched the Trust Chain Initiative, a blockchain platform that works with various companies in the industry to track and authenticate diamonds and precious metals throughout the supply chain.[140] In May of the same year, diamond giant De Beers announced that it tracked one hundred high-value diamonds from mine to the retailer on its Tracr platform, which also relies on blockchain technology.[141]

Just as pharmaceutical precursors may be sourced in one country, produced in another, and packaged and repackaged in intermediary countries before the finished product finally arrives at its last point of sale, diamonds and precious stones rarely have a straightforward journey from the earth to potential buyers. As one industry spokesperson, whose company had recently launched a blockchain initiative, explained to *Forbes*, "what we will be able to say is that these minerals have come from a mine in Colombia, where they were shipped to India to be cut and polished, and combined in a bulk container and transferred to a wholesaler in Switzerland, and from there they were sent to multiple retailers in the UK and Canada. And we're tracking every single movement of those stones around the world and know exactly where they are going."[142]

Few industries have expressed more enthusiasm for the promise of blockchain technology, however, than the pharmaceutical industry, in part because it is easy to extrapolate how the use cases described above are directly applicable. A September 2018 survey by the Pistoia Alliance ("a not-for-profit alliance of life science companies, vendors, publishers, and academic groups"),

135 Orcut, Mike. "In 2019, blockchains will start to become boring," MIT Technology Review. 2 January 2019. https://www.technologyreview.com/s/612687/in-2019-blockchains-will-start-to-become-boring/

136 Corkery, Michael and Popper, Nathaniel. "From Farm to Blockchain: Walmart Tracks Its Lettuce," New York Times. 24 September 2018. https://www.nytimes.com/2018/09/24/business/walmart-blockchain-lettuce.html

137 Orcut, Mike. "With Walmart's veggie tracker, blockchain for supply chains will finally get real," The Download. 25 September 2018. https://www.technologyreview.com/the-download/612197/with-walmarts-veggie-tracker-blockchain-for-supply-chains-will-finally-get-real/

138 Corkery, Michael and Popper, Nathaniel. "From Farm to Blockchain: Walmart Tracks Its Lettuce," New York Times. 24 September 2018. https://www.technologyreview.com/the-download/612197/with-walmarts-veggie-tracker-blockchain-for-supply-chains-will-finally-get-real/

139 Nash, Kim. "Walmart Requires Lettuce, Spinach Suppliers to Join Blockchain," Wall Street Journal. 24 September 2018. https://blogs.wsj.com/cio/2018/09/24/walmart-requires-lettuce-spinach-suppliers-to-join-blockchain/

140 "Consortium of Jewelry Industry Leaders Announce TrustChain, First Global Blockchain Initiative to Bring Full Transparency to Consumers," IBM News Room. 26 April 2018. https://newsroom.ibm.com/announcements?item=122899

141 Wood, Aaron. "De Beers Tracks Diamonds With Blockchain For The First Time," Cointelegraph. 10 may 2018. https://cointelegraph.com/news/de-beers-tracks-diamonds-with-blockchain-for-the-first-time

142 Marr, Bernard. "How Blockcahin Could End The Trade In Blood Diamonds – An Incredible Use Case Everyone Should Read," Forbes. 14 May 2018. https://www.forbes.com/sites/bernardmarr/2018/03/14/how-blockchain-could-end-the-trade-in-blood-diamonds-an-incredible-use-case-everyone-should-read/#3377a3d2387d

for example, found that 50 percent of pharmaceutical companies are experimenting with blockchain technology, compared to just 22 percent surveyed in 2017. Furthermore, a plurality of respondents believed that the greatest opportunities for using blockchain technology were in medical supply chain.[143]

This enthusiasm comes at a time when governments around the world are requiring greater supply chain integrity. In the United States, the Drug Supply Chain Security Act gives pharmaceutical companies until 2023 to institute "full, unit-level track-and-trace systems for products as they move through the supply chain," while in Europe, the Falsified Medicines Directive required that companies "serialize their products for track-and-trace" by February 2019.[144] As a result, pharmaceutical companies are keen to improve supply chain integrity out of necessity. Blockchain technology, analysts believe, is likely to augment existing software rather than replace it, and enable companies to monitor their products at "much lower grain of detail," making recalls due to bad ingredients more accurate and efficient.[145] In theory, blockchain systems could be developed through which drugs are scanned and entered into secure ledgers at every step of the process, with records being updated in real-time and viewable by any authorized party, including retailers and consumers.[146]

In terms of direct applications by pharmaceutical companies, Novartis has reportedly been experimenting with internal blockchain projects "to identify counterfeit medicines and track temperature with real-time visibility for all participants in the supply chain" since 2016.[147] In April 2017, IBM announced a partnership with Sichuan Hejia, a Chinese supply chain management firm, which is intended to track pharmaceuticals throughout the supply chain using blockchain technology.[148] A number of other projects, including a public-private partnership between the EU and pharmaceutical companies, called the Blockchain Enabled Healthcare program,[149] as well as the MediLedger Project (which is building an industry-owned permissioned databased that uses blockchain technology), were launched in the last year.[150]

Amid the enthusiasm that the pharmaceutical industry has shown for blockchain technology, however, there are good reasons to temper expectations. To start, in many of these proposed applications, it is not clear to what extent blockchain technology is even necessary, as "permissioned" blockchain databases run by central authorities (whether they be IBM or MediLedger) are not necessarily an improvement over conventional online databases.[151]

Additionally, a blockchain ledger has no way of knowing if someone enters fraudulent or mistaken data about a given item.[152] As noted by Ramana Pinnam, director of product management at rfXcel, a company that focuses on software used to track and trace pharmaceutical supply chains, "blockchain locks in data so it cannot be changed or altered. This is quite a positive when trying to track products, but user error can make this problematic. That is why appropriate education and training will be needed for those who adopt blockchain within the supply chain."[153]

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143 Staines, Richard. "60% of pharma companies using or trying blockchain – survery," Pharmaphorum. 28 September 2018. https://pharmaphorum.com/news/60-of-pharma-companies-using-or-trying-blockchain-survey/

144 Lo, Chris. "Blockchain in pharma: opportunities in the supply chain," Pharmaceutical Technology. 31 October 2017. https://www.pharmaceutical-technology.com/digital-disruption/blockchain/blockchain-pharma-opportunities-supply-chain/

145 Leising, Matthew. "Pharma industry mulls blockchain to help keep track of drugs," Bloomberg. 26 September 2018. https://www.businesslive.co.za/bd/world/2018-09-26-pharma-industry-mulls-blockchain-to-help-keep-track-of-drugs/

146 Lo, Chris. "Blockchain in pharma: opportunities in the supply chain," Pharmaceutical Technology. 31 October 2017. https://www.pharmaceutical-technology.com/digital-disruption/blockchain/blockchain-pharma-opportunities-supply-chain/

147 Morris, Nicky. "Novartis explores blockchain's potential for pharmaceuticals," Ledger Insights. https://www.ledgerinsights.com/novartis-pharma-blockchain/

148 Lo, Chris. "Blockchain in pharma: opportunities in the supply chain," Pharmaceutical Technology. 31 October 2017. https://www.pharmaceutical-technology.com/digital-disruption/blockchain/blockchain-pharma-opportunities-supply-chain/

149 For more information on the Blockchain Enabled Healthcare Program, see: http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/topics/imi2-2018-15-02.html

150 For more information on MediLedger, see: https://www.mediledger.com/

151 Orcut, Mike. "With Walmart's veggie tracker, blockchain for supply chains will finally get real," The Download. 25 September 2018. https://www.technologyreview.com/the-download/612197/with-walmarts-veggie-tracker-blockchain-for-supply-chains-will-finally-get-real/

152 Orcut, Mike. "With Walmart's veggie tracker, blockchain for supply chains will finally get real," the Download. 25 September 2018. https://www.technologyreview.com/the-download/612197/with-walmarts-veggie-tracker-blockchain-for-supply-chains-will-finally-get-real/

153 "Blockchain Technology in Pharmaceutical Supply Chain," rfXcel. https://rfxcel.com/blockchain-pharmaceutical-supply-chain/

Furthermore, as the *New York Times* notes in reference to the Walmart use case, "a blockchain can capture the digital record of a box of spinach. But it cannot tell if someone opened the box and changed the spinach inside, replacing it with arugula or illegal drugs."[154] The same logic would apply to the pharmaceutical industry, where packaging can be seamlessly tracked, but the content can still be tampered with.

Lastly, although the potential benefits of blockchain technology are clear, there is still the oft-overlooked reality that it remains a nascent technology that has not been sustainably and successfully applied beyond cryptocurrencies. Put another way, it is still not clear that blockchain technology can actually deliver what its proponents say it can.[155] Although the "point-of-dispense verification model" does not offer all of the benefits of full traceability models, it may be a more cost-effective approach that delivers most of the benefits of full traceability within the context of certain countries.[156]

Promise versus skepticism aside, an overabundance of faith and investment in "game-changing" technology also risks drawing attention away from lower-tech, context specific solutions that may be better suited toward helping consumers in certain settings.

After counterfeit malaria medicine contributed to the death of more than 100,000 children in Africa in a single year, for example, Ghanaian entrepreneur Bright Simons developed software that manufacturers can use to label individual packs of medication with random twelve-digit codes hidden under a scratch-off panel. Upon purchasing anti-malarial pills, customers can text the code free of charge to designated phone numbers and receive instant confirmation that the product is authentic.[157] These types of schemes—which share some similarities with the heavily criticized codentify serializations system developed by Philip Morris International for the tobacco industry[158]—may have potential in low- and middle-income countries if designed to address specific challenges in local contexts. As more complex systems and technologies develop and proliferate, these lower-cost and easier to implement measures may help mitigate the dangers of certain counterfeit and contraband pharmaceuticals in the interim.

Additionally, material-based security measures may be integrated with digital or cyber security technologies. Such measures alter the physical composition of the packaging or labeling materials, or in some cases the good itself, facilitating verification of the product's authenticity by consumers, medical professionals, law enforcement officials, and others. Currencies around the world incorporate technologies that are integrated into or onto the paper, including specialized inks, holograms, and other such markers of authenticity. In the pharmaceutical case, the easiest form of material-based intervention is to a product's packaging or labeling materials, rather than to the pill or liquid medicine, for several reasons. The first and most obvious reason involves the fact that as medicines are ingested, there are serious technical and regulatory hurdles involved in altering the chemistry of the medicine. Although technologies have been developed to add unique genetic markers to medicines, for example, these face daunting obstacles to widespread adoption.[159] The second reason involves the desired level of security. Simply put, it is wise to put easy-to-use technological tools into the hands of consumers. In the pharmaceuticals case, as with alcohol, tobacco, or currencies, this task involves the creation of technically sophisticated packaging and labeling materials that, at the same time, are easy for the consumer to identify as legitimate. One core goal with such material-based security measures is to enable the consumer to distinguish between genuine and fake products with the naked eye or with readily available detection tools.

Part of the allure of technology solutions, both material and digital, is that they often promise to change paradigms in ways that elide socio-political realities, when in fact the conditions that create markets for counterfeit

154 Corkery, Michael and Poppoer, Nathaniel. "From Farm to Blockchain: Walmart Tracks Its Lettuce," New York Times. 24 September 2018. https://www.nytimes.com/2018/09/24/business/walmart-blockchain-lettuce.html

155 "Blockchain Technology in Pharmaceutical Supply Chain," rfXcel. https://rfxcel.com/blockchain-pharmaceutical-supply-chain/

156 Pisa, Michael and McCurdy, Denise. "Improving Global Supply Chains through Traceability," Center for Global Development. February 2019. https://www.cgdev.org/sites/default/files/improving-global-health-supply-chains-through-traceability.pdf

157 Yeebo, Yepoka. "The African Startup Using Phones to Spot Counterfeit Drugs," Bloomberg Businessweek. 31 July 2015.

158 Geller, Martine. "Big Tobacco squares up as EU rules am to track every cigarette," Reuters. 18June 2014. https://uk.reuters.com/article/us-tobacco-tracking-insight-idUSKBN0ET0I720140618

159 Alexandra Ossola, "Authentic drugs tagged with plant DNA could help snare fake meds," Scientific American (January 12, 2016), https://www.scientificamerican.com/article/authentic-drugs-tagged-with-plant-dna-could-help-snare-fake-meds/.

and contraband pharmaceuticals are inherently political. As such, there is a desperate need for pilot programs that enable a better understanding of which traceability systems are most appropriate for different contexts.

One such pilot on pharmaceutical serialization and traceability, promoted by GS1 Mexico (a not-for-profit organization that develops and maintains global standards for business communication), with participation from technology providers and other actors within the pharmaceutical industry, has just been finalized in Mexico.[160] According to GS1, the pilot followed best practices implemented in the United States and the European Union in accordance with the aforementioned entry into force of the United States Drug Supply Chain Security Act and the European Union Falsified Medicine Directive. GS1 indicates that the pilot demonstrated that the traceability of medicines and medical devices in Mexico can be done by means of an identification with Data Matrix codes (a type of two-dimensional code) which allows registration in a platform of each product movement bringing full visibility and traceability of the supply chain from manufacturer to end user. GS1 also states that the pilot validated some use cases such as detection of illicit product in the supply chain and recalls. Results will soon be presented to Mexico's Federal Commission for the Protection against Sanitary Risk (COFEPRIS). Such results suggest a need for further research into this suite of technologies.

A pilot program in Costa Rica, for example, could go a long way in understanding which traceability models work best within the context of a country that regularly ranks among the best healthcare systems in the world, but is in a region where trafficking, smuggling, and production of illicit pharmaceuticals is a growing concern. A similar pilot study in Guatemala would enable public and private sector actors to assess which traceability systems are most effective in contexts where state capacity is weak and public health systems are struggling to meet the needs of citizens. The need for better information predicated on case studies cannot be overstated, so as to avoid developing global health policies that are insensitive to country-level realities.

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