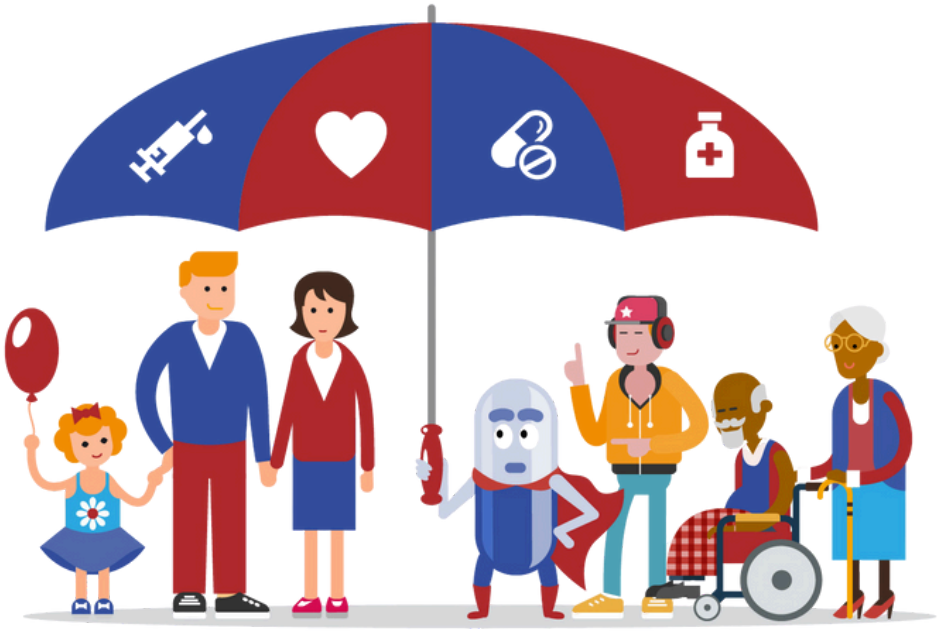
FIGHT THE FAKES

SPEAK UP ABOUT FAKE MEDICINES

Identifying Critical Enablers in the Prevention, Detection, and Response to Substandard and Falsified Medicines



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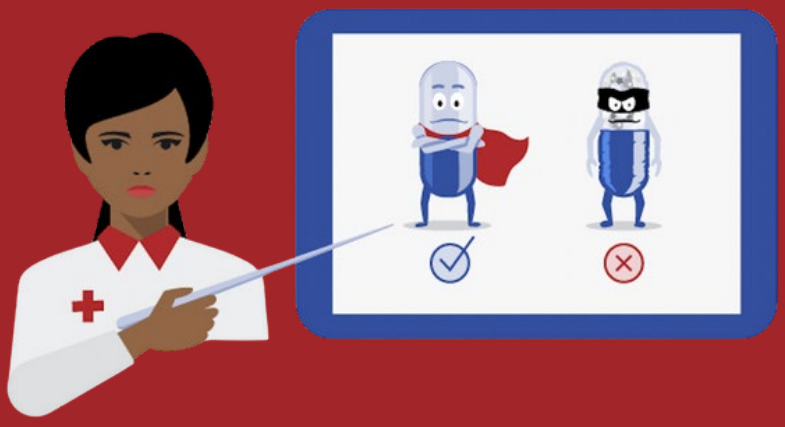


The Growing Problem of Fake and Substandard Medicines

Substandard and falsified medicines (SFs) trafficking is one of the world's fastest growing criminal enterprises, with the global market for fake medicine estimated to be worth $200 billion to $432 billion annually. Fake pharmaceuticals are the number one illicit activity, ahead of other underground economic activities like prostitution, human trafficking and illegal arms sales. [1] [2]

In real terms, this means that an estimated one in ten medicines in low-and-middle-income countries (LMICs) is substandard or falsified, although this problem is not limited to just those countries but is of global nature.[3]

And the crime is not victimless: it's estimated that over 1 million people die each year as a result of treatment with counterfeit drugs.[4] Substandard and falsified medicines fail to treat and prevent disease and, in some cases, may even lead to death. For example, such medicines have become an acute problem in Sub-Saharan Africa, especially in regard to malaria medicine, costing $12-$44.7 million a year to care for people who have used falsified or substandard medical products for malaria treatment in this area.[5] [6] At the systems level, they contribute to the increase of antimicrobial resistance, jeopardize health resources, and undermine the patient and consumer.[7] [8]

SFs are on the rise due to a confluence of global conditions such as medicine shortages, the opioid epidemic, an increase in online pharmacies, and the increased participation in fake medicine production by criminal enterprises.[9] A report by the Organization for Economic Co-operation and Development (OECD) and the EU Intellectual

Property Office (EUIPO) found that the most falsified types of pharmaceuticals seized by customs between 2014 and 2016 were antibiotics, sexual impuissance treatment, pain killers, and anti-malarials – however, this phenomenon involves all therapeutic categories and all countries and all therapeutic categories from generic and innovator medicines to very expensive cancer products to very inexpensive pain treatments.[10] [11] A report by the PSI found that pharmaceutical crime incidents spiked 38% as a result of the COVID-19 Pandemic and SFs have continued to increase since.[12] In addition to medicines, substandard and falsified health products and vaccines were in circulation globally. Between March and September 2020, Europe alone seized falsified products related to COVID-19 amounting to almost 33 million face masks, tests, and diagnostics kits, 8 tons of raw materials, chemicals, and antivirals, and

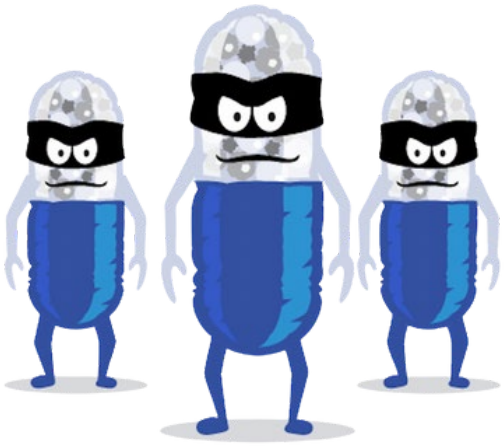
70,000 liters of sanitizers.[14] In the case of anti-malarial treatments, there is strong evidence that up to 60% of those treatments are fake or substandard medicines in Sub-Saharan Africa, resulting in hundreds of thousands of deaths and increased drug resistance in the region.[15] Substandard and fake medicines impact all facets of the pharmaceutical industry, including originators, generic, and local manufacturers. In 2019, substandard and fake medical products caused an estimated loss of over 80,000 jobs in the pharmaceutical sector and related industries that provide goods and services to it.[16] Nevertheless, SFs are not just an issue in LMICs - in November 2023, for example, UK's Medicines and Healthcare Products Regulatory Agency (MHRA) seized a considerable amount of falsified Ozempic pens.[17]

In low- and middle-income markets, such as many of those in Africa where out-of-pocket expenditures can reach up to 40% or more of total health spending, patients are likely to seek out the most accessible treatment options, often lowest-cost and from unverified outlets, which increases their risk of buying and consuming substandard and fake medicines.[18] [19]

> *"Poor adherence to antimalarials therapy resulting in incomplete dosing, plus the use of falsified and substandard medicines, which is hard to quantify, are both driving the increase in antimalarials resistance."*
>
> **Adam Aspinall**, Senior Director, Access & Product Management, Medicines for Malaria Venture

***Call-out-box:* WHO's Definition of substandard and fake medicines**

The World Health Organization (WHO) defines substandard, also called "out of specification", as these that are authorized medical products that fail to meet either their quality standards or specifications, or both, and falsified medical products as those that deliberately/fraudulently misrepresent their identity, composition, or source.[13]



How Stakeholders are Responding to the Crisis

With global health policymakers and practitioners taking notice, now is the time to catalyze the diverse stakeholder actions and collaboration needed to effectively combat this many faceted challenge.

Some of this work is already underway: the Medicines We Can Trust campaign, a global movement advocating for access to quality medicines and stronger health regulatory systems which ran until 2021 following the "The Oxford Statement, A Call for Global Access to Quality-Assured Medical Products", aimed to raise awareness of substandard and fake medicines and actions patients, health workers, governments, policy makers, the pharmaceutical industries, and others can take against them. The Oxford Statement was signed by 150+ global researchers, advocates, and policymakers in 2019, and calls on investments, policy change, and action to eliminate substandard and falsified medical products. The statement was born out of discussion between governments, national and international agencies, non-governmental organizations, professional associations, and academic institutions that came together at the first Medicine Quality and Public Health Conference in 2018. [20] [21] [22] Another tool, the Infectious Diseases Data Observatory, is available at no cost, and is aimed at assisting researchers and public health authorities globally in monitoring potential occurrences of SF medical products within their communities and countries.[23]

Additionally, a 2018 report from the European Alliance for Access to Safe Medicines and the Alliance for Safe Online Pharmacy (ASOP EU) called upon member states and civil society to raise awareness among the public about the escalating danger posed by illicitly operating websites that sell medicines and associated healthcare products. Examination of public awareness initiatives across member states reveals that the majority of EU countries have established competent authority websites featuring campaign materials following that call to action. ASOP Global's two main advocacy focuses are internet accountability, especially regarding the easily accessible domain creation, and the dangers of drug importation from foreign pharmacies that seem regulated, legitimate, and safe.[24]

Since 2013, the Fight the Fakes Alliance has been committed to supporting and advancing the global fight against SFs through collective action and advocacy.

At the global level, a number of bodies and mechanisms are in place to support countries in fighting SFs, including the World Health Organization (WHO) Member State Mechanism on Substandard and Falsified Medical Products.[25] The mechanism, which brings together WHO member states in a voluntary, self-governing body, was formed to increase member state collaboration on the prevention and control of the areas covered. In addition, the WHO Surveillance and Monitoring System works with Member States in improving the quantity, quality and analysis of accurate data concerning SF medical products, and to use that data in the better prevention, detection and response to those products, in order to protect public health.[26]

Furthermore, the Council of Europe has developed the MEDICRIME Convention, which provides countries worldwide with a model legal framework for criminalizing falsified medicines and other types of pharmaceutical crime that threaten public

health. The aim is, in part, to provide a framework that will allow for more international co-ordination in the investigation of suspected falsified medicines, and in the prosecution of criminals. This is especially important as substandard and falsified medicines is of global nature.[27]

Other organizations, including Interpol, the United Nations Office on Drugs and Crime (UNODC), and the European Medicines Agency (EMA) are also engaged in the fight against SFs. Interpol provides for the coordination of enforcement activities in countries, involving both regulators and police/customs, as well as training on the specificities of the health aspects of counterfeit medicines. Interpol's Illicit Goods and Global Health Programme (IGGH) formed a Public Health and Pharmaceutical Crime Unit, which part of their work involves pharmaceutical crime. Additionally, Interpol oversees Operation Pangea, which has been fighting the global trafficking of counterfeit pharmaceutical marketed and online since 2008.[28] UNODC has been given a mandate to assist member states in the fight against trafficking in fraudulent medicines by focusing on the transnational organized crime dimension of the fraudulent medicine trade, and has provided a guide to good legislative practices in combatting falsified medical product-related crime.[29][30] [31] In Europe, the European Union's Falsified Medicines Directive (FMD) has established an end-to-end verification system aiming at preventing SFs to be sold or dispensed to patients. A 2013 Directive introduced harmonized European measures to fight medicine falsifications and ensure that medicines are safe and that the trade in medicines is rigorously controlled. Measures included a globally standardized unique identifier captured in a 2D DataMatrix barcode and an anti-tampering device on the outer packaging of medicines, a common EU-wide logo to identify legal online pharmacies, tougher rules on import of active pharmaceutical ingredients, and strengthened record-keeping requirements for wholesale distributors.[32]

Manufacturers are also taking actions, including implementing identification solutions, such as anti-tampering together with serialization, harmonizing guidelines, and raising awareness.[33] [34] Thanks to these technologies, partners across the supply chain can scan the packaging codes to determine whether a particular product originates from a genuine batch of a brand or not, and whether a package might have been tampered with.[35] Though no single solution can prevent SFs altogether, these tools play an important role in hampering SFs to enter the legal supply chain of medical products.[36]

Call-out-box: the Lome Initiative[37]

In Africa, through the Lome Initiative, launched by the Brazzaville Foundation in 2020, six countries including Congo, Ghana, Niger, Uganda, Senegal and Togo, committed to strengthen and harmonize legislation to fight against SFs trafficking, and to sign and ratify international agreements, notably the MEDICRIME Convention, the Palermo Convention against transnational organized crime of the UNODC, and the treaty establishing the African Medicines Agency (AMA).[38] [39]

Why Greater Action is Needed to Combat Substandard andFalsified Medicines

Gaps in regulatory frameworks and limited law enforcement are among the major challenges to the prevention, detection, and response to SF medical products globally. Moreover, the growing complexity of pharmaceutical supply chains, coupled with limited financial and human resources, and weak coordination among stakeholders at national, regional, and global levels, contribute to the SFs problem.

Though an increasing number of countries are recognizing the need to take action against SFs, awareness of policymakers but also of the general public and healthcare providers on the issue remain low.[40] [41] In particular, youth-focused public awareness campaigns would be beneficial as SFs are increasingly being trafficked on TikTok and other social media platforms primarily used by younger generations.

The SFs ecosystem is complex, with drivers ranging from inadequate access to healthcare providers, to gaps in law enforcement, to insufficient consumer understanding of the risks associated with using substandard or fake medicines. Despite the diversity of the ecosystem, all SFs stakeholders do have one crucial commonality: all SFs stakeholders would benefit from additional education on SFs risks and mitigation.

Awareness is always the antecedent to action – absent an adequate awareness of the scale and implications of the global SFs challenge, stakeholders cannot be expected to mobilize to fight substandard and fake medicines. Because there is currently no fully inclusive global health governance body in place to marshal regulatory resources and the diverse set of stakeholders necessary to mitigate SFs, individual stakeholder awareness and mobilization is supremely important.

Three Priority Enablers for Transforming the Fight Against SFs

Drivers of the proliferation of SFs are diverse and often overlap – in this section, we define three priority enablers to prevent and manage SFs at the national, regional, and global levels.

1. Expand Education and Awareness

Successful efforts to combat SFs will need to include awareness and education campaigns aimed at both the supply-side of the SFs challenge - that is, regulators, policymakers, and law enforcement - as well as the demand-side of the challenge – that is, patients and consumers. And, in between the supply and demand side sit healthcare providers and pharmacists, making them especially important stakeholder targets for awareness and education campaigns.

Policymakers

Today, global and national policymakers and regulatory bodies are aligned: SF medical products are a serious public health issue demanding immediate attention.[42] However, that alignment splinters when the discussion moves from identifying the problem towards assigning responsibility for generating a solution. Sometimes, policymakers perceive SFs as peripheral concerns that ought to be addressed in relation to specific conditions, such as when they are linked directly to malaria or antimicrobial resistance.[43] And, at the country-level, it is often only a small subset of individuals working directly on the issue of SFs within the Ministry of Health that possess a comprehensive understanding of the problem's magnitude, while judges, prosecutors, and parliamentarians also demonstrate limited awareness of the matter.[44] While the Minister of Health and Minister of Trade – for example – may be very aware of SFs and the immense public health risk it represents, community-level action is hindered when this awareness is not translated into educational resources for frontline civil servants, such as law enforcement officers, border control agents, and local judges. Interviews with experts suggest that in some cases, countries might be reluctant to report openly on SF as they fear that this could be negatively perceived by the public.

> *"Even though substandard and falsified medicines is still low on the agendas of high-income countries, it doesn't mean that the issue doesn't exist in those countries – substandard and falsified medicines truly are a global problem. In addition, they undermine people's trust in healthcare systems."*
>
> **Pernette Bourdillon-Esteve**, Technical Officer, Incidents and Substandard/Falsified Medical Products, World Health Organization

Law Enforcement

While law enforcement agencies such as police and customs authorities may possess an understanding of the problem, they might not be able to investigate pharmaceutical crime because of the lack of legislation or, in cases where the legislation is in place, may lack the specialized expertise and the human and financial resources required to enforce

sanctions promptly and efficiently.[45] This demonstrates the need for advocacy towards adopting the appropriate legislation and, in places where legislation exists, to expand the training programs that organizations, such as INTERPOL, WHO, the World Customs Organization, UNODC, and MEDISAFE already offer to customs officers. The expanded training should aim to furnish them with the necessary tools and techniques for conducting more effective risk analysis and targeting pharmaceutical crime.[46] [47] [48] [49]

Government acts that protect the supply chain need legal measures to ensure the policy can be enforced. For example, when the Drug Supply Chain Security Act (DSCSA) was rolled out in the United States in 2013 criminals resorted to falsifying supply chain sourcing documentation to sneak their counterfeits into the mainstream pharmaceutical supply chains, fooling pharmacists and endangering patients. However, to counteract this, a new criminal law was created at the same time as DSCSA which enabled the U.S. Department of Justice to charge counterfeiters who operate under the banner of licensed wholesalers. Under the new legislation, wholesalers who cause harm to patients can face sentences as high as 30 years in jail. Enforcement of the policy has significantly deterred violators in recent years.[50]

Finally, more work is needed to engage regulatory agencies at country-level as awareness about the issue remains low amongst most patients and consumers. A great example is the US Drug Enforcement Administration's (DEA) campaign, One Pill Can Kill, which aims to spread public awareness on the surge in counterfeit pills. They utilize innovative ways to educate the public including sponsoring a video game tournament and partnering with NFL Alumni Health.[51]

Patients & Consumers

Public awareness regarding SFs remains universally inadequate, with comprehensive awareness campaigns being sporadic. A study conducted in 2021 indicated that just slightly over 30% of respondents from the general public were capable of recognizing falsified medicines.[52] This number is likely even lower today, as SFs produced by large criminal enterprises can "look identical to real prescription medications, including OxyContin, Percocet, and Xanax," and even come in sealed bottles, according to the United States Drug Enforcement Agency. [53] [54]

There is also dangerously low awareness of the risks associated with buying medicines from unverified online sources. A study in the United States revealed that nearly 25% of surveyed adults had purchased prescriptions online, and that 20% of consumers made purchases via websites with no links to local pharmacies or health insurance plans.[55] These purchases put consumers at risk: WHO states that half of drugs sold online are fake, and a UK survey indicated that 25% of patients reporting an adverse drug effect had purchased the medication from an online pharmacy.[56]

There are, arguably, two types of consumers of substandard and fake medicines. The first group unknowingly obtains SFs – they may receive what they think is a safe and legitimate medicine from a licensed pharmacy, including online pharmacies, but because of weak supply chains or criminal activity, the medicine that they receive is substandard or fake. The second group of consumers purchase medicines that they know *may* be substandard or fake because they are obtaining it from "the street," or from an unlicensed and/or online pharmacy. Education campaigns must be tailored to

each of these consumer groups in order to address their specific blind spots in relation to SF risks.

Spotlight: Public Education Campaign

In 2019, Czech Republic launched a campaign by the State Institute for Drug Control named "Dangerous drugs" ("Nebezpečné léky"). The primary goal of the campaign is to alert the general public to the presence of falsified and illicit medicinal products, frequently available online and in other publicly accessible locations. Additionally, the website provides details about seizures of falsified and illicit medicinal products conducted within the Czech Republic and globally. Brochures for different categories of healthcare providers are also provided.

Healthcare Providers

In 2021, the International Pharmaceutical Federation (FIP), in partnership with the WHO, launched a curriculum guide to support educators in ensuring that pharmacists are better able to prevent substandard or falsified medicines and medical products from reaching patients. The guidance highlights that lack of awareness is among the main barriers to reporting among healthcare providers.[57] Unfortunately, medical and pharmacy students frequently encounter information on SF medical products in supplementary courses rather than as part of their core curriculum, or through isolated workshops.[58]

The lack of organized instruction on substandard and falsified medicines for pharmacists poses a significant obstacle that needs to be addressed to adequately tackle the global health threat posed by such products. A study conducted in Sub-Saharan Africa in 2019, involving 355 pharmacy students, revealed that the introduction of a specialized educational program for undergraduate pharmacy students significantly improved their comprehension of substandard and falsified medicines. This improvement was corroborated by self-assessment, and both students and instructors expressed high levels of appreciation for the course.[59]

Pharmacists and healthcare professionals need to be made aware of the key role they play in mitigating the flow of SFs: educational resources on the identification and reporting of SFs, as well as on helping to raise consumer awareness of the dangers of unlicensed and online pharmacies would help to empower them to protect their communities from the threat of SF medical products. Enhanced advocacy in the pharmacy student arena is a clear opportunity to make a lasting impact at a grassroots level.

2. Facilitate Greater Collaboration

Collaboration among stakeholders is absolutely essential to combat SFs. At regional and global levels, there is a lack of coordination and information sharing between countries due to the lack of established procedures, lack of resources, and sometimes language barriers. Moreover, the lack of regulatory harmonization hampers a cross-border approach to tackling SFs.

Transnational Coordination Mechanisms

Bolstering the capacity of transnational mechanisms will be critical to the ongoing fight against SFs due to the complexity of the threat. First, stakeholders need to implement the recommendations outlined in the WHO Member States Mechanism on substandard and falsified medical products, which provides a collaborative, inclusive, and transparent means for countries to address this problem.[60] Key recommendations include improving Member States' understanding of detection technologies, methodologies and "track and trace" models, promoting shared understanding among Member States from a public health perspective regarding medical products in transit, and identifying and developing appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet, among others.

Second, SFs-related crimes are still not prosecuted as they should be due to weak penal sanctions in most countries - the MEDICRIME Convention and United Nations Convention against Transnational Organized Crime and the Protocols Thereto offer key frameworks that countries can adopt and use to prosecute falsified medical product-related crime. In addition, stakeholders must work to bolster the funding and capacity of multinational law enforcement agencies, such as INTERPOL and the United Nations Office of Drugs and Crime (UNODC), to give countries the resources they need to go after major perpetrators.[61]

Third, stakeholders need to work with international regulators such as the WHO, UNODC, and the Council of Europe MEDICRIME Convention to develop and harmonize a robust and uniform set of regulatory standards across countries in both the manufacturing and sale of pharmaceuticals, especially in regions where the existing regulatory frameworks are weak. As stated in UNODC's Guide to Good Legislative Practices on Falsified Medical Product-Related Crime, "SFs are less likely to emerge where there is a well-regulated supply chain for medical products." [62] This is paramount as weak regulatory and monitoring systems allow for SFs to infiltrate legitimate channels of distributions of pharmaceutical products more easily.[63]

Spotlight: MEDICRIME Convention

In December of 2010, the Committee of Ministers of the Council of Europe adopted the MEDICRIME Convention. The MEDICRIME Convention is *"a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health."* The goal is to protect the rights of the victims of SF and offers a legal framework to prosecute criminals. The Convention also facilitates the national and international co-operation of involved authorities, including judicial, health, and law enforcement.

Since its establishment, 23 countries have ratified, and 20 countries have signed the Convention. The MEDICRIME Convention supports countries with integration into national legal frameworks and established a committee to follow-up with signatories. It is the only international legal instrument able to fight against falsified medical products.

Fourth, stakeholders should work with the WHO's Global Surveillance and Monitoring System (GSMS) and International Coalition of Medicines Regulatory Authorities (ICMRA) to implement detection and surveillance technologies, methodologies and "track and trace" models to better regulate international pharmaceutical supply chains across borders and inside countries.[64] For this to happen, it is necessary to collect date that can be directly applied to projects like surveillance systems, where data can be used to detect and ultimately report.

Finally, it is important to underline that people need to feel empowered to report SFs crimes without fear of death or retribution for themselves or their families, such as losing their job. They also need the assurance that action will be taken through legislative and law enforcement reforms and investment.

Multilateral Actions

Transnational mechanisms will play a key role in the fight against SFs, but multilateral actions and coordination agreements between regional governments are important as well. First, stakeholders should establish transnational cooperation on regulating medicines in transit and designate a national contact point responsible for transmitting and receiving requests for information and cooperation in relation to falsified medical product-related crime.[65] [66]

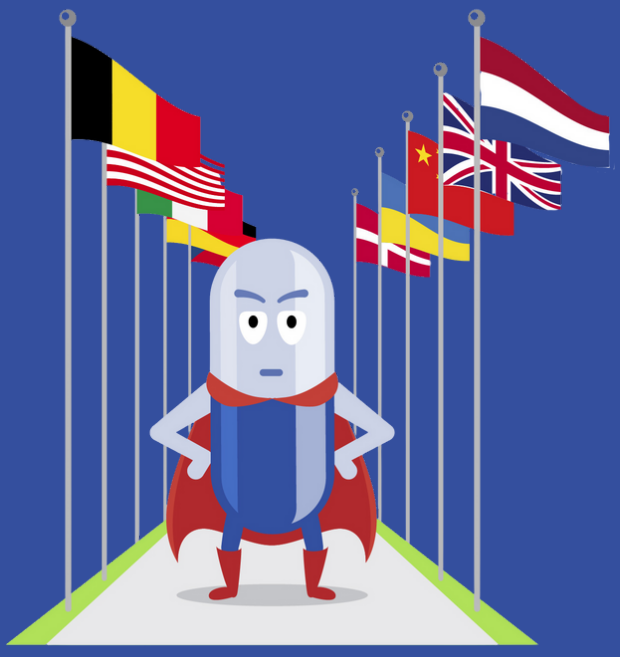
> *"There are a number of different points within the supply chain where SF can be inserted – part of it is down to the corruption by bribing people at the ports of entry; part of it is down to the lack of detection equipment at ports of entry and other points along the supply chain."*
>
> **Adam Aspinall**, Senior Director, Access & Product Management, Medicines for Malaria Venture

Second, stakeholders must design a systematic and extensive multinational approach for recording and sharing data on the adverse effects that falsified products can have on public health, safety and the environment.[67] By sharing this information among relevant stakeholders, including regulatory agencies, law enforcement authorities, and public health organizations, countries can better understand the scope and impact of the problem and develop targeted interventions to address it.

Third, stakeholders need to strengthen transnational law enforcement cooperation against falsified medicines, starting with the ratification of the MEDICRIME Convention, and support the adoption of legal instruments and initiatives that allow for mutual legal assistance, extradition, and joint investigations. [68] By doing this, countries can effectively disrupt criminal networks engaged in the illicit trade of substandard and falsified medicines, ultimately protecting public health and safety.

***Call-out-box:* Priorities of WHO Member State Mechanism on Substandard and Falsified Medical Products**

1. **Develop and promote** training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products.
2. **Expand and maintain** the global focal point network among national medicines regulatory authorities to facilitate cooperation and collaboration.
3. **Improve** Member States' understanding of detection technologies, methodologies and "track and trace" models.
4. **Increase** Member States' knowledge of the links between substandard and falsified medicines and access to quality, safe, efficacious and affordable medical products.
5. **Develop and leverage** existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products.
6. **Enhance** Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.
7. **Promote** shared understanding, from a public health perspective, among Member States, regarding medical products in transit.
8. **Identify and develop** appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.



3. Accelerate Domestic Anti-SFs Initiatives

National Policy Plans

Countries often lack national strategies and plans specifically dedicated to preventing, detecting, and responding to SFs with clear targets and commitments, which results in a lack of dedicated financial and human resources to fight SFs.

The Brazzaville Foundation and its partners are currently working with six African countries to establish national policy plans to fight SFs though the Lome Initiative. After commissioning a legislative audit and a study on the pharmaceutical supply chain in 2020 and 2021, the Brazzaville Foundation developed, in 2022, a methodological proposal to address the issue of combating SFs trafficking in a systemic manner. These plans will focus on strengthening the rule of law, reinforcing the security of the states, implementing a health economics approach, and improving public health. To achieve this, member states will support a cross-functional policy approach based on interministerial action and the adoption of stronger regulations, but also foster a systemic and coordinated approach of public authorities, private sector and civil society. [69] The signatory States are the project owners of the program. Host of the launch summit, the Republic of Togo ensures political coordination. The Brazzaville Foundation is the project manager of the program and as such ensures technical coordination. As this effort ramps up, expanding this initiative to other countries should be evaluated and planned utilizing existing partnerships.

Overall, dedicated SFs plans should include the following elements:

- A solid regulatory and institutional framework that target SFs specifically;
- Secured pharmaceutical supply chains;
- Empowered healthcare professionals able to raise awareness, spot, and report SFs;
- The general public is aware of the risks posed by SFs, and knows how to avoid, spot and report them.[70]

These dedicated SFs plans need to be designed collaboratively with all stakeholders, including civil society, regulators and law enforcement, custom officers, academia, patient groups, as well as manufacturers and other industry partners.

Call-out-box: SFs and Universal Health Coverage

Many countries still do not make the connection between SF, quality of medicines and patient safety, and Universal Health Coverage. In 2023, the Fight the Fakes Alliance launched a call-to-action to ensure quality medicines are a key part of universal health coverage:[71]

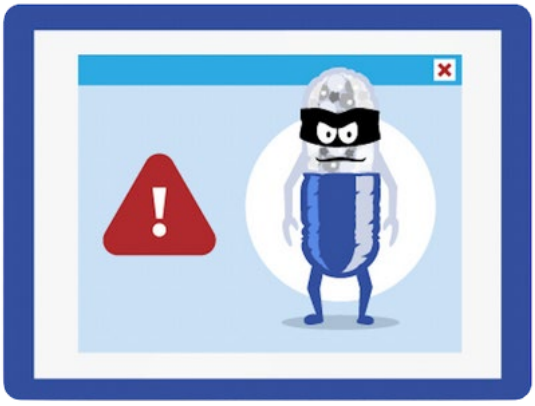
- Prevention: Ensure quality medicines are at the centre of Universal Health Coverage and health systems by implementing comprehensive policies to prevent substandard and falsified medicines, including adhering to standards for medical product quality, building global regulatory capabilities and strengthening regulatory systems, enhancing global cooperation, and creating economic incentives for product innovation and quality.

- Detection: Develop and implement national surveillance and traceability systems with appropriate regulations; streamline and simplify reporting of substandard and falsified medical products.

- Response: Increase collaboration with law enforcement and customs authorities.

Enhance Internal Coordination

At country-level, there is often a lack of coordination and information exchange between Ministries of Health, Trade and Economy, and Justice, law enforcement bodies such as custom and police services, regulatory agencies, and government departments and agencies, including national pharmacovigilance centers, national poison centers and national quality control laboratories. Increasing collaboration amongst these institutions, alongside regulatory systems strengthening, and efficient product approvals disincentivizes SF activities for criminals while simultaneously increasing consumer trust in the healthcare system. For examples, consumers might be less tempted to turn to unverified sources when purchasing medicines if they trust that regulatory approval processes are necessary for ensuring safety and working as efficiently as possible to bring needed products to the market.



Spotlight: Dispensing outlets in Tanzania[72]

There are also a variety of proven interventions that countries could borrow from to ensure that safe and effective medications reach patients. Tanzania has had success with accredited drug dispensing outlets.

The government built a national network of ADDOs, where the dispensing staff were trained, and procedures put in place to verify the quality of medicines. It was particularly useful in rural areas, where patients often turn directly to pharmacists for medical care in the absence of health clinics. This way, they were at least guaranteed quality products, explained Tedla, a pharmacist with action medeor, a Europe-based medical aid organization.

But even though these programs have been in place in Tanzania since 2003, Tedla told Devex that only Ghana has shown an interest in adopting something similar.

That might be, in part, because of a lack of awareness or a lack of start-up funding — something that might be resolved by regional collaborations that allow governments to pool the limited funds they have for monitoring drug safety.

Surveillance, Monitoring, & Oversight Programs

WHO stated that "fewer than 30% of the world's medicines regulatory authorities are considered to have the capacity to perform the functions required to ensure medicines, vaccines, and other health products actually work and do not harm patients." [73] A robust and sustainable regulatory framework will guarantee impartial and capable supervision of medical products, effectively averting the presence of falsified items while also providing the necessary infrastructure to identify and address them, facilitating both reactive measures like recalls and proactive strategies.

Many countries have not adopted the best practices when it comes to traceability of medical products, including the implementation of track and trace systems with an authentication process for medical products such as electronic barcodes, holograms on packaging, smart scanners, testing laboratories, and others. The WHO policy paper on traceability of medical products delineates the characteristics of current traceability systems and offers advice on formulating practical traceability regulations, serving as a valuable reference document.[74] For example, Türkiye started with a globally standardized product identifier captured in a barcode that matches with a database managed by the Ministry of Health. The barcode of a medical product therefore needs to be scanned at different stages – and this is fully integrated into the health system. Traceability system databases are often hosted by governments, and therefore the infrastructure needs to be managed by the IT teams of the government. Another example is the Lagos Call to Action for the Africa Strategy for Pharmaceutical Traceability, which has spurred numerous African countries to progress toward embracing established global supply chain standards for pharmaceutical traceability.[75]

Many countries do not conduct regular targeted and random market surveillance activities for substandard and falsified medical products within the regulated and unregulated supply chains. In many countries, entities engaged in the manufacture (including relabeling/repackaging), importation, distribution/wholesale and supply/sale of medical products do not always apply procedures and "best practices" as they should, which can result in an increased risk of SFs entering the market. The GPHF-Minilab represents an inexpensive solution for rapid drug quality verification and falsified medicines detection, using a simple drug quality verification process in four steps.[76]

Reporting mechanisms for SFs that are overly burdensome might be a barrier for custom officers, healthcare providers and other stakeholders to report on SFs in regular, timely, and effective ways. Despite some countries having an approved, clear procedure concerning the issuing, receipt and response to WHO's Rapid Alerts concerning substandard and falsified medical products, most still do not offer simplified, easily accessible reporting systems of SFs for healthcare providers and the general public, resulting in underreporting of SFs and delayed procedures.

Spotlight: Argentina's National Traceability System[77]

Drug traceability consists of a new way of identification, individual and unambiguous, of each of the pharmaceutical products to be marketed, to allow its traceability all along the distribution chain, from the laboratory of the manufacturer/imported till it is dispensed to the patient.

In 2011, the National Administration of Drugs, Foods and Medical Devices (ANMAT) of Argentina introduced a catalogue of drugs covered by its national drug traceability scheme, listing more than 3.000 medicines such as cancer and HIV but also analgesics and cough medicines, that require the placing of 2D DataMatrix barcode encoding a globally standardised product code, serial number, expiry date and lot number which creates a unique combination, and tamper-evident features on the secondary packaging. The automatic capture of data in the barcodes allows it to be checked at each point of the supply chain it is scanned. The National Traceability System imposes that all drugs be serialized and identified with a globally unambiguous product code, based on GS1 Standards.

The drugs listed are recorded in real time in a central database managed by the ANMAT, which uses Global Location Numbers (GLNs) to identify the various actors in the supply chain. This system ensures that the drug has never abandoned the legal trail of production and distribution, and that patients receive quality medical products.

Today, ANMAT has shown that the implementation of the system has delivered more than favorable results.

"Argentina started with high-value medical products in oncology that are highly counterfeited causing a risk to patients and the economy – the government noticed that these counterfeited products were having a negative impact on the expenses of the health system. Now with their National Traceability System, every time a medical product enters Argentina, this product can be scanned at every stage of the supply chain to verify that it matches every time, limiting the risk of SF in the country."

Geraldine Lissalde-Bonnet, Vice-President Healthcare, GS1

Enforcement Infrastructure & Capabilities

Better enforce existing laws

Too often, the manufacture, distribution, storage, supply, and sale of SFs is not criminalized and therefore not prosecuted accordingly, resulting in few condemnations of those that engage in these activities. An OECD/UNODC report found that in most countries, sentences for falsification of medical products are not proportionate to the gravity of the act. Moreover, falsification of medicine or medical products is not an international crime.

A study carried out by the Council of Europe in 2020 highlighted the inadequacy of legislation on pharmaceutical crime considering its serious potential repercussions on public health in Europe. The survey showed that applicable criminal charges remained mostly generic and were not fit for the specific implications for public health that derive from falsifying medicines. From theft of goods or handling of stolen goods to criminal association – which can currently only be punished under provisions for mafia associations (Italy) or for conspiracy (UK) – most regulatory frameworks do not take into consideration the fact that reintroducing stolen medicines to markets represents a far greater risk for patients than ordinary thefts. Similarly, sanctions for manufacturing illegal medicinal products or for manipulating authentic medicines, although covered in most criminal codes, are often subordinate to proof of damage to patients or considered as a breach of trademark, contrary to the provisions in the MEDICRIME Convention, which foresees direct charges thanks to its focus on the intention to falsify medical products or its documentation and the potential risk for patients.[78][79]

In 2019, the African Union countries signed a treaty to create the African Medicines Agency (AMA) to strengthen and modernize national regulatory systems. Investment into NMRAs and track and trace systems will be needed in cooperation with the Africa Centres for Disease Control and Prevention to reduce the market opportunities for SFMP medicines to enter the supply chain. Harmonized legislation is particularly important for substandard medicines, which do not necessarily result from criminal activities and are not covered in the MEDICRIME Convention, as this will help to ensure that only quality medical products enter the supply chains.[80]

Through the Lomé Initiative in 2020, substandard and falsified medical products (SFMPs) were declared to be on the highest political agenda among seven African leaders. The Initiative is a political declaration and legally binding agreement intended to criminalize the trafficking of SFMPs.

> *We need more national and international funding to tackle the many facets of SF, especially to support all national medicine regulatory authorities to be optimally functional. Unfortunately, it's still incredibly hard to raise funding for research groups to assess the impact of SF, including how to detect them, their economic cost, their impact on patient outcomes – there are also very few data on the effectiveness of SF campaigns and targeted initiatives, mostly because of a lack of global interest in the issue.*

Dr. Paul Newton, Head of Medicine Quality Research Group, Nuffield Department of Medicine, Oxford University

Reform legal and regulatory frameworks

Stakeholders in many countries have expressed worries that existing legal and regulatory frameworks are insufficient to combat the ongoing threats of SFs, pointing out that legal processes are often slow and bureaucratic, with weak enforcement exacerbating the crisis in some countries. Typically, legislation does not anticipate scenarios involving the trade of SFs, complicating the implementation of preventive measures.

To address current deficiencies and ensure regulatory authorities effectively combat the threat of SFs, countries should strengthen the sanctions associated with the trafficking of SFs, enhance national legislation to make it commensurate to the size of the SFs problem, bolster bilateral and interstate cooperation to curb the circulation of SFs across borders of neighboring countries, and allocate adequate financial and human resources to enforce domestic laws efficiently.

A recent study recommended that African states should establish bilateral agreements to facilitate mutual legal assistance and extradition for effective prosecution of offenders while introducing more severe penalties for offenders engaged in the production and sale of falsified medicines at the country level. Combatting corruption is another broader issue that countries should focus on.[81]

> *We need to have better visibility across supply chains around the world, coordinate law enforcement against counterfeiters from a law enforcement perspective, and anticipate the risk that any medical product might end up being counterfeited before reaching the consumers by taking a 'risk forecasting' approach.*

Geraldine Lissalde-Bonnet, Vice-President Healthcare, GS1

Empower custom officers

Many countries do not have the capacity to control the quality, safety or efficacy of the medicines circulating on their markets or passing through their territories. In addition, falsified medical products are often clandestinely concealed or smuggled, with their accompanying documentation deliberately misrepresenting their true

nature. Solutions include training custom and police officers, including at borders, in the screening of SFs following documented procedures and with the right equipment.

Conclusion

Actions against SFs require the cooperation of various stakeholders, including policymakers, healthcare professionals, international organizations but also academia, the public, and civil society.

The need for education and awareness among policymakers, healthcare providers, the public, and private sector must remain a priority and a necessary foundation in the fight against SFs. Enhanced training for law enforcement authorities, but also health professionals is essential to improve the detection of SFs and enforcement capabilities more broadly.

Supporting more countries to implement existing laws and regulations, and to adhere to global multilateral frameworks such as the MEDICRIME Convention, would ensure that the trade and circulation of SFs can be curbed in a more efficient and effective way. Domestically, countries should adopt dedicated national plans against SFs, and adopt the necessary laws to ensure that SFs traffickers are properly prosecuted. Establishing robust surveillance and monitoring systems, securing pharmaceutical supply chains, and empowering law and custom officers is primordial.

As a multi-stakeholder platform, the Fight the Fakes Alliance is committed to work collectively with all stakeholders and help lead them in building and implementing solutions to curb the growing threat of SFs globally. To ensure that these efforts are successful, we call on pharmaceutical manufacturers, policymakers, academia, civil society organizations, innovators, and others to get in touch with our Alliance to explore opportunities for further collaboration.

Join the fight against fake medicines! Explore what actions are underway to curb this growing threat to health systems globally and take part in initiatives against fake medicines by joining the Fight the Fakes Alliance now.
To learn more about what you can do to help, please contact Fight the Fakes Alliance at secretariat@fightthefakes.org.

We are a multi-stakeholder non-profit association that aims to raise understanding of and influence action to combat the proliferation of substandard and falsified medicines. Our partners include health care professionals, manufacturers, wholesalers, researchers, and patients, with a collective mission to enhance awareness and drive impactful change with SFs.

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