



Issue 06 | November 2018

# The rise of counterfeit pharmaceuticals in Africa

*Robin Cartwright and Ana Baric*

## Summary

Sustainable Development Goal 3 (SDG 3) places significant emphasis on populations' health, and sub-target 3.8 specifies access 'to safe, effective, quality and affordable essential medicines and vaccines for all'. Yet, remarkably missing from the discourse around achieving this goal is the need to address the growing phenomenon of counterfeit medicines, which disproportionately affects developing countries. Counterfeit medicines put people's lives at risk, finance criminal groups and cause profound public health challenges. The full scale of the challenge in Africa is not fully understood, but research suggests that the problem and its impact are severe. If the continent is to make headway in achieving SDG 3, the issue of counterfeit medicines must move higher up on policy agendas. Experience elsewhere suggests that there would be scope for significant positive results.

## Key points

- Addressing counterfeit medicines in Africa may help prevent widespread loss of life, including an estimated 64 000–158 000 avoidable deaths from malaria alone, as well as mitigating other public health and public safety risks.
- Much greater prioritisation of the issue by African states and continental or regional bodies is needed. The response should include a substantial overhaul of the analytical, legal, educational, regulatory and enforcement systems around medical supply chains. The legal and regulatory frameworks for combating medicine fraud will need strengthening.
- These responses would need to be coordinated within a global effort, including setting up a database of intelligence on counterfeits, and improved awareness-raising and training campaigns. National medicines regulation authorities should investigate mass serialisation forms of track-and-trace.

This brief focuses on:



The UN's sustainable development goals (SDGs) place a significant emphasis on populations' health. SDG 3 aims to 'ensure healthy lives and promote wellbeing for all, at all ages' and sub-target 3.8 specifies access 'to safe, effective, quality and affordable essential medicines and vaccines for all'.

But beneath the progress reports of reductions in communicable and non-communicable diseases<sup>1</sup> lies a dark and worrying rising trend in fake pharmaceuticals. This significant rump of the pharmaceutical market – up to 30% – is an irreducible barrier to eradicating many health issues. Thus, the counterfeit pharmaceutical problem undermines the gargantuan efforts of governments, drug companies and non-governmental organisations (NGOs) to improve access to medication for the poorest communities.

## Counterfeiters find Africa an easier target, because it has not developed the West's armoury of responses

The growing incidence of so-called falsified and substandard medical products – which we have categorised with the all-encompassing term 'counterfeit' – is arguably the most insidious and evil form of illegal trade. It leads to widespread loss of life: between 64 000 and 158 000 otherwise avoidable deaths from malaria alone in sub-Saharan Africa every year. This phenomenon is not specific to Africa, but counterfeiters prey on poorer countries more than their richer counterparts, with up to 30 times greater penetration of fakes in the supply chain.

Counterfeiters find Africa an easier target, because it has not developed the West's armoury of responses to counterfeit pharmaceuticals. Europe and the USA's enviable supply chain regulation, track-and-trace technology and enforcement regimes are almost wholly lacking in African countries.

This paper sets out the scale and effect of the problem, and recommends a comprehensive programme of awareness-raising, measurement, legal, supply chain and enforcement activities to begin the enormous task of reducing counterfeits in Africa.

## The rise of fake pharmaceuticals and their impact

It has been estimated that, worldwide, the counterfeit drug market is worth up to US\$200 billion. According to World Health Organization (WHO) statistics, 42% of detected cases of substandard or falsified pharmaceuticals occurred in Africa. Although more incidents of medical counterfeiting crime are reported in wealthier countries, a report by the UN Office on Drugs and Crime (UNODC) shows that the penetration of counterfeit pharmaceuticals is actually much greater in the developing world: the report estimates that poorer countries experience about 30% penetration, as opposed to less than 1% in the developed world. Africa suffers the most as an 'easy target' for counterfeiters.

### Definitions

The fight against fake pharmaceuticals has been complicated by disagreements over what falls under their definition. Since May 2017, WHO has used the phrase 'substandard and falsified', replacing 'substandard/spurious/falsely labelled/falsified/counterfeit.' The former term was criticised for confusing substandard and falsified products with intellectual property rights protection.<sup>2</sup> For the purposes of this paper, we will use the WHO definitions. For ease of reference, we have used the term 'counterfeit' to refer to false and substandard products.

Substandard medical products are those that are 'out of specification'. They are defined as ostensibly authorised medical products that fail to meet manufacturing, supply or distribution quality standards. Unregistered or unlicensed medical products are those which have not undergone evaluation or approval by the relevant regulatory bodies. Falsified medical products, meanwhile, purposefully conceal or lie about their identity, composition or source. This may mean that they are contaminated, do not contain the active ingredient they claim to have or have an incorrect dosage of the active ingredient. They are often found where unethical practices by sellers, distributors and healthcare personnel compound inadequate regulation and governance.<sup>3</sup>

Some bodies, such as UNODC, make an additional distinction between fraudulent and counterfeit pharmaceuticals. Fraudulent medicines deceive buyers about the content of what they are purchasing, whereas counterfeit medications are falsely branded or unlicensed. The crime in the former case is fraud, whereas in the latter it is intellectual property theft.<sup>4</sup>

## Developing countries suffer the most

Globally, the trade in counterfeit pharmaceuticals has been estimated to be worth up to €188 billion (US\$200 billion) annually, making it the most lucrative sector in illegally copied goods.<sup>5</sup> According to a 2016 US Department of Commerce report, the size of the global counterfeit drug market ranges from US\$75 to US\$200 billion.<sup>6</sup> According to the UNODC, it may actually only be US\$1.6 billion. The problem in assessing the size of the market stems from the unfortunate reality that understanding, testing, detection, capture and reporting of global pharmaceutical quality are neither systematic nor consistent.

A landmark 2017 study by WHO, estimated that one in 10 medical products in low- and-middle-income countries is either substandard or falsified. Since 2013, the organisation has received more than 1,500 reports of cases of substandard or falsified medical products, with antimalarials and antibiotics being those most commonly reported. The majority of reports (42%) are from Africa.<sup>7</sup> Even higher numbers have been reported by non-profit organisation the Pharmaceutical Security Institute (PSI), which documented over 3 500 'pharmaceutical crime incidents'.<sup>8</sup>

Regardless of the size of the market, it is clear that the poorest and most vulnerable populations also suffer the most. A University of Edinburgh report estimates that between 72 000 and 169 000 children die each year from pneumonia due to counterfeit or substandard antibiotics. The London School of Hygiene and Tropical Medicine says that fake malaria drugs cause an additional 64 000–158 000 deaths every year in sub-Saharan Africa, and come at a cost of between US\$21 million and US\$52 million due to additional treatment.<sup>9</sup>

Corruption adds another layer of complexity and murkiness. In many cases, public officials are bypassed as the counterfeits reach retailers unhindered. However, according to a 2016 report from global watchdog

Transparency International, as much as 6% of annual global health expenditure – over US\$300 billion – is lost to corruption. Efforts 'to measure the scale of the problem and respond effectively are few and far between'.<sup>10</sup> Transparency International argues that one of the challenges in combating corruption in pharmaceuticals is that healthcare and corruption are often viewed as two distinct public policy areas, with global health interventions focusing on curing specific diseases rather than good governance and anti-corruption policymaking.

As the market has grown, so have the number of falsified products. According to the PSI, there has been an upward trend globally in pharmaceutical counterfeiting, illegal diversion and theft. Numbers have risen from 2 018 incidents<sup>11</sup> in 2012 to 3 147 in 2016. The majority of these (1 579) were identified in North America and the minority (94) in Africa.<sup>12</sup> WHO's Global Surveillance and Monitoring System (GSMS) for Substandard and Falsified Medical Products reports a much higher share (42%) of cases in Africa.<sup>13</sup> This may be explained by PSI's focus on incidents that have been identified as crimes. Africa may have a relatively low number of pharmaceutical crimes, but that may be a consequence of competing law enforcement priorities, lack of funding and inadequate regulatory institutions, which allow counterfeit medicines to go undetected.

According to the UNODC, the 'value of the global [pharmaceutical] trade is heavily concentrated in richer countries, where incidence of fraudulent medicines appears to be less than 1%'.<sup>14</sup> 'Sellers of fraudulent medicines often target low-value markets, where consumers spend less than US\$100 per year on pharmaceuticals, such as Southeast Asia and Africa. The size of these markets makes these regions a worthwhile catch— per capita expenditures in African counties are about US\$8, collectively worth around US\$4 billion.

## Africa in the global context

Africa's domestic pharmaceutical market is growing quickly, creating new opportunities and challenges for the continent. According to consulting firm McKinsey, the value of Africa's pharmaceutical industry jumped from US\$4.7 million in 2003 to US\$20.8 billion in 2013. The firm predicts that by 2020 the market will be worth between US\$40 billion and US\$65 billion.<sup>15</sup> According to a 2016 article published in UN magazine

*Africa Renewal*, African states import 70% of their pharmaceutical products, spending disproportionate amounts of state resources on procuring rather than creating drugs.<sup>16</sup> Only 37 out of 54 African states have some level of pharmaceutical production. As new, legitimate firms enter these markets, so will additional counterfeiters.

Substandard and falsified medical products pose a significant threat to Africa. According to Dr Mariângela Simão, assistant director-general for Access to Medicines, Vaccines and Pharmaceuticals at WHO, they 'not only have a tragic impact on individual patients and their families, but also are a threat to antimicrobial resistance, adding to the worrying trend of medicines losing their power to treat.'<sup>17</sup> In addition to helping spread drug-resistant illness, counterfeit medicines undermine confidence in health professionals and systems. They also put added monetary pressure on families with already limited means, who pursue additional or alternative medicines and treatments after the counterfeit medicines inevitably fail.

There have been large-scale seizures in Africa of counterfeit antimalarial, antibiotic, steroid and cardiac medicines. Among the most significant, UNODC lists Operation Mamba in East Africa (2008), Operation Zambezi in Southern Africa (2009), and Operation Cobra and Operation Harmattan in West Africa (2011). But sporadic seizures do not fully capture the situation on the ground.<sup>18</sup>

## Fake pharmaceutical trails: counterfeit product sources and routes

Globalisation has made it harder to regulate, track and quality assure medical products. Medicines are manufactured, printed, and shipped to and from a number of countries. Fraud can occur at any point in the supply and distribution chain. As these linkages become increasingly globalised and complex, so do their paper and digital trails, which criminals can obscure by using offshore companies and bank accounts.

Despite this complexity, there are certain well-known criminal routes. According to UNODC, the top five origins of fraudulent and counterfeit medicine are in China, India, Paraguay, Pakistan and the UK.<sup>19</sup> Between 2008 and 2010, China was the departure point for nearly 60% of the counterfeit medical products seized worldwide.<sup>20</sup> Growing Chinese engagement with Africa has also

increased smuggling on the continent, where visas are often obtained relatively easily on arrival. This does not necessarily mean that China should be the sole focus of law enforcement and regulatory bodies, however. As pressure in China has increased, aspects of production may be moving elsewhere, including to North Korea, Myanmar, and Vietnam, with the Middle East serving as a transshipment route.

The global pharmaceutical sector is complex and demands confidentiality. However, pharmaceutical companies and government officials can have high levels of autonomy in key decision-making in the supply chain. Their desire for profits can trump ethical considerations. Meanwhile, whistle-blowers may not be powerful enough to report and get rid of bad actors.<sup>21</sup>

In September 2015, a UK court jailed two former UN consultants for rigging a contract for life-saving drugs between a Danish pharmaceutical company and officials in the Democratic Republic of Congo (DRC). Guido Bakker and Sijbrandus Scheffer took £650 000 to secure a £66 million contract and then laundered the funds. In an email to Bakker, Scheffer joked, 'supplying small amounts of grossly overpriced drugs to dying and starving Africans is a very good start' for 'making loads of cash.'<sup>22</sup>

## Drug types: antimalarials and antibiotics

In terms of drug categories, antimalarials and antibiotics are among the most widely reported counterfeits. Counterfeiters target high-demand drug types, with deadly consequences. Nearly half of antimalarials fail to meet quality standards, while antibiotics account for a significant share of falsified medical products reported to WHO.

According to WHO, antimalarials and antibiotics are among the most commonly reported substandard or falsified medical products.<sup>23</sup> The average global antimalarial failure rate is around 47%. UNODC puts the percentage of failed malarial drugs test in Africa at between 12% and 82%.<sup>24</sup> Every year, between 655 000 and 1.2 million people die from the *P. falciparum* infection that causes malaria. Children in sub-Saharan Africa and Southeast Asia are at highest risk of contracting and dying from the disease, and more than 3 billion people in 106 countries are at risk of contracting malaria.<sup>25</sup>



Many media outlets have reported that, globally, one-third of malaria drugs tested fail chemical or packaging quality tests. The same proportion of countries are reported in effect to have no drug regulations in place.<sup>26</sup> Medical studies support these figures. For example, a 2012 study in *The Lancet Infectious Diseases*<sup>27</sup> found that in 21 drug surveys in sub-Saharan Africa, 35% of 2 297 drugs failed chemical analysis, 36% (of 77) failed packaging analysis and 20% (of 389) were falsified. However, this study demonstrated not only regional variation, but also variability caused by timing and the testing methodology. A 2005 test by Kibwage showed a 69% chemical analysis failure for antimalarials in Kenya.<sup>28</sup> Thoithi et al. (2008) found a 27% failure rate using a sample from 2001–05. This is a significant discrepancy for studies completed in the same country and over an overlapping time period (see ‘Measurement and communication’, below).<sup>29</sup>

## Antimalarials and antibiotics are among the most commonly reported substandard or falsified medical products

International health financing partnerships and organisations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Gavi, the Vaccine Alliance, have established and funded purchasing and distribution systems to provide better quality control for anti-malarial medicines. More than half of the patients in sub-Saharan Africa get their malaria medicines from these organisations, which use ‘Green Leaf’ logos as guarantees of medicinal safety and efficacy. Yet, even these packages can be tampered with or falsified. In 2012, customs officials in Angola found 33 million doses of counterfeit Coartem, a malaria treatment, in a shipment from China. There were enough tablets to treat more than half of Angola’s yearly malaria cases. They were packaged in boxes that carried the Green Leaf logo, in addition to a stamp of approval from the Nigerian pharmaceutical regulatory agency. Testing showed that the tablets did not contain any of the expected active ingredients.<sup>30</sup>

The falsification of expensive, life-saving medicines often makes news headlines. However, cheaper pharmaceuticals that are sold in high volumes are

just as enticing for criminals, who are attracted by the potential profits. According to a 2017 WHO report, antibiotics accounted for 17% of the falsified products reported to the GSMS between 2013 and 2017.<sup>31</sup> Visibility of troubling statistics such as these has created an environment for a greater response to the problem.

## Existing responses to the fake pharmaceutical problem

The growing problem of counterfeit pharmaceuticals has been attracting policy and enforcement attention, often with the assistance of major aid organisations, such as the European Commission’s MEDICRIME Convention, an international instrument in the criminal law field on counterfeiting of medical products. The problem with current responses, however, is that they are often not robust enough in an African context and tend to be piecemeal in their approach.

In this context, WHO has developed the GSMS in an attempt to more accurately measure and report on discoveries of counterfeit products.<sup>32</sup> Nigeria demonstrates how bespoke and comprehensive policy needs to be linked with the political will to bring about real solutions. Nigeria managed to achieve an 80% reduction in counterfeit drug circulation by implementing targeted regulatory activities. The Nigerian food and drug agency, NAFDAC, banned all imports of medicines through all but two national points of entry.

International, regional, regulatory and law enforcement authorities have attempted to address the counterfeit issue with varying degrees of success, due to factors ranging from the public’s lack of awareness, to an absence of adequate reporting methodologies, to weak responses from regulatory and law enforcement authorities, underscored by a lack of financial resources.

Transparency International has identified four overarching global challenges when it comes to pharmaceutical crime: lack of objective data and understanding around corruption; weak legislative and regulatory frameworks; the potential for undue influence from pharmaceutical companies; and an absence of strong leadership committed to anti-corruption. WHO breaks down the fight against illicit pharmaceuticals into three key components: prevention, detection and response.<sup>33</sup>

## Recognition and regulation

The high-profile reporting of the counterfeit pharmaceutical trade has led to some regional policy reflection, but little action. A crucial step is the national legislation seen in developed countries and Nigeria, which is needed to criminalise the counterfeiting of drugs, and set the baseline for an enforcement and regulation regime.

In Africa, there is a regional understanding of this problem. In February 2018, for example, ministers from more than 15 African countries participated in the second National Conference of Medicines and Health Products. The conference examined factors that facilitated the production and circulation of counterfeit medicines, and helped participants identify challenges and solutions to the fight against falsified medicines and health products.<sup>34</sup> But there is scant evidence of practical follow-up from this conference, highlighting the problem of follow-through and effective policymaking in combating counterfeit pharmaceuticals.

## The high-profile reporting of the counterfeit pharmaceutical trade has led to some regional policy reflection, but little action

A comprehensive legal framework needs to be in place, as well as multi-stakeholder engagement and prioritisation of supply chain integrity. When counterfeit pharmaceuticals are detected, responses to incidents need to be quick and proportionate, protecting patients and taking appropriate action against those responsible, without causing unnecessary shortages or distrust in medicines.<sup>35</sup> This requires coordinated participation from national and regional governments, global organisations, the private and non-profit sectors, and civil society. It will also require expansive information sharing and cooperation between health, customs and law enforcement authorities, pharmaceutical and logistics companies, and consumers.

The MEDICRIME Convention is the only international legal instrument that has made it a criminal offence to produce and distribute fake medical products or

commit similar crimes. Developed by the Council of Europe and ratified by certain African countries – Morocco, Burkina Faso and Guinea – it was adopted in December 2010 to punish the production and trafficking of fake medical products at global level.<sup>36</sup>

According to *The Journal of Global Health*, Nigeria used to have one of largest counterfeit pharmaceutical markets in the world.<sup>37</sup> In 1987, a nationwide study found that 70% of drugs in the country were falsified, an issue that gained widespread media attention after more than 100 children died from taking counterfeit paracetamol syrup that contained a toxic solvent. In response to the crisis, the Nigerian government established the National Agency for Food and Drug Administration and Control (NAFDAC) and introduced a law criminalising the manufacture and sale of counterfeit drugs. It emphasised that there must be a ‘workable framework’ for co-operation between law enforcement, health and customs authorities, as well as effective prosecution of crimes and protection of victims, at national and international levels.<sup>38</sup> The legislation eventually led to much improved interception (see ‘Enforcement’, below).

## Measurement and communication

Market surveys of substandard and falsified medical products in African markets have become more widespread, but they are often too unreliable to paint a coherent picture of the challenge as it presents itself on the continent. Publicity and education relating to counterfeits, among consumers and the medical profession, are inadequate and hampered by underinvestment.

Key stakeholders, including international aid agencies, and the public and private sectors, need to collaborate to raise awareness and drive policy change. At present, many in Africa are not aware of the scale the fake pharmaceuticals sector.

In June 2015, at a pharmaceutical crime conference, Diane de Laubadère, the editor of the French National Institute of Advanced Studies in Security and Justice (INHESJ)’s publication *Défis*, highlighted how fake pharmaceuticals have become a protected ‘silent epidemic.’

Despite the official communication from international agencies such as Interpol, which

regularly publicise spectacular assessments of their seizures of illegal products, and awareness campaigns orchestrated by various foundations, associations and interest groups, most of our questions about fake medicines remain unanswered.<sup>39</sup>

She stressed how there is a dearth of information and hard data on the scope of the problem, as well as a lack of communication from drug makers and other stakeholders, who are worried about reputational costs.

In a 2015 interview for the International Peace Institute Global Observatory, an HIV/AIDS activist insisted that counterfeit medicine in South Africa was not a problem. According to the Global Observatory, the activist shared a commonly held viewpoint in South Africa.<sup>40</sup>

## Studies have been piecemeal and patchy, and have yielded a skewed picture of the problem

Furthermore, studies on global pharmaceuticals have been piecemeal and patchy, and have yielded a skewed picture of the problem. In 2016, the ACT Consortium Drug Quality Programme (ACTcDQP) shared findings from a multi-country study on over 10 000 antimalarial drugs.<sup>41</sup> ACTcDQP found that the majority of drug quality surveys in Africa used a convenient, but not necessarily accurate, 'convenience sampling' approach. This entails

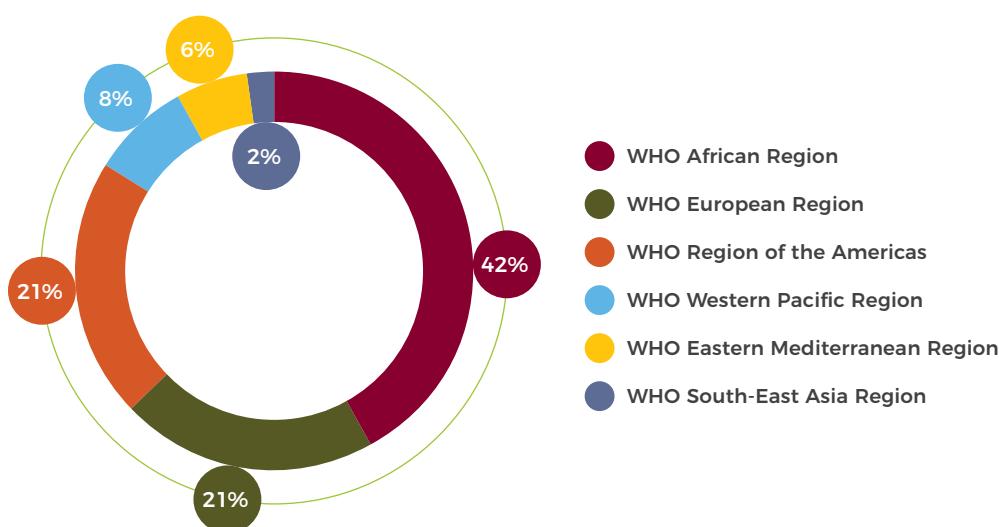
taking a non-random sampling approach for drug-testing purposes, allowing surveyors to test drugs based either on ease of access or severity of perception of risk. This has the potential for significant sampling bias. In sub-Saharan Africa, this meant that the antimalarial drug quality studies were often dominated by data from Nigeria, Tanzania and Ghana, but lacked information concerning geographies or markets that were harder to penetrate.

These numbers underscore the difficulty in quantifying the problem. UNODC acknowledges this when it refers to the WHO statistics that 10% of the global medicine supply and 30% of the developing world medicine supply is counterfeit. Measurement is the crucial first step in addressing the counterfeit problem. Without a consensus, the problem is unlikely to receive the policy and response attention it deserves. Moreover, pinpoint studies allow authorities to direct scarce resources to higher-risk areas.

A 2016 presentation by the Global Health Assurance Partnership (GHAP) promoted the use of more statistically valid market intelligence, developed by GHAP's respected measurement studies.<sup>42</sup>

GHAP's market assurance reviews are conducted to identify suspect health products and reveal trends. Survey analysis and forensic laboratory testing facilitate information sharing. GHAP recommends that risk-based supply chain assurance reviews be conducted to identify supply chain weaknesses. In addition, national governments need to implement engagement to support operations, follow up incidents and support further capacity-building initiatives.<sup>43</sup>

**Figure 1: Percentage of reports from each WHO region to the GSMS (2013–2017)**



Source: WHO GSMS

**Figure 2: Image of falsified Coartem**



Picture credit: GHAP<sup>44</sup>

GHAP published summary findings in 2016. Between 2013 and 2015 GHAP personnel discovered falsified versions of WHO pre-qualified Artesunate Combination Therapies (ACTs) an antimalarial, bearing the Global Fund-promoted Green Leaf logo in all six West African countries surveyed – Benin, Cameroon, Ghana, Ivory Coast, Nigeria and Togo – including the world's first detection of a WHO pre-qualified generic ACT. Whilst similar surveys in East and Southern Africa revealed no falsified ACTs at that time, in 2016 fake Green Leaf anti-malarial medicines were identified in Uganda for the first time, indicating how the trade is spreading to previously unaffected areas.

## Supply chain controls

In a move to tackle the problem more effectively, tightening controls over the supply chains has already shown great potential to thwart the penetration of falsified medical products and enforce compliance. Models exist that have worked elsewhere. For instance, track-and-trace systems of the sort currently in use in Europe and North America could pave the way for more effective

enforcement in Africa, but have not been introduced on the continent. Furthermore, Europe's Falsified Medicines Directive (FMD) requires drug companies in the European Union (EU) to add unique identification numbers to all drug packaging – a proven and efficient way of authenticating medical products. Introducing a similar system in Africa could go a long way to help achieve compliance.

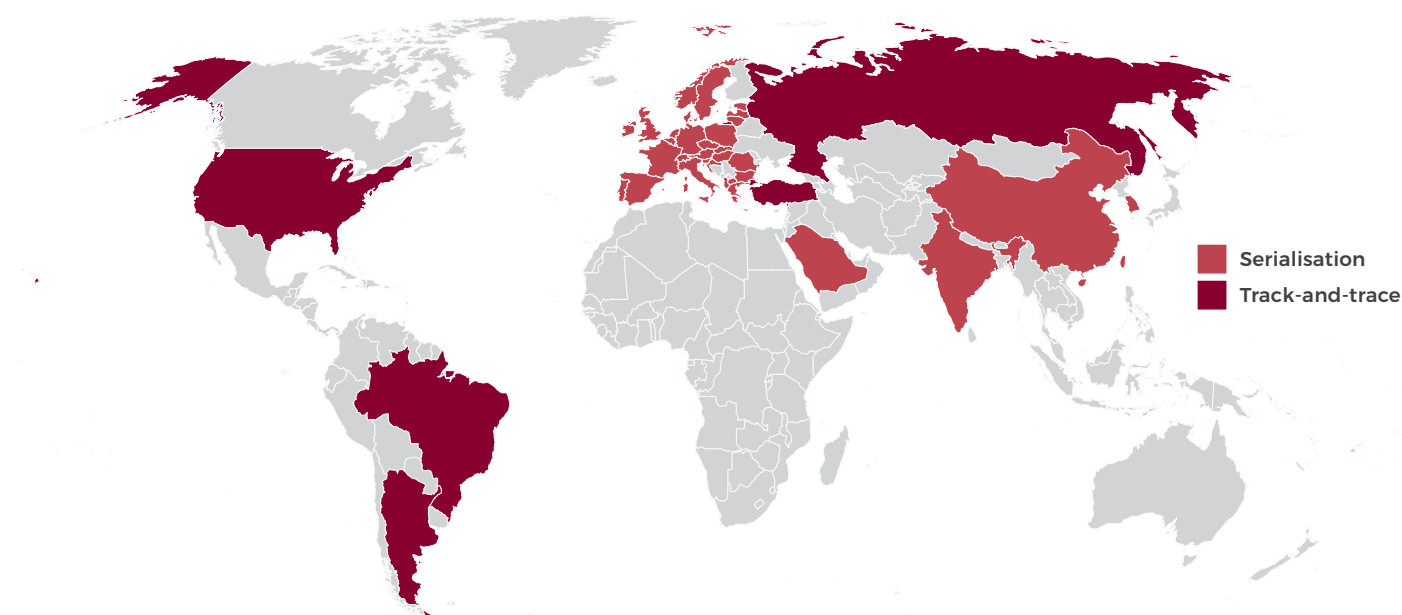
Substandard or falsified products already in the supply chain need to be detected. Greater assurance in supply chains allows suppliers to verify their product through its journey to a customer, without expensive regulatory controls 'upstream'. National track-and-trace systems are an effective way of quality-assuring products. From 2019, the FMD will require drug companies in the EU to add unique identification numbers to the outer packaging of all prescription drugs and sealed containers.<sup>45</sup> This is in line with the trend towards mass serialisation and track-and-trace requirements, which are becoming worldwide standards for combating counterfeit pharmaceuticals.

Track-and-trace allows brand owners, manufacturers, governments and customs officials to track the location of an item, as well as its movement history, for quality control and counterfeiting-prevention purposes. To do so, mass serialisation encodes drug packages with a unique identifier, usually a scannable barcode. Holograms, watermarks and taggants (chemical or physical markers) such as RFID (radio-frequency identification) tags can also be used.<sup>46</sup> As packages leave production lines, their identifying codes are entered into an online database. Equipment such as handheld scanners can then be used to monitor and check their movement at various points in a supply chain.

Where this mass serialisation solution has been implemented successfully, it is usually mandated nationally or regionally by enabling legislation. Systems' implementation is then funded largely by the pharmaceutical industry, as in the case of FMD. But African countries currently lack either the enabling legislation or the technology to prove the impact case. There are some encouraging small-scale projects: in Ghana, consumers can text label codes from their mobile phone to a verification service, which confirms whether the medicine is from a legitimate source and batch in less than 20 seconds.<sup>47</sup> But wide-scale deployment of this effective form of authentication remains absent from Africa, as Figure 3 illustrates.



**Figure 3: Mass serialisation and track-and-trace around the world**



Country	Deadline for implementation*	Type of protection
Argentina	In place	Track-and-trace
Brazil**	In place	Track-and-trace
China	December 2015	Serialisation
EU & Switzerland	Enforcement begins in 2019	Serialisation
India	In place	Serialisation
Russia***	2019	Track-and-trace
Saudi Arabia	Expected in 2017	Serialisation
South Korea	In place	Serialisation
Turkey	In place	Track-and-trace
US	Serialisation by 2019, full track-and-trace by 2025	Track-and-trace

**Notes:**

\* For pharma industry

\*\* Situation in Brazil unclear

\*\*\* Regulatory requirements in Russia not yet clearly defined

Source: "Pharmaceutical Serialization Track & Trace,"  
Infosys, 2014; TraceLink

Source: Behner, Hecht and Wahl (2017)<sup>48</sup>

Moreover, Africa's pharmaceutical supply chain suffers from a highly inefficient and expensive structure. In a 2012 IMS Health whitepaper, Daniel Rosen explains that the supply chain in sub-Saharan Africa has resulted in 'some of the highest branded drug prices in the world, despite also demonstrating some of the lowest average incomes for its population.'<sup>49</sup> Looking at a basket of 50 essential medicines, he reports that out-of-pocket consumer prices were 20.9 times higher than the international reference price for original brands.

'This is not because pharmaceutical manufacturers are making more money off their medicines, but instead the complexity of the supply chain adds incrementally to the cost of medicines such that typically the price of a medicine triples between the manufacturer and the

patient,' Rosen explains. This price premium provides a fertile market for criminal suppliers of falsified and substandard medicines.

Added to this inefficiency, many African countries' supply chains lack even basic quality assurance. Pharmaceutical chains are cross-border and complex, involving multiple stakeholders. An absence of harmonised regulatory protocols results in varying degrees of oversight across inspections, screenings and training. Staffing, equipment and training resources are not always sufficient to manage the problems at hand and regional variation leads to inconsistent results.

As mentioned previously, WHO's GSMS aims to combat substandard and falsified pharmaceuticals. It trains 'nationally designated focal points' in regulatory agencies, who communicate with global authorities

about medicine quality. The largest number of trained focal points are in sub-Saharan Africa, due to the high concentration of risk factors and potential public health gains that come with increased and improved resources and communication.<sup>50</sup>

In the Nigerian case, NAFDAC has continued its fight against counterfeit drugs using quality-testing technology. In 2011, it bought 100 mobile 'minilabs' for customs officials, enabling them to identify counterfeit drugs using visual inspections, a disintegration test, two types of chemical analyses, colorimetry and chromatography – with 99% accuracy.<sup>51</sup> In a quality-testing initiative in Mali, thin wire probes hooked to electrodes have been used to analyse drugs used in treating the most common problems of ear infections, heart failure, HIV/AIDS and malaria.<sup>52</sup>

Another example of external sponsorship of quality initiatives is the United States Pharmacopeia (USP) Convention, which opened the Center for Pharmaceutical Advancement and Training (CePAT) in Ghana to improve pharmaceutical quality across Africa.<sup>53</sup> The centre trains African professionals in drug quality testing and screening, and has helped more than 190 professionals from 32 African countries build their skills. It has already proved its potency in Ghana, finding serious issues with 90% of oxytocin, which is used to treat excessive blood loss immediately after birth. As a consequence of this finding, the Ghana Food and Drugs Authority (FDA) met the Ministry of Health procurement unit to ensure that government-procured products are registered and vetted. The FDA also issued a nationwide press release about the quality issues with drug.

'Millions of people across Africa can still be at risk every time they walk into a pharmacy or drug shop'

But these initiatives are the exception rather than the rule in African countries. 'Millions of people across Africa can still be at risk every time they walk into a pharmacy or drug shop,' USP's Ronald Piervincenzi said. 'Given the sheer number of fake and poor-quality medicines on the market, we're going to need quite a bit more help building the capacity to detect them.'<sup>54</sup>

## Enforcement

Enforcement activities tend to be better executed in developed countries than in Africa. There have been a number of high-profile operations cracking down on illegal sales of medicines – Interpol's Operation Pangea X, which seized medicines worth US\$51 million, being a prime example. But national efforts, rather than NGO operations, are weak. Nigeria has set a good precedent, achieving an 80% reduction in counterfeit drug circulation by implementing targeted enforcement activities. NAFDAC banned all imports of medicines from all but four national points of entry.

Combating illegal pharmacies and counterfeiters is challenging from law enforcement and regulatory perspectives. WHO recommends a comprehensive, multi-stakeholder approach. This includes building up border control, with designated ports for the import and export of medical products. Customs, police and regulatory agencies need to work together; and risk-based inspection and surveillance systems are recommended for manufacturers, importers, wholesalers, distributors and sellers within the pharmaceutical supply chain. Those involved in inspections also need to have access to laboratories and screening technologies.

High-profile international operations to address the problem are impressive but rare. From 21 May to 4 June 2014, the International Institute of Research Against Counterfeit Medicines and the World Customs Organization conducted Operation Biyela 2, a customs sweep that targeted trafficked products in 14 sub-Saharan, West and East African nations. Among the 118 million articles intercepted, more than 113 million were illicit or counterfeit drugs.<sup>55</sup>

In September 2017, Interpol's Operation Pangea X seized more 25 million articles of illicit and counterfeit medicines – including pain, epilepsy, and anti-psychotic medication – worth more than US\$51 million. With the help of customs and regulatory authorities from 123 countries, the operation led to 400 arrests.<sup>56</sup> In addition to medicines, counterfeit medical devices, such as dental implants, condoms, syringes, medical testing strips and surgical equipment were recovered. Authorities in the DRC alone confiscated nearly 650 kg of antimalarials. In addition to on-the-ground seizures,

the operation also targeted online sales, shutting down illegal domain name registrars, electronic payment systems, delivery services and social media sites.

In the Nigerian case, after NAFDAC introduced a law criminalising the manufacture and sale of counterfeit drugs, little was done to enforce new legislation due to inadequate infrastructure and political will. Counterfeits continued to inundate the marketplace and it was only when neighbouring Cameroon and Niger banned imports of Nigerian drugs that Nigerian authorities took 'drastic domestic action,' according to Silas Webb of *The Journal of Global Health*.<sup>57</sup>

## Fake pharmaceuticals in Africa continue to account for up to 30% of the market

NAFDAC was restructured, with new a management team and director-general. Under the new leadership, NAFDAC increased monetary penalties and introduced prison sentences for those found guilty of producing or knowing about the distribution of counterfeit pharmaceuticals. It also mandated that training for pharmacists had to be improved, which should include a specific focus on identifying counterfeit drugs using visual aids and quality of printing and holograms on the packaging.<sup>58</sup>

NAFDAC also looked at how to better use its limited enforcement resources. The body realised that the majority of Nigeria's medicines were being imported, mostly from India, because national drug manufacturers were meeting less than 30% of the country's pharmaceutical needs. Imports were estimated to account for 75% of the counterfeit problem. NAFDAC in 2003 ruled that drugs could only be imported through four designated ports and airports.

In the five years following the ban, customs officials destroyed counterfeit pharmaceuticals worth US\$109 million. NAFDAC also began working more closely with the Indian authorities, mandating that Indian pharmaceutical companies performed pre-export inspections of drugs and that the Indian authorities shared information about blacklisted pharmaceutical companies. Between 2001 and 2006, counterfeit drug circulation reportedly dropped by over 80%.<sup>59</sup>

## Conclusion

We are still in the foothills of combatting falsified medical products in Africa. In the past 10 years, Western regulatory, technology and measurement systems have successfully adapted to the threat of counterfeit medicines. SDG 3 needs to emphasise the need to 'ensure healthy lives'<sup>60</sup> through 'quality, affordable medicines'. Yet fake pharmaceuticals in Africa continue to account for up to 30% of the market. The EU's FMD and similar legislation in the US have helped to shore up a leaky supply chain. Moreover, evidence of successful enforcement of countermeasures and investigations show a strong bias towards more economically developed countries. In Africa, WHO's CSMS is the first large-scale monitoring mechanism. African national medicines regulatory authorities, in co-operation with each other, must complement international efforts with local enforcement, monitoring and reporting.

## Recommendations

Our recommendations call for a substantial overhaul of the regulatory, legal, enforcement and education systems around African medical supply chains. The legal and regulatory frameworks for combating medicine fraud will need to be enacted and established nationally. A consistent and regular assessment of counterfeits should be undertaken, and awareness-raising and training campaigns improved. Options to introduce mass-serialisation forms of track-and-trace should be investigated and evaluated, and supply chains will need to be carefully assessed to identify risk areas. Capacity building in enforcement should follow the successful Nigerian example.

## Recognition and regulation

The problem of counterfeits needs to occupy more prominence on the agenda of policymakers and the public alike. Limited capacity and capability, and corruption within regulatory authorities, often hamper measures to counter activities against falsified and stolen medicines and health products. We recommend the following key programmes:

- Health and anti-organised crime NGOs should play a leading role in raising awareness at

national levels in key countries, and should convene the required political, enforcement and industry leaders to originate national solutions.

- As in the case of Nigeria, African nations should enact enabling legislation that criminalises the manufacture and sale of counterfeits. Legislation should also provide clear authority and responsibility for the investigation, detection and seizure of counterfeit products.
- Working with the medicines regulation authorities, enabling legislation should also establish a framework for supply chain security and assurance, providing minimum standards for drug authentication.

## Measurement and communication

There is a need to prevent the manufacture, sale and consumption of substandard and falsified medical products. This involves first measuring – reliably – the scale and incidence of the problem in each nation. It then entails educating the public, healthcare professionals, and media and civil society groups. We recommend the following key programmes:

- A pan-African measurement and reporting methodology should be developed, and operated on a continual basis to provide consistent and regular market reporting on the availability and use of substandard pharmaceuticals, to include:
  - A global ‘spectral library’ (of expected drug compositions) for a subset of WHO Essential Medicines, which would allow users to identify/authenticate samples by comparing them with those held in the library; and
  - An online data-sharing platform to act as a central repository of intelligence on the trade in falsified and stolen medicines (e.g. market surveillance and customs data).
- A review of existing campaigns should be undertaken that could be used to raise public awareness about falsified and stolen medicines. A pilot should be developed to harness locally impactful means of communication to spread awareness and educate people about falsified and stolen medicines.

## Supply chain controls

African medical supply chains lack basic security and monitoring capabilities. A lack of equipment and training significantly hampers detection; and serialisation capabilities are not currently used widely or effectively, despite evidence from other markets that they substantially reduce illicit trade. We recommend the following:

- Initial research should be commissioned to assess the use of serialisation to authenticate medicines at the point of dispensing and/or at the point of use by the patient. Following this regulation, agencies should implement a track-and-trace system with specific application for medical products.
- National supply chains should be analysed from a risk perspective to identify areas of weakness, on their journey from importing or manufacturing locations to pharmacies or medical outlets.
- National medicines regulatory authorities should establish a reporting and monitoring function for receiving and collating evidence of falsified products.
- Staff in the supply chain should be trained and equipped to identify, report and respond to suspected substandard and falsified medical products.

## Enforcement

In many African nations, enforcement resources are rarely targeted at the counterfeit pharmaceutical problem. We recommend the following:

- Within an overall strategy for capacity building, enforcement agencies should develop a risk-based strategy to best target resources on areas of highest risk (following NAFDAC’s example).
- Agencies should raise awareness among enforcement professionals, with NGO assistance (e.g. through workshops, training courses and seminars) to educate professionals about how to identify, detect and respond to falsified medicines.
- Agencies should train and equip enforcers with a field-screening capacity at appropriate scale.



## Notes

- 1 See: <https://sustainabledevelopment.un.org/sdg3>.
- 2 WHO, WHO Member State Mechanism on Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit (SSFFC) Medical Products, Working Definitions, (Appendix 3), A70/23, Geneva: World Health Organization, 29 May 2017, [www.who.int/medicines/regulation/ssffc/A70\\_23-en1.pdf?ua=1](http://www.who.int/medicines/regulation/ssffc/A70_23-en1.pdf?ua=1).
- 3 WHO, WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, Executive Summary (WHO/EMP/RHT/SAV/2017.01), Geneva: World Health Organization, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_ExecutiveSummary\\_EN.pdf?ua=1](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_ExecutiveSummary_EN.pdf?ua=1).
- 4 UNODC, Fraudulent essential medicines from East Asia to Southeast Asia and Africa, in UNODC, Transnational Organized Crime Threat Assessment, East Asia and the Pacific, United Nations Office on Drugs and Crime, 2015, 129–137, [www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA\\_EAP\\_c12.pdf](http://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA_EAP_c12.pdf).
- 5 P Behner, ML Hecht and F Wahl, Fighting counterfeit pharmaceuticals: New defenses for an underestimated – and growing – menace, *strategy&*, 29 June 2017, [www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals](http://www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals).
- 6 M Finn, 2016 Top Markets Report: Pharmaceuticals, US Department of Commerce/International Trade Administration/Industry & Analysis, May 2016, [www.trade.gov/topmarkets/pdf/Pharmaceuticals\\_Top\\_Markets\\_Reports.pdf](http://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Top_Markets_Reports.pdf).
- 7 WHO, 1 in 10 medical products in developing countries is substandard or falsified, Geneva: World Health Organization, 28 November 2017, [www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified](http://www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified).
- 8 Pharmaceutical Security Institute, Counterfeit Situation: Incident Trends, [www.psi-inc.org/incidentTrends.cfm](http://www.psi-inc.org/incidentTrends.cfm).
- 9 WHO, 1 in 10 medical products in developing countries is substandard or falsified, Geneva: World Health Organization, 28 November 2017, [www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified](http://www.who.int/en/news-room/detail/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified).
- 10 JC Kohler, MG Martinez, M Petkov and J Sale, Corruption in the Pharmaceutical Sector: Diagnosing the challenges, Transparency International UK, June 2016, [www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.W2GsFNhKjsk](http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.W2GsFNhKjsk).
- 11 Incidents are defined as involving the seizure of more than 1 000 dosage units.
- 12 Pharmaceutical Security Institute, Counterfeit Situation: Geographic Distribution, 2018, <http://psi-inc.org/geographicDistributions.cfm>.
- 13 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, Geneva: World Health Organization, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_Report.pdf](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf).
- 14 UNODC, Fraudulent essential medicines from East Asia to Southeast Asia and Africa, in UNODC, Transnational Organized Crime Threat Assessment, East Asia and the Pacific, 2015, [www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA\\_EAP\\_c12.pdf](http://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA_EAP_c12.pdf).
- 15 T Holt, M Lahrichi and J Santos da Silva, Africa: A continent of opportunity for pharma and patients, *McKinsey & Company*, June 2015, [www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients](http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/africa-a-continent-of-opportunity-for-pharma-and-patients).
- 16 T Pheage, Dying from lack of medicines, *Africa Renewal*, December 2016–March 2017, [www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines](http://www.un.org/africarenewal/magazine/december-2016-march-2017/dying-lack-medicines).
- 17 Ibid.
- 18 Ibid.
- 19 Ibid.
- 20 Ibid.
- 21 JC Kohler, MG Martinez, M Petkov and J Sale, Corruption in the Pharmaceutical Sector: Diagnosing the challenges, Transparency International UK, June 2016, [www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.W2GsFNhKjsk](http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.W2GsFNhKjsk).
- 22 *The Guardian*, Ex-UN consultants jailed for bribes over drugs supplied to ‘starving Africans’, 23 September 2015, [www.theguardian.com/uk-news/2015/sep/23/un-guido-bakker-sijbrandus-scheffer-jailed-contracts-drugs-congo](http://www.theguardian.com/uk-news/2015/sep/23/un-guido-bakker-sijbrandus-scheffer-jailed-contracts-drugs-congo).
- 23 WHO, Substandard and falsified medical products, 31 January 2018, Geneva: World Health Organization, [www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products](http://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products).
- 24 UNODC, Fraudulent essential medicines from East Asia to Southeast Asia and Africa, in UNODC, Transnational Organized Crime Threat Assessment, East Asia and the Pacific, United Nations Office on Drugs and Crime, 2015, 129–137, [www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA\\_EAP\\_c12.pdf](http://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA_EAP_c12.pdf).
- 25 GML Nayyar, JG Breman, PN Newton and J Herrington, Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa, *The Lancet* Vol 12(6), 488–496, DOI [https://doi.org/10.1016/S1473-3099\(12\)70064-6](https://doi.org/10.1016/S1473-3099(12)70064-6).

- 26 C Abraham, The Most Reprehensible Black Market, Slate, 26 October 2014, [www.slate.com/articles/health\\_and\\_science/new\\_scientist/2014/10/fake\\_anti\\_malarial\\_drugs\\_artemisinin\\_and\\_other\\_pills\\_in\\_worldwide\\_survey.html](http://www.slate.com/articles/health_and_science/new_scientist/2014/10/fake_anti_malarial_drugs_artemisinin_and_other_pills_in_worldwide_survey.html).
- 27 GML Nayyar, JG Breman, PN Newton and J Herrington, Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa, *The Lancet* Vol 12(6), 488–496, DOI [https://doi.org/10.1016/S1473-3099\(12\)70064-6](https://doi.org/10.1016/S1473-3099(12)70064-6).
- 28 Ibid.
- 29 Ibid.
- 30 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, Geneva: World Health Organization, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_Report.pdf](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf).
- 31 Ibid.
- 32 The WHO system provides training at 'nationally designated focal points' in national and regulatory agencies that communicate with global authorities about medicine quality; see *ibid*.
- 33 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, Geneva: World Health Organization, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_Report.pdf](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf).
- 34 Ibid.
- 35 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, World Health Organisation, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_Report.pdf](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf).
- 36 Fondation Chirac, The MEDICRIME Convention, *Fight the Fakes*, 2 February 2018. <http://fightthefakes.org/resources/the-medicrime-convention-2/>.
- 37 S Webb, A bitter pill to swallow: the problem of, and solutions to, Sub-Saharan Africa's counterfeit pharmaceutical trade, *The Journal of Global Health*, 1 November 2014, [www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/](http://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/).
- 38 Council of Europe, Handbook for Parliamentarians: The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention, CETS No. 211), November 2015, <https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=09000016806a9674>.
- 39 D De Laubadère, Introduction, in INHESJ, Pharmaceutical Crime: A Silent Epidemic, *Défis* no. 5, June 2015, 2, [https://inhesj.fr/sites/default/files/fichiers\\_site/sececo/defis/defis5\\_en.pdf](https://inhesj.fr/sites/default/files/fichiers_site/sececo/defis/defis5_en.pdf).
- 40 D Knudsen and BP Nickels, South Africa falling short in counterfeit medicines fight, IPI Global Observatory, 16 March 2015, <https://theglobalobservatory.org/2015/03/south-africa-falling-short-in-counterfeit-medicines-fight/>.
- 41 H Kaur et. al., Fake antimalarials: start with the facts, *Malaria Journal* 15(86), 13 February 2016, [www.ncbi.nlm.nih.gov/pmc/articles/PMC4752758/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4752758/).
- 42 The Global Fund, The Joint Inter-Agency Task Force (JIATF) and The Global Health Assurance Partnership (GHAP), presentation, no date, <https://healthcommcapacity.org/wp-content/uploads/2016/11/Martin-Cinnamond-SSFFC-Presentation.pdf>.
- 43 Ibid.
- 44 Ibid.
- 45 European Commission, Falsified medicines – Major developments, [https://ec.europa.eu/health/human-use/falsified\\_medicines\\_en](https://ec.europa.eu/health/human-use/falsified_medicines_en).
- 46 R Cartwright, A Underwood, A Purchase and D Weatherby, Track and Trace: Approaches in Tobacco, KPMG and GS1UK, April 2014, [www.gs1uk.org/-/media/documents/white-papers/gs1\\_uk\\_and\\_kpmg\\_track\\_and\\_trace\\_in\\_tobacco\\_may\\_2014.pdf?la=en](http://www.gs1uk.org/-/media/documents/white-papers/gs1_uk_and_kpmg_track_and_trace_in_tobacco_may_2014.pdf?la=en).
- 47 Ibid.
- 48 P Behner, ML Hecht, and F Wahl, Fighting counterfeit pharmaceuticals: New defenses for an underestimated – and growing – menace, *strategy&*, 29 June 2017, [www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals](http://www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals).
- 49 D Rosen, Solving pharma's supply chain issues in sub-Saharan Africa, Pharmaforum, 12 May 2014, <https://pharmaphorum.com/views-and-analysis/solving-pharma-s-supply-chain-issues-in-sub-saharan-africa/>.
- 50 WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, World Health Organisation, 2017, [www.who.int/medicines/regulation/ssffc/publications/GSMS\\_Report.pdf](http://www.who.int/medicines/regulation/ssffc/publications/GSMS_Report.pdf).
- 51 Ibid.
- 52 S Redpath, Trade in illegal medicine hits pharmaceutical sector, *World Finance*, 20 April 2012, [www.worldfinance.com/special-reports/trade-in-illegal-medicine-hits-pharmaceutical-sector](http://www.worldfinance.com/special-reports/trade-in-illegal-medicine-hits-pharmaceutical-sector).
- 53 R Piervincenzi, Making progress in fighting counterfeit drugs in Africa, SciDevNet, 22 February 2016, [www.scidev.net/sub-saharan-africa/medicine/opinion/fighting-counterfeit-drugs-africa-medicine.html](http://www.scidev.net/sub-saharan-africa/medicine/opinion/fighting-counterfeit-drugs-africa-medicine.html).
- 54 Ibid.
- 55 IRACM, Operation Biyela 2: Record interceptions of products that are a threat to consumer health and safety, 22 September 2014, [www.iracm.com/en/operation-biyela-2-2/](http://www.iracm.com/en/operation-biyela-2-2/).

- 56 Ibid.
- 57 S Webb, A bitter pill to swallow: the problem of, and solutions to, Sub-Saharan Africa's counterfeit pharmaceutical trade, *The Journal of Global Health*, 1 November 2014, [www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/](http://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/).
- 58 P Behner, ML Hecht and F Wahl, Fighting counterfeit pharmaceuticals: New defenses for an underestimated – and growing – menace, *strategy&*, 29 June 2017, [www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals](http://www.strategyand.pwc.com/reports/counterfeit-pharmaceuticals).
- 59 S Webb, A bitter pill to swallow: the problem of, and solutions to, Sub-Saharan Africa's counterfeit pharmaceutical trade, *The Journal of Global Health*, 1 November 2014, [www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/](http://www.ghjournal.org/a-bitter-pill-to-swallow-the-problem-of-and-solutions-to-sub-saharan-africas-counterfeit-pharmaceutical-trade/).
- 60 See: <https://sustainabledevelopment.un.org/sdg3>.



## About the authors

Robin Cartwright is an executive director at UK Government Investments within HM Treasury; a director at Social Finance, a non-profit social investment organisation; and a senior fellow at the Global Initiative against Transnational Organized Crime. Before joining the non-profit sector, Robin was a partner for 15 years in the Global Strategy Team of global business adviser KPMG, where he worked on evaluating major merger and acquisition transactions and built a capability to measure and counter illegal trade. He began his career in intelligence and security in the UK Ministry of Defence.

Ana Baric is a writer, researcher and anti-corruption advocate. She is currently the policy coordinator for the All Party Parliamentary Group on Anti-Corruption in the UK and was formerly a reporter for the Organized Crime and Corruption Reporting Project in Sarajevo and Thomson Reuters in London. Ana is a research assistant at the Global Initiative against Transnational Organized Crime.

## About ENACT

ENACT builds knowledge and skills to enhance Africa's response to transnational organised crime. ENACT analyses how organised crime affects stability, governance, the rule of law and development in Africa, and works to mitigate its impact.

ENACT is implemented by the Institute for Security Studies and INTERPOL, in affiliation with the Global Initiative against Transnational Organized Crime.

## Acknowledgements

ENACT is funded by the European Union (EU). This publication has been produced with the assistance of the European Union.



**THE GLOBAL INITIATIVE  
AGAINST TRANSNATIONAL  
ORGANIZED CRIME**

Cover image: © emuck – Adobe Stock

The contents of this publication are the sole responsibility of the author and can in no way be taken to reflect the views or position of the European Union, or the ENACT partnership. Authors contribute to ENACT publications in their personal capacity.

© 2018, ENACT. Copyright in the volume as a whole is vested in ENACT, its partners, the EU and the author, and no part may be reproduced in whole or in part without the express permission, in writing, of the author and the ENACT partnership.