



U.S. Chamber of Commerce
Global Innovation
Policy Center

Trade in Unsafe Medicines Index

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A growing threat to public health and safety

A growing need to understand the true scope of the risk

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Pugatch Consilium

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The U.S. Chamber of Commerce's Global Innovation Policy Center works around the world to champion innovation and creativity through intellectual property standards that create jobs, save lives, advance global economic and cultural prosperity, and generate breakthrough solutions to global challenges.

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About Pugatch Consilium

This report was conducted by Pugatch Consilium, a boutique consultancy that provides evidence-based research, analysis, and intelligence on the fastest growing sectors of the knowledge economy.

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Executive Summary

The trade and proliferation in unsafe and illicit medicines has long been recognized as a threat to global public health. Every year, counterfeit, substandard, and diverted medicines cause hundreds of thousands of preventable deaths and negatively affect the health of many thousands more. Further, this trade damages national health systems, strengthens organized crime, and undermines public confidence and trust in government and the rule of law.

International institutions and national governments are not blind to these threats. The World Health Organization (WHO), the World Customs Organization (WCO), INTERPOL, the Organisation for Economic Co-operation and Development (OECD), the European Union Intellectual Property Office (EUIPO), and most national governments have established programs and dedicated efforts to combat this trade. Yet as damaging as these products are to public health and national economies across the globe, significant gaps remain in our understanding of how to define this trade and its scale.

The U.S. Chamber of Commerce's Global Innovation Policy Center (GIPC) strives to fill this information gap with the *Trade in Unsafe Medicines Index*. By highlighting and benchmarking the growing menace of the trade in all forms of unsafe and illicit medicinal products, the *Index* offers national and international policymakers a more complete and actionable picture of the threat. Importantly, the findings highlight a persistent gap between existing regulatory frameworks and their effective implementation. The *Index* demonstrates how this undermines efforts to combat unsafe medicines.

Key Findings

This report puts forward three key findings:

Key Finding 1:

For the 12 sampled economies, the world is failing to successfully tackle the trade in unsafe and illicit medicines both at the level of effective regulatory frameworks and their enforcement.

The *Trade in Unsafe Medicines Index* demonstrates that few economies are in a position to effectively fight the trade in unsafe and illicit medicines. It does this by measuring two distinct phenomena related to the trade in unsafe and illicit medicines:

- i. The likelihood of an economy to foster the spread of unsafe and illicit medicines.
- ii. Economies' ability to effectively identify and counter this trade.

The four factors used in the *Trade in Unsafe Medicines Index* range from those relating to the existing legal and regulatory environment in each economy sampled—including, for example, the protection of intellectual property rights (IP) such as patents and trademarks as well as drug regulatory standards—to measured levels of the trade in unsafe and illicit medicines.

All but 1 of the 12 economies included in the *Trade in Unsafe Medicines Index* demonstrate significant weaknesses as captured in one of the four factors. The

overall average score in the *Index* being less than 50% illustrates this. Eight out of the 12 economies—two-thirds of the sample—achieve a score of 45% or less. Almost half the sample achieve a score of 25% or less. These results strongly suggest that, beyond the trade in unsafe and illicit medicines being widespread in the economies sampled, not enough is being done to deter and prevent it. This poor performance should alarm policymakers, given the major public health threat that the trade in unsafe and illicit medicines presents for patients and healthcare systems around the world.

Key Finding 2:

Of the 12 economies analyzed in the *Trade in Unsafe Medicines Index*, the 5 African economies suffer the most from the trade in unsafe and illicit medicines and have the poorest legal infrastructure in place to address it.

The *Trade in Unsafe Medicines Index* includes 5 economies from the African continent: Egypt, Ghana, Kenya, Nigeria, and South Africa. None of these economies achieve a score of over 50%. As Factor 3 measures, the sample of African economies suffer the most from the ill-effects of the trade in unsafe and illicit medicines. This includes high domestic prevalence rates of these medicines and/or a high propensity to contribute

to the international trade of these medicines. These economies also score low on Factors 1 and 4 (measuring the strength and availability of existing IP enforcement and drug regulatory standards relating to parallel imports). these findings demonstrate the public safety issue that unsafe and illicit medicines pose in these African economies.

In addition to reforms targeting the specific factors covered in the *Trade in Unsafe Medicines Index*, there are other policy areas that need strengthening. These include health system infrastructure and pharmaceutical distribution. It also encompasses supply chain standards, which include drug regulations and post-marketing surveillance programs known as pharmacovigilance.

Key Finding 3:

The trade in unsafe and illicit medicines is a transnational problem that requires more sustained policy action in economies all over the world.

The latest available OECD data on the global seized value of counterfeit and illicit medicines demonstrates how India and China (including, Hong Kong) combined are the source for the largest proportion of the world's supply of unsafe and illicit medicines. Notably, this share has remained constant over the past decade. However, the results of the *Trade in Unsafe Medicines Index* also

demonstrate that the threat broadens as these unsafe products fan out into the international supply chain. In the economies analyzed, unsafe and illicit medicines are transshipped through other economies, such as Singapore, Egypt, and the UAE. These three economies achieved econometric model scores under an OECD rating known as the GTRIC-e of 0.66, 0.84, and 0.95 respectively,

suggesting a high propensity to be an economy of provenance for unsafe and illicit medicines. All these economies should be doing more to limit the trade in unsafe and illicit medicines, even though the products in question may not originate there. Greater enforcement efforts in these economies would contribute to reducing such trade globally.



Recommendations

Based on the factor-by-factor results of the *Trade in Unsafe Medicines Index*, this report makes three policy recommendations.

Recommendation 1:

National and international definitions of unsafe and illicit Medicines must be expanded to include all types of unsafe and illicit medicines.

Currently, no standardized and universally accepted international definition of what constitutes an unsafe or illicit medicine exists. Most international institutions, enforcement bodies, and national drug regulators focus either solely or primarily on strictly counterfeit medicines. It is only in recent years that organizations such as

the WHO have included a more pronounced focus on other types of harmful medicines, such as medicines improperly manufactured, sold, bought, stored, shipped, or administered.

International and national institutions must recognize that existing definitions do not cover the full spectrum

of unsafe and illicit products. Consequently, these definitions do not adequately reflect the scale of the problem when seeking to assess the public health challenge. The phenomenon of unsafe and illicit medicines can only be effectively addressed if the scale of the problem is adequately defined and addressed.

Recommendation 2:

IP enforcement must be improved in most economies included in the *Trade in Unsafe Medicines Index*, especially at borders and in transit.

The *Trade in Unsafe Medicines Index*, in particular, Factor 1, shows the overall weakness of IP enforcement in the sampled economies. Only the United States achieves a score of over 75%. Nine out of the 12 economies sampled—that is, three-quarters of the sample—achieve a score of less than 40%. The results for this

factor demonstrate how poor IP rights enforcement remains one of the key challenges in the fight against unsafe and illicit medicines. Economies that have notable weaknesses in this area (less than 25% of the available score) are Ghana, India, Kenya, Egypt, and Nigeria. IP enforcement at the border remains a critical issue in these economies.

This includes the extent to which customs authorities have sufficient authority to effectively act against suspected counterfeit and pirated goods—both intended for the domestic market and in transit. The extent to which available powers are used is also critical.

Recommendation 3:

Sub-Saharan African economies included in the Trade in Unsafe Medicines Index must address both legal and enforcement gaps in their drug regulatory standards and sanitary registration requirements.

Unsafe and illicit medicines range from purely falsified and counterfeit products to substandard, grey-market, and diverted products. The policy responses to combating their spread cannot be uniform.

Criminal enforcement is an essential policy measure in dealing with the trade in illicit medicines. However, it is not in itself enough to effectively combat the spread of these products. Other policy areas, such as improving drug regulations and regulatory standards, are also imperative. Specifically, the work of drug regulatory authorities (DRAs) and the quality, design, and enforcement of drug

regulatory standards have a tremendous impact on the prevalence of illicit medicines.

This is of critical importance in Sub-Saharan Africa. The results of the *Trade in Unsafe Medicines Index* show how the three economies sampled from the region—Ghana, Kenya, and Nigeria—have either gaps in their drug regulatory frameworks or, as important, struggle with the de facto application of these frameworks. For example, comparing the achieved score on Factor 4 with that of Factor 3 for Kenya and Nigeria suggests that there is a clear discrepancy between the legal and regulatory environment for unsafe and

illicit medicines. This includes imported and/or parallel-traded products.

Both economies have an estimated high national prevalence of unsafe and illicit medicines, much of which will have been imported for lack of domestic sources. This, in turn, calls into question the effectiveness of the existing legal framework. Other economies such as Ghana also have high prevalence rates of unsafe and illicit medicines. However, unlike Nigeria and Kenya, Ghana serves as an example for countries having no equivalent regulatory standards and sanitary registration requirements for imported products.



Introduction

“Up to two billion people around the world lack access to necessary medicines, vaccines, medical devices including in vitro diagnostics, and other health products, which creates a vacuum that is too often filled by substandard and falsified products.”

– World Health Organization¹

As the WHO reports, unsafe and illicit medicines present a serious threat to global public health. Every year, hundreds of thousands of patients die or experience adverse health impacts due to the consumption of such products. The WHO has estimated that the annual consumption of counterfeit medicines alone—the most easily tracked of all the different types of illicit medicines—results in the deaths of up to 169,000 children from pneumonia and over 100,000 from malaria.²

However, unsafe and illicit medicines are present in all kinds of pharmaceuticals, created to address maladies both minor and grave. These span from simple medicines such as cough syrup to incredibly complex products developed to treat HIV/AIDS and cancer. In low- and middle-income economies, sampled medicines fail safety tests at rates of over

10%.³ Unsafe and illicit medicines also accelerate the development of widespread drug resistance.

The use of unsafe and illicit medicines poses an additional, indirect threat to global and national public health.⁴ As detailed in the *Trade in Unsafe Medicines Index*, there are many reasons why unsafe and illicit medicines proliferate. At its core, this distribution demonstrates a failure by the existing global health system. This includes pharmaceutical rules and regulations—both de jure and de facto practices—and their application to adequately ensure a safe and secure pharmaceutical supply chain.

Outside of the immediate health impact on individual patients and public health, the wider negative socioeconomic consequences of these medicines are many. On the economic side, the

WHO estimates that the total amount of spending on just counterfeit and substandard medicines—not counting other forms of unsafe or illicit products—in low- and middle-income economies is over 30 billion USD.⁵ Other estimates of the economic impact place the cost at between 75 billion–200 billion USD.⁶ The OECD has estimated that the global trade in counterfeit pharmaceuticals alone was worth just under 1% of global pharmaceutical imports.⁷ Regardless of the exact negative economic impact, the direct costs of this trade are substantial. Moreover, patients suffering from the adverse effects of unsafe and illicit medicines often require extensive additional medical treatment and care. This places further financial strain on national health systems.

More broadly, the trade in unsafe and illicit medicines also has a detrimental impact on governance

and the public's trust in national institutions. When unsafe and illicit medicines penetrate a health system's pharmaceutical supply chain, public institutions suffer from decreased credibility. In parallel, domestic and transnational criminal organizations profit from this

trade. This is no surprise as the trade in illicit medicines has many characteristics favorable to organized crime. It is highly lucrative, supply chains are hyper globalized, complex, and prone to penetration, and illicit medicines are difficult to detect.⁸

As damaging and as great a threat as unsafe and illicit medicines are to public health and national economies everywhere, many fundamental questions about this trade remain unanswered. One of the most important questions is: What are unsafe and illicit medicines?

Defining the Scope of the Issue

Unsafe and illicit medicines cover different categories of pharmaceutical products. Historically, the focus of national authorities and international institutions has been on counterfeit medicines, that is, medicines that are produced and sold outside the IP rights holders' control or permission. Counterfeiting remains a serious and growing problem, particularly in developing and emerging markets. Nonetheless, the spread of substandard medicines and legitimate products illicitly diverted from their intended supply chain means that patients, consumers, and policymakers around the world face far more diversified and multilayered risks.

For example, substandard medicines are not strictly counterfeit. These products have been legally authorized for manufacturing and, importantly, approved for sale by a national or

regional DRA. Substandard medicines instead do not meet the required quality or safety requirements for that particular drug or treatment. The most common reasons why a specific medicine becomes substandard include poor manufacturing practices, the use of impure formulation ingredients, and the inadequate quality of active ingredients. Inadequate quality can also be caused by decomposition due to uncontrolled exposure to high temperatures and humidity.

Similarly, legitimate products diverted from their intended market or supply chain are not strictly counterfeit or substandard. Examples include medicines that have been stolen, misappropriated, or otherwise diverted from their intended destination. Regardless of how or why these products have been diverted, once these products are no longer part of the

legitimate pharmaceutical supply chain, they become illicit and potentially harmful.

Most international institutions, enforcement bodies, and national drug regulators focus either solely or primarily on counterfeit medicines. It is only in recent years that bodies such as the WHO have included a more pronounced concentration on other areas of unsafe and illicit medicines. For instance, the WHO had originally in 2012 defined illicit medicines as "substandard/spurious/falsely labelled/falsified/counterfeit medical products," or "SSFFC," in short.⁹ However, this definition was viewed as insufficient. The WHO adopted a new classification system in 2017.

This system created three distinct categories of unsafe and illicit products cited in Table 1:

The 2017 WHO definition is more comprehensive than the preceding 2012 working definition. Nevertheless, this definition still does not cover the full spectrum of

unsafe and illicit products. The 2017 WHO definition does not explicitly consider stolen medicines or products that have in some way been diverted from the legitimate

supply chain. The definition also does not refer to cases whereby national drug regulations and sanitary registration procedures for parallel imported products fall below internationally established safety and quality assurance standards.

Under these circumstances, a product is technically not illicit, but there is a high risk that the safety and quality profile of the product has been compromised. Consequently, it becomes an unsafe medicine. The bottom line is that—as international institutions like the OECD and the EUIPO¹⁰ have also noted—there remains a lack of uniform definitions of what constitutes unsafe and illicit medicines both at the national and international levels.

The *Trade in Unsafe Medicines Index* seeks to contribute to a more comprehensive definition of what constitutes unsafe and illicit medicines. Table 2 provides a definition of the different types of pharmaceutical products that together make up unsafe and illicit medicines and are used throughout this report.

Given the lack of uniform definitions on what constitutes unsafe and illicit pharmaceutical products, basic questions remain on how widespread this trade is and what tactics and resources are needed to effectively counter it.

Table 1. Unsafe and Illicit Medicines: WHO 2017 Definition

Category of Medicine	WHO Definition
Substandard medical products	Authorized medical products that fail to meet either their quality standards or their specifications or both. Also called “out of specification.”
Unregistered/unlicensed medical products	Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority (NRRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation. These medical products may or may not have obtained relevant authorization from the NRRRA of its geographical origin.
Falsified medical products	Medical products that deliberately/fraudulently misrepresent their identity, composition, or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product, or the manufacture of a medical product that is not an authorized product. “Identity” shall refer to the name, labelling, or packaging or to documents that support the authenticity of an authorized medical product. “Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by the NRRRA. “Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor, or retailer, as applicable. Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

Table 2. Defining Unsafe and Illicit Medicines

Category of Illicit Medicine	Definition
Counterfeit/falsified product	The WHO defines counterfeit medicines as those “deliberately and fraudulently mislabeled with respect to identity and/or source.”
Substandard product	Substandard medicines are those that have been legally authorized for manufacturing and, often, approved for market and sale by a national or regional DRA but which do not meet the required quality or safety requirements for that particular drug or treatment.
Diverted or grey-market product	A legitimate product that was diverted and removed from a legitimate pharmaceutical supply chain and introduced into a health system and pharmaceutical supply chain outside of its intended use.

How Widespread Is the Trade in Unsafe and Illicit Medicines?

While primarily affecting lower-income and developing economies, unsafe and illicit medicines have today penetrated all national pharmaceutical supply chains. This includes high-income OECD economies.¹¹ In 2012, the WHO established the Member State Mechanism on Substandard and Falsified Medical Products, an international monitoring system to help Member States detect and report the

spread of substandard and falsified medical products. The latest activity report published in 2022 shows a pharmacovigilance system in which a total of 1,462 incidents were reported between 2013 and 2021.¹² It is important to note that this data and these incident reports include only information pertaining to counterfeit and substandard medicines. They do not

include or refer to other medicines such as diverted and grey-market products.

Likewise, these reports rely on the detection, reporting, and monitoring capabilities of individual Member States. Given the wide disparity in WHO Member States’ capacity for effective monitoring of the pharmaceutical supply chain—a pronounced problem in low- and middle-



income economies with underdeveloped health systems and accompanying regulations—these detection reports almost certainly severely undercount the extent of the problem. Nevertheless, these incident reports show how all regions around the world are affected by the trade in unsafe and illicit medicines.

For example, in the reporting period 2017–2021, the European region identified 151 incidents of detected substandard and/or counterfeit medicines.¹³ The WHO views this as noteworthy. Member States in the region generally maintain high and stringent drug regulatory systems and a high level of pharmaceutical supply chain surveillance. The spread of substandard and counterfeit medicines in Europe demonstrates that all economies and health systems—regardless of income level or level of development—are at risk.

Overall, the WHO estimates that around 10.5% of the pharmaceutical supply chain in low- and middle-income

economies is made up of counterfeit and substandard medicines.¹⁴ The WHO's data has been corroborated by other academic and international studies. For example, a 2018 academic meta-analysis summed up the prevalence of substandard and falsified medicines and their potential impact on public health.¹⁵ The analysis estimated that 13.6% of medicines in low- and middle-income economies are substandard or falsified based on a systematic review of previous studies and drug sampling data. Additional data collected by private-sector institutions, such as the Pharmaceutical Security Institute (PSI), shows the breadth of the problem.¹⁶ The PSI has focused on collecting information on rates of pharmaceutical counterfeiting, illegal diversion, and theft incidents since the early 2000s. For the latest available year (2025), the PSI tracked over 7,000 pharmaceutical crime incidents. Its analysis described this as “the highest annual total on record and an 11% increase year-over-year.”¹⁷

As useful as this research is in indicating the scale of the challenge, the existing data on the trade in unsafe and illicit medicines only gives us a partial understanding of the problem. In some respects, this is an inherent challenge given the illegal nature of this trade. Counterfeiting and other black-market activities are, by definition, illegal activities and challenging to comprehensively track or measure. Similarly, given the lack of uniform drug regulatory standards and national implementation, existing international and national monitoring systems for substandard, diverted, and grey-market medicines cannot capture a complete picture of the trade in these products.

Moreover, international and national definitions of unsafe and illicit medicines concentrate primarily on counterfeits and substandard medicines. Thus, the existing data sources cannot provide a complete picture or breakdown of which economies have a higher propensity to manufacture and export these medicines.



What Can Be Done to Effectively Counter the Trade in Unsafe and Illicit Medicines?

Unsafe and illicit medicines range from purely falsified and counterfeit products to substandard, grey-market, and diverted products. As a result, the policy responses to combating their spread cannot be uniform. Criminal enforcement is an essential policy measure in dealing with the trade. However, it is not enough to effectively combat the physical spread of these products. Other policy areas, such as improving drug regulations and regulatory standards, are critical.

Specifically, the work of DRAs and the quality, design, and enforcement of drug regulatory standards have a tremendous impact on the prevalence of unsafe and illicit medicines. Before they receive marketing approval, all medicines and new medical treatments must undergo a wide range of tests and safety procedures. After approval, these goods are closely monitored through pharmacovigilance.

Likewise, manufacturing, shipping, and delivery practices have a direct impact on the safety, quality, and efficacy of a medicinal product. The manufacture of medicinal products requires close oversight and regulation through setting and ensuring continuous adherence to

current Good Manufacturing Practices (cGMP). Post-marketing procurement, storage, and distribution practices all have an impact on maintaining the integrity of the pharmaceutical supply chain and are part of any national or regional system of drug regulations. Medicines that are subject to poor storage and distribution practices can degrade and become ineffective or harmful.

This is not only a danger to individual patients. It also creates a threat to public health more generally in the form of drug resistance. Specifically, medicines in which a product's active ingredient has degraded due to poor distribution and storage practices can develop drug and antimicrobial resistance among patients. Ensuring that medicines and medical products meet high quality, safety, and efficacy requirements from the point of manufacturing to the end patient through an effective drug regulatory system is essential in fighting the trade in illicit medicines.

Drug regulations also matter for grey-market and diverted medicines. Potentially dangerous products can easily penetrate a given economy's pharmaceutical

supply chain as imported or parallel trade products if drug regulatory standards do not have in place adequate quality control, safety testing, and sanitary registration requirements. However, standards for drug safety control, quality, and enforcement are not the same or even similar across the world. Some economies have weak drug regulatory standards in place. Others may have established comprehensive regulatory systems, but there remains doubt over whether these regulations and guidelines are being comprehensively implemented and adhered to.

Similarly, there are huge knowledge gaps among patients and healthcare providers about the dangers of unsafe and illicit medicines. Accordingly, effective national and international awareness-raising efforts are critical in combating the trade in unsafe and illicit medicines. Both healthcare professionals and patients must be made aware of the risks these products pose to their individual health and the wider community and what they can do to help keep their national and regional pharmaceutical supply chains safe.

The development of high-standard pharmacovigilance

practices (i.e., systems of post-marketing surveillance) are of critical importance. Post-marketing monitoring relies on DRAs and health systems of pharmacovigilance. Pharmacovigilance provides the needed system with the capacity first to detect adverse effects from

a medicine or medical treatment and second to prevent the further use of the affected drug or treatment in that healthcare system.

Healthcare providers (HCPs) must be able to report adverse drug reactions (ADRs) and ensure that healthcare systems can take timely and effective action. This can

include suspending market approval of the affected drug, recalling drug batches, and having a system of regional and national warning for HCPs. A strong and effective system of pharmacovigilance both relies on and allows patients and healthcare professionals to report any ADRs.

Filling the Information Gap: Building a Dedicated *Trade in Unsafe Medicines Index*

Given the lack of actionable data on the trade and dissemination of all types of unsafe and illicit medicines, the U.S. Chamber of Commerce's Global Innovation Policy Center (GIPC) collaborated with Pugatch Consilium to create a new and unique empirical benchmarking tool, the *Trade in Unsafe Medicines*

Index. The *Index* seeks to highlight and benchmark the growing menace of all types of unsafe and illicit medicinal products that are circulated outside their intended pharmaceutical supply chain and/or market.

The *Trade in Unsafe Medicines Index* offers policymakers a more complete

picture of the threat that these medicines present than was previously available. The *Index* aims to protect the health and safety of patients and the effectiveness of and respect for healthcare systems everywhere.





Trade in Unsafe Medicines Index

Construction and Methodology

In the social sciences, indices are highly acceptable statistical models. They aim to benchmark performance against a predetermined standard, be it economic, political, legal, scientific, social, or otherwise. Significantly, an index is predetermined; the creator of the index determines the best practice or standard. The creator then evaluates performance vis-à-vis this standard and assigns an overall score. An index constitutes a top-down approach to benchmarking the performance of a set of variables. Depending on the objectives, different indices are based on varying sets of criteria and methodologies. However, all indices share the same goal of benchmarking performance along a continuum from positive to negative.

The *Trade in Unsafe Medicines Index* seeks to

benchmark and quantify the trade in unsafe and illicit medicines. Specifically, it measures two phenomena relating to this trade:

- i. How likely an economy is to contribute to the spread of unsafe and illicit medicines. The *Index* measures economies' propensity to contribute to this trade internationally and domestically.
- ii. Determining economies' ability to effectively deter and counter the trade in unsafe and illicit medicines. This is measured through existing de jure legal and regulatory standards as well as de facto practices.

Methodologically, the *Trade in Unsafe Medicines Index* posits that the trade in unsafe and illicit medicines is a given negative; this is the basic assumption and starting point for the construction of the *Index*. The higher a sampled economy's propensity to

contribute to this trade and the lower its ability to effectively deter and counter this trade, the lower its overall performance and score on the *Index*.

Conversely, the lower an economy's propensity to contribute to the trade in unsafe and illicit medicines and the higher its ability to effectively deter and counter this trade, the higher its overall performance and score on the *Index*.

Trade in Unsafe Medicines Index: Construction and Factors

The *Trade in Unsafe Medicines Index* consists of four distinct factors that together provide a snapshot of the *Index*'s goal to measure an economy's (i) propensity to contribute to the trade in unsafe and illicit medicines and (ii) its ability to effectively deter and counter this trade. Each factor included has

equal weight in the *Index*, making up 25% of the total value.

The factors used in the *Trade in Unsafe Medicines Index* are extracted from existing research contained in a sample of internationally accepted indices and surveys relating to key aspects of the trade in unsafe and illicit medicines. Thus, the *Index* is a compilation and

reflection of these existing measures and relies on their methodological strengths and weaknesses. Each data source and measure used in the *Index* is detailed in its data sources section and scoring methodology, together with country-specific data availability.

Table 3 defines each of the four factors used.

Table 3. *Trade in Unsafe Medicines Index*: Factors

Factor	Definition
Factor 1: National IP enforcement capacity	This factor captures the enforcement environment in each economy relating to the protection of IP rights as measured by the U.S. Chamber of Commerce's annual <i>International IP Index</i>. It includes the following: • The existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of IP infringing and counterfeit goods, as well as their effective application. • The existence of preestablished damages and/or mechanisms for determining damages generated by IP infringement. • Criminal standards, including minimum imprisonment and minimum fines, in place for IP infringement and their application. • Effective border measures (measured by the extent to which goods in transit suspected of IP infringement may be detained or suspended, as well as the existence of ex officio authorities). • Transparency and public reporting by customs authorities of trade-related IP infringement.
Factor 2: National corruption	This factor captures the rate of perceived corruption within an economy, as measured by Transparency International's <i>Corruption Perceptions Index</i>. This assumes that a strong relationship exists between corruption and all forms of illicit trade, including for medicines, i.e., authorities in economies that struggle with the trade of unsafe and illicit medicines tend to also overlook or place less emphasis on combating other illicit and criminal activities.
Factor 3: Propensity for trade-related counterfeit pharmaceuticals	This factor captures the extent to which an economy contributes to the international and/or domestic trade of unsafe and illicit medicines. For most of the economies sampled in the <i>Trade in Unsafe Medicines Index</i>, the data is drawn from the OECD's GTRIC-e for counterfeit pharmaceuticals, which seeks to measure an economy's "relative propensity to be an economy of provenance for counterfeit pharmaceuticals." However, because the GTRIC-e methodology is based on customs seizure data and international trade statistics, its application to less trade-intensive economies is more limited. For these economies, the trade in unsafe and illicit medicines is measured based on estimated rates of domestic trade.
Factor 4: Regulatory control and licensing of parallel imported medicinal products	This factor captures the extent to which an economy has established a drug regulatory framework designed to ensure the safety and quality of all products imported, including those manufactured in a third economy and imported by someone other than the manufacturer or original seller.

Trade in Unsafe Medicines Index: Data Sources and Scoring Methodology

Data Sources

The *Trade in Unsafe Medicines Index* comprises several different international and national data sources. Together, these data sources provide a snapshot of the trade in unsafe and illicit medicines in the sampled economies. These sources are as follows:

- **The U.S. Chamber of Commerce's International IP Index:** The *International IP Index*, published annually, provides an important industry perspective on the IP standards that influence both long- and short-term business and investment decisions. The *International IP Index* is a unique and continuously evolving instrument Year by year, this *International IP Index* assesses the state of the international IP environment. It also provides a roadmap for any economy that wants to be competitive in the 21st century's knowledge-based global economy.

The *International IP Index* consists of 53 indicators across 10 categories measuring the strength of an economy's national IP environment. It has a dedicated Category 7 (Enforcement) that measures the prevalence of IP rights infringement. Category 7 assesses the criminal and civil legal procedures available to rights holders, the authority of customs officials to carry out border controls

and inspections, and transparency of customs authorities' actions.

- **Transparency International's Corruption Perceptions Index:** Transparency International is a global non-governmental organization founded in 1993 and headquartered in Berlin, Germany. This organization is dedicated to fighting corruption and promoting transparency, accountability, and integrity worldwide. Transparency International's *Corruption Perceptions Index* (CPI) ranks 180 economies around the world on levels of perceived corruption. The latest edition is based on an aggregated dataset from 13 data sources collected from 12 institutions.
- **OECD's and EUIPO's Research on Counterfeiting and Piracy:** Since the late 2000s, the OECD and the EUIPO have dedicated research streams to studying the magnitude and impact of illicit trade. In its first study from 2008—*The Economic Impact of Counterfeiting and Piracy*—the OECD embedded seizure data, customs and industry survey data, and international trade data into an econometric model known as the GTRIC-e. The GTRIC-e estimated the magnitude of physical counterfeiting both internationally and within each economy. This research has subsequently been updated periodically with

new estimates on the global scale and volume of illicit trade.

The OECD and the EUIPO also have published several sector-specific, thematic, and economy-specific reports on illicit trade, including *Trade in Counterfeit Pharmaceutical Products* in 2020. This publication maps the trade in illicit pharmaceutical products and includes a pharmaceutical-specific GTRIC-e indicator. This measures the contribution of different economies to global trade in illicit pharmaceuticals.

- **Academic estimates on scale of national trade and prevalence of illicit medicines:** In addition to an economy's contribution to the international trade in unsafe and illicit medicines, there are studies and estimates on the extent to which a national pharmaceutical market has been penetrated by unsafe and illicit medicines. In some of the economies included in the *Trade in Unsafe Medicines Index*, international trade statistics are less relevant due to, for example, lower rates of medicinal exports. Academic and international estimates on domestic levels of unsafe and illicit medicines supplement the OECD's GTRIC-e in these cases.
- **National and/or regional drug regulatory standards and sanitary registration**

requirements for imported medicines, including parallel-traded products:

Drug regulatory standards and sanitary registration requirements vary from economy to economy and legal jurisdiction to legal jurisdiction. The *Trade in Unsafe Medicines Index*'s Factor 4 examines whether economies sampled have established drug regulatory

frameworks designed to ensure the safety and quality of all products imported. This includes those manufactured in a third economy and imported by someone other than the manufacturer or original seller. National and/or regional primary and secondary

legislation is sampled from each jurisdiction and benchmarked for this factor.

Each factor can score a value between 0%–100%. The *Trade in Unsafe Medicines Index* expresses overall scores as the average percentage score of all four factors. The aggregated score of the *Index* ranges from 0%–100%.

Factor 1: National IP Enforcement Capacity

Factor 1 of the *Trade in Unsafe Medicines Index* uses six indicators from the *International IP Index*. Factor 1 has a total aggregated value of 6.00 as each indicator extracted from the *International IP Index* is worth a value of 0–1. Once the

relevant indicators and scores per economy sampled in the *Trade in Unsafe Medicines Index* have been extracted, these aggregated scores are standardized into a percentage score of 0%–100%.

Table 4 lists the six indicators used and extracted from the *International IP Index* together with corresponding definitions. All indicator titles, descriptions, and definitions are copied from the latest edition of the *International IP Index*.¹⁹



Table 4. *Trade in Unsafe Medicines Index*: Indicators Extracted From the International IP Index

Factor	Definition
Indicator 32. Counterfeiting piracy rates	Measured by estimated rates of general trade-related physical counterfeiting using the U.S. Chamber's Global Measure of Physical Counterfeiting.
Indicator 34. Civil and procedural remedies	Measured by (i) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods as well as (ii) their effective application. This indicator also reflects administrative enforcement measures where applicable.
Indicator 35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement	Definition provided in indicator description.
Indicator 36. Criminal standards, including minimum imprisonment and minimum fines	Measured by the extent to which (i) actual legislation is in place and (ii) is applied (i.e., where reliable source material is available, the actual level of prosecution and penalties applied).
Indicator 37. Effective border measures	Measured by the extent to which border guards have the ex officio authority to seize suspected counterfeit and pirated goods, including goods in transit, without complaint from the rights holder.
Indicator 38. Transparency and public reporting by customs authorities of trade-related IP infringement	The extent to which customs authorities in a given economy publish statistics and data on trade-related IP infringement. This indicator measures (i) the extent to which data is published on a regular and systematic basis and (ii) the level of detail of this data.

Factor 2: National Corruption

Factor 2 of the *Trade in Unsafe Medicines Index* uses the overall score achieved by an economy on Transparency International's CPI. The CPI is measured on a scale of 0–100. The lower the score

on this scale, the higher the perceived levels of national corruption. Conversely, the higher the score, the lower the perceived levels of national corruption.²⁰ The *Trade in Unsafe Medicines Index*

extracts the CPI score of each economy sampled as is and directly incorporates it as the score used under Factor 2.

Factor 3: Propensity for Trade-Related Counterfeit Pharmaceuticals

Factor 3 of the *Trade in Unsafe Medicines Index* uses three different data sources and two different scoring systems.

The first data source and scoring system is the OECD's GTRIC-e measure. The GTRIC-e is a statistical tool developed by the OECD to rank economies according to their propensity to export counterfeit goods.²¹ It is based on customs seizure and import data. The GTRIC-e has been applied to individual product categories, including pharmaceuticals with economy-specific results published in two stand-alone reports: the 2020 *Trade in Counterfeit Pharmaceutical Products* and the 2017 *Mapping the Real Routes of Trade in Fake Goods*.²²

The GTRIC-e is measured on a scale of 0–1. The lower the score on this scale, the lower an economy's relative propensity to export counterfeit goods. Conversely, the higher the score, the higher an economy's relative propensity to export counterfeit goods. Of the 12 economies included in the *Trade in Unsafe Medicines Index*, the GTRIC-e score is used as the basis for the score on Factor 3 for 8 of the sampled economies: China, Egypt, India, Singapore, Türkiye, UAE, United States, and Vietnam.

Table 5. *Trade in Unsafe Medicines Index*: Economy and GTRIC-e Score

Economy	GTRIC-e score
China	1.00
Egypt	0.84
India	1.00
Singapore	0.66
Türkiye	0.31
UAE	0.95
United States*	0.07
Vietnam*	0.12

* GTRIC-e score and data used from 2017

Table 5 shows the latest available GTRIC-e scores for these economies.

Once extracted, the *Trade in Unsafe Medicines Index* inverts the relevant GTRIC-e score for pharmaceuticals and converts it into a standardized percentage score from a low of 0% to a high of 100%.

Although the GTRIC-e provides individual scores for the remaining four economies included in the *Trade in Unsafe Medicines Index* (Ghana, Kenya, Nigeria, and South Africa), these countries have a relatively limited engagement in the international pharmaceuticals trade. Their GTRIC-e scores

are not good proxies for propensity to trade in unsafe and illicit medicines. To address this information gap, the *Trade in Unsafe Medicines Index* utilizes additional data sources and a different scoring system and evaluation methodology that is specific to these economies. The additional data sources used follow:

- i. A 2018 peer-reviewed academic paper published in the *Journal of the American Medical Association* (JAMA). This study is a meta-analysis of 96 academic studies together representing almost 70,000 drug samples. Based on this data, the article estimates the prevalence of unsafe and illicit (counterfeit and substandard) medicines in low- and middle-income economies.
- ii. WHO estimates the prevalence level of substandard and counterfeit medicines in low- and middle-income economies based on Member States reporting to the WHO's Global Surveillance and Monitoring System for substandard and falsified medical products.
- iii. U.S. Centers for Disease Control and Prevention (CDC) estimates on the prevalence of counterfeit medicines in the United States and other high-income economies.²³

The 2018 JAMA meta-analysis and underlying reports provide economy-specific data on estimated prevalence levels of substandard and counterfeit medicines for the four African economies included in the *Trade in Unsafe Medicines Index*. Once extracted, these economy-specific prevalence levels are translated into a 0%–100% score. That score represents these individual economies' performance in Factor 3 of the *Trade in Unsafe Medicines Index*. Specifically, the individual estimated prevalence levels are compared to two separate benchmarks:

- i. The average prevalence level of substandard and counterfeit medicines found for all sampled low- and middle-income economies estimated by the WHO of 10.5%.
- ii. The average prevalence level of substandard and counterfeit medicines estimated by the CDC in the

U.S. and other developed high-income economies of 1% or less.

With these established benchmarks, Factor 3 scores for Ghana, Kenya, Nigeria, and South Africa are allocated according to the following scoring system:

- i. Economies with an estimated average prevalence level of substandard and counterfeit medicines equal to or less than 1%–100% allocation of available score.
- ii. Economies with an estimated average prevalence level of substandard and counterfeit medicines higher than 1% but less than the average level found by the WHO for all sampled low- and middle-income economies of 10.5%–50% allocation of available scores.
- iii. Economies with an estimated average prevalence level of substandard and counterfeit medicines equal to or higher

than the average level found by the WHO for all sampled low- and middle-income economies of 0% - 10.5% allocation of available score.

Table 6 shows the estimated prevalence of counterfeit and substandard medicines in the four sampled African economies per the JAMA meta-analysis.

Table 6. Estimated Prevalence of Counterfeit and Substandard Medicines

Economy	Estimated prevalence of counterfeit and substandard medicines, % of pharmaceutical supply chain
Ghana	45.65%
Kenya	10.72%
Nigeria	14.31%
South Africa	8.90%

Factor 4: Regulatory Control and Licensing of Parallel Imported Medicinal Products

Factor 4 of the *Trade in Unsafe Medicines Index* uses national legislative data sources. Factor 4 applies a factor-specific scoring system and evaluation methodology, as drug regulatory standards and sanitary registration requirements vary across economies and legal jurisdictions. Factor 4 examines whether economies sampled have in place drug regulatory frameworks designed to ensure the safety and quality of all products imported. This includes those manufactured in a third economy and imported by someone other than the manufacturer or original seller.

Economies' regulatory standards and sanitary registration requirements are compared to three benchmarks:

Economies' regulatory standards and sanitary registration requirements require full safety and quality inspection requirements

for all products imported, including those manufactured in a third economy and imported by someone other than the manufacturer or original seller.

i. Economies' regulatory standards and sanitary registration requirements require partial safety and quality inspection requirements for all products imported, including those manufactured in a third economy and imported by someone other than the manufacturer or original seller.

ii. Economies' regulatory standards and sanitary registration requirements require no or limited safety and quality inspection requirements for all products imported, including those manufactured in a third economy and imported by someone other than the manufacturer or original seller.

Economies that have established full safety and quality inspection requirements for all imports receive a Factor 4 score allocation of 100%. Economies that have in place partial safety and quality inspection requirements for all products imported receive a Factor 4 score allocation of 50%. Economies that have established no or limited safety and quality inspection requirements for all products imported receive a Factor 4 score allocation of 0%.

Economies Sampled

Given this is the first edition of the *Trade in Unsafe Medicines Index* focusing on developing a robust index methodology, only 12 economies have been analyzed and scored. As the *Trade in Unsafe Medicines Index* evolves, future editions

will include a larger sample of economies. The 12 economies featured here represent a good cross-section of different levels of global development and geography. As such, these economies are a mix of high-income,

developed OECD economies and emerging markets from all major regions of the world.

Table 7 shows the economies included in the *Trade in Unsafe Medicines Index* by major geographical region as defined by the World Bank.

Table 7. *Trade in Unsafe Medicines Index*: Economies by World Bank Region

Asia	Middle East and North Africa	Sub-Saharan Africa	North America	Europe and Central Asia
China	Egypt	Ghana	United States	Türkiye
India	UAE	Kenya		
Singapore		Nigeria		
Vietnam		South Africa		





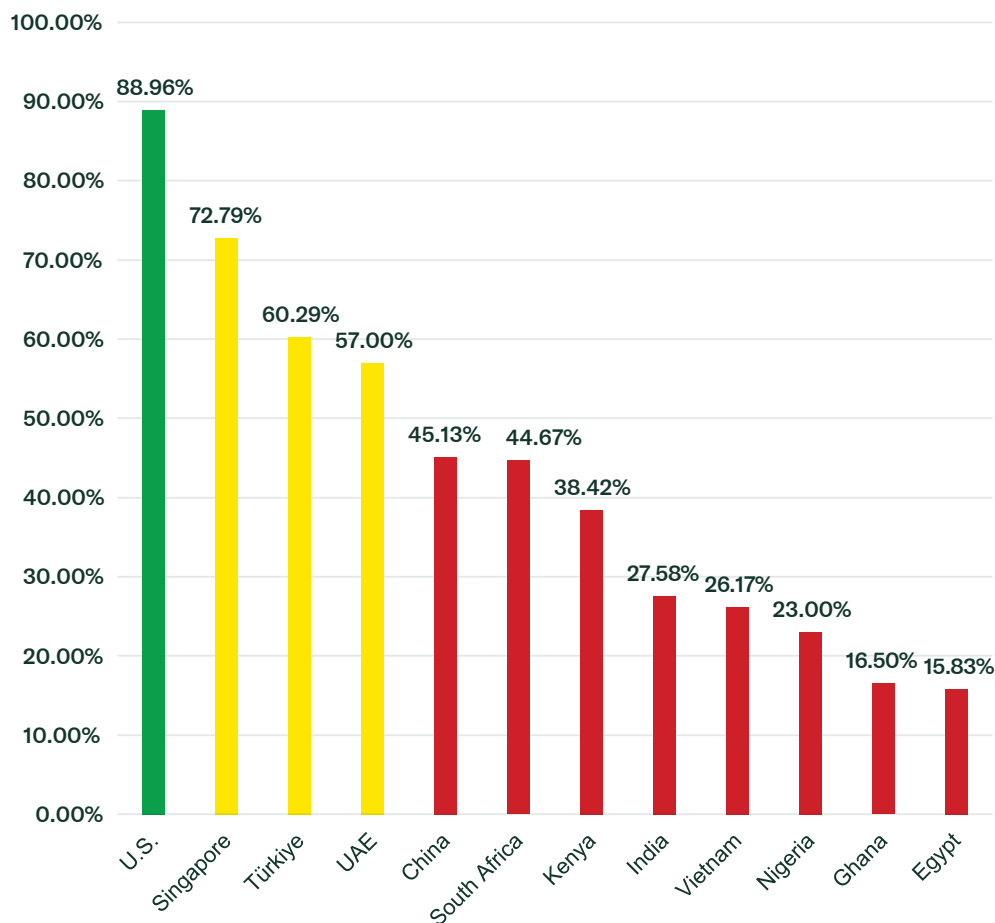
Trade in Unsafe Medicines Index: Results

Figure 1 displays the overall results of the *Trade in Unsafe Medicines Index* for all 12 analyzed and scored economies. Overall results are the average percentage score across all four factors

of the *Trade in Unsafe Medicines Index*. Throughout this section of the report, results are shown according to a traffic-light schedule: Economies scoring over 75% of the available score are

colored in green, economies scoring between 50% and 75% of the available score are colored in yellow, and economies scoring below 50% of the available score are colored in red.

Figure 1. *Trade in Unsafe Medicines Index*: Overall Results



The results from the *Trade in Unsafe Medicines Index* paint a picture of contrasts.

First, the most striking fact is the poor performance of most sampled economies. Only one economy, the United States, achieves a score close to 100% or even significantly over 75%. Eight of the 12 economies sampled—two-thirds of the sample—achieve a score of 45% or less. Almost half the sample achieve a score of 25% or less.

Given the major public health threat that the trade in unsafe and illicit medicines poses to patients and healthcare systems worldwide, this poor performance is alarming.

Second, note the large performance spread with a score range of 16%–89%. This equates to almost the full range of the available score. Even with a relatively small sample size of 12 economies, one of the *Trade in Unsafe Medicines Index*'s central takeaways is the lack of uniform regulations

and enforcement standards against unsafe and illicit medicines globally.

As important as these big-picture findings are drawn from the overall results may be, the factor-by-factor results are also revealing. There are large performance discrepancies across the *Trade in Unsafe Medicines Index* when comparing average scores per each factor.

Figure 2 presents the factor-by-factor and overall mean scores for the *Trade in Unsafe Medicines Index*.

Figure 2. *Trade in Unsafe Medicines Index*: Overall Score Averages

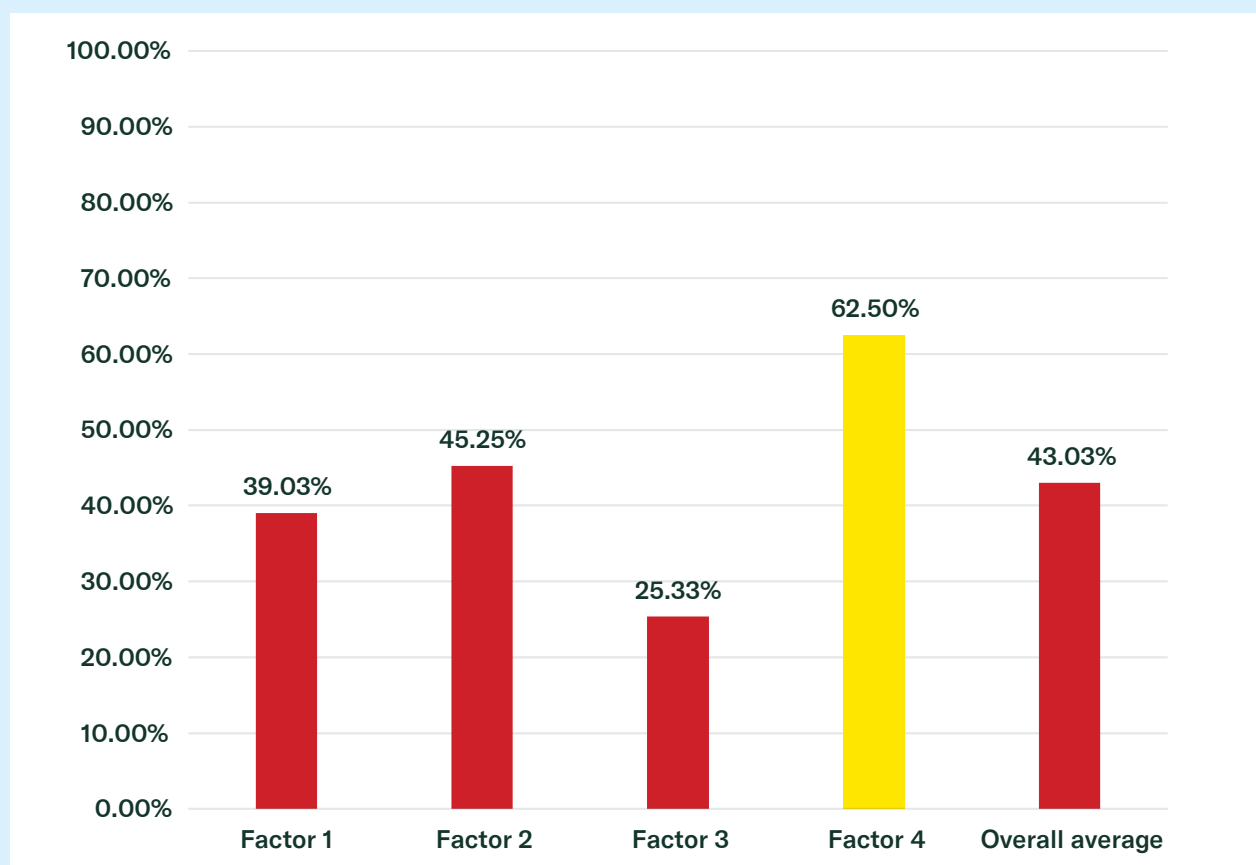


Figure 2 demonstrates that an economy's overall score on the *Trade in Unsafe Medicines Index* is not necessarily a true reflection

of its performance on all the underlying factors. Many of the economies sampled show disproportionate strengths and weaknesses on

these underlying measures. They consequently display disproportionate strengths and weaknesses in the *Trade in Unsafe Medicines Index*.

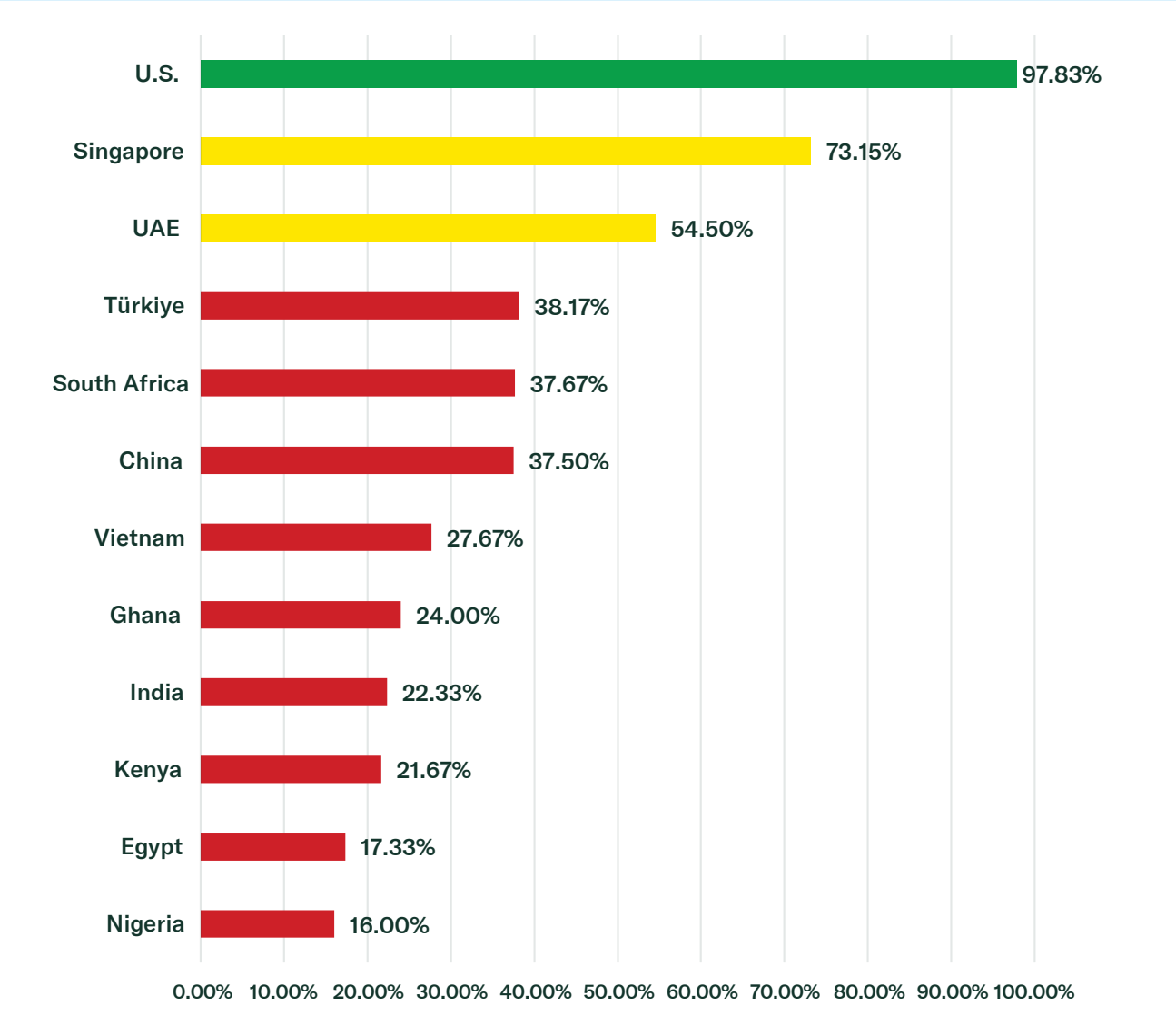
Factor 1: National IP Enforcement Capacity Results

The results for Factor 1 show the overall weakness of IP enforcement in the sampled economies. Only the United States achieves a score of over 75%. Nine out of the 12

economies, three-quarters of the sample, achieve a score of less than 40%. Almost all the sampled economies underperform their overall results on the *Trade in Unsafe*

Medicines Index. Poor IP enforcement remains one of the key challenges in the fight against illicit medicines.

Figure 3. Factor 1 Results



Factor 2: National Corruption

Figure 4. Factor 2 Results

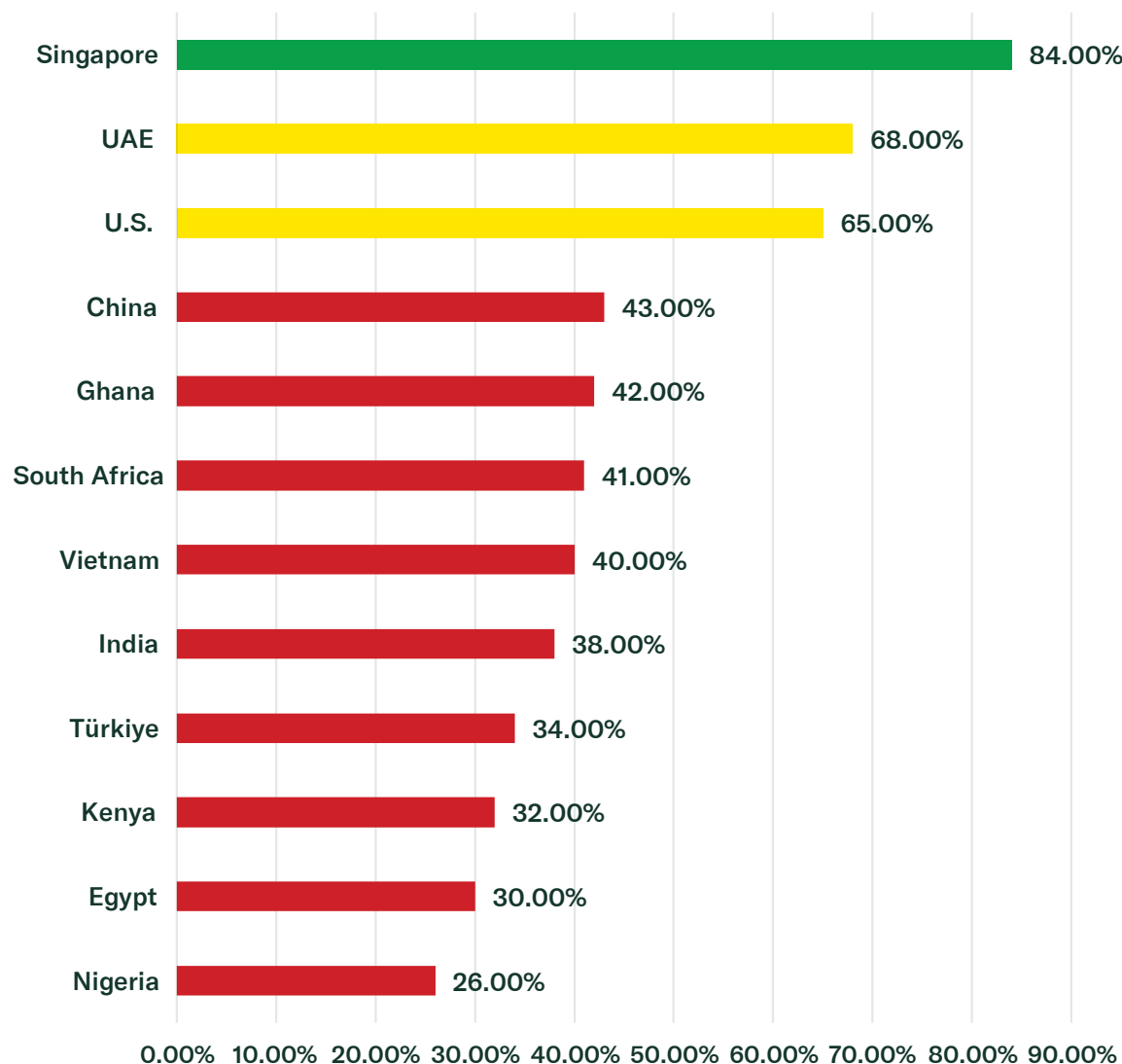


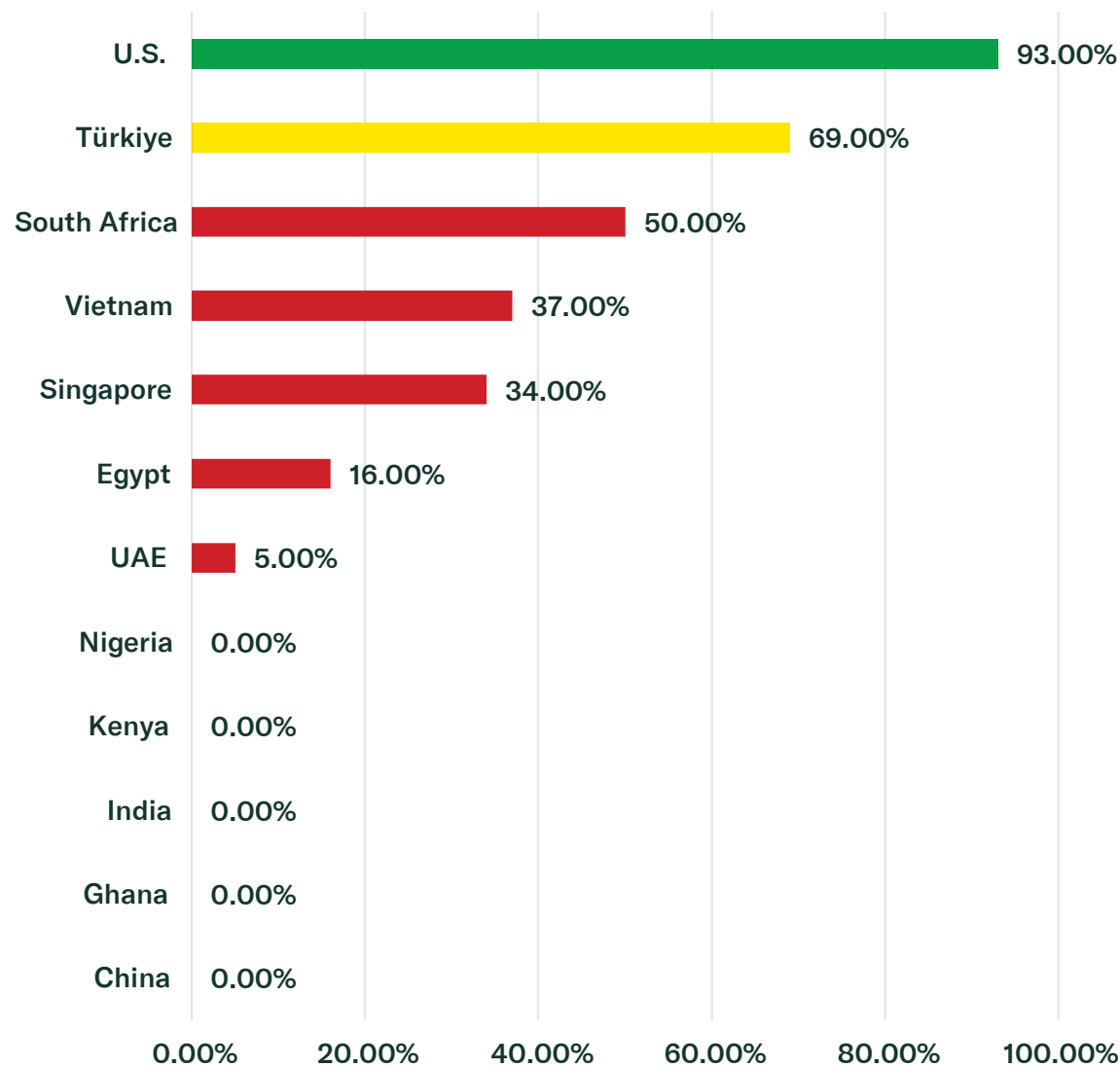
Figure 4 shows that perceived levels of corruption are a weakness in most of the economies sampled. Only one economy achieves a score of over 75%. Even the United States struggles, achieving only a score of 65%. Seventy-

five percent, a vast majority of the sample, achieve a score of less than 50%. As mentioned, economies with high rates of corruption struggle to enforce existing laws and to counter the public perception that these laws will not be

enforced. Consequently, the public's lack of trust in public institutions and the rule of law are almost as big a challenge in this context as actual levels of malfeasance and corruption.

Factor 3: Propensity for Trade-Related Counterfeit Pharmaceuticals

Figure 5. Factor 3 Results



Factor 3 represents a shift in what the *Trade in Unsafe Medicines Index* is measuring. Unlike Factors 1 and 2, Factor 3 examines the sampled economies’ propensity for the trade in unsafe and illicit medicines. Factor 3 does so by using different data

sources. The results of Factor 3 provide the best estimate of the scale of the challenge.

These results are alarming. Half the sample score is either 0% or 5%. This suggests an almost perfect propensity for either housing the trade in unsafe and illicit medicines within

their domestic markets or the likelihood of being a provenance economy for the export of such products.

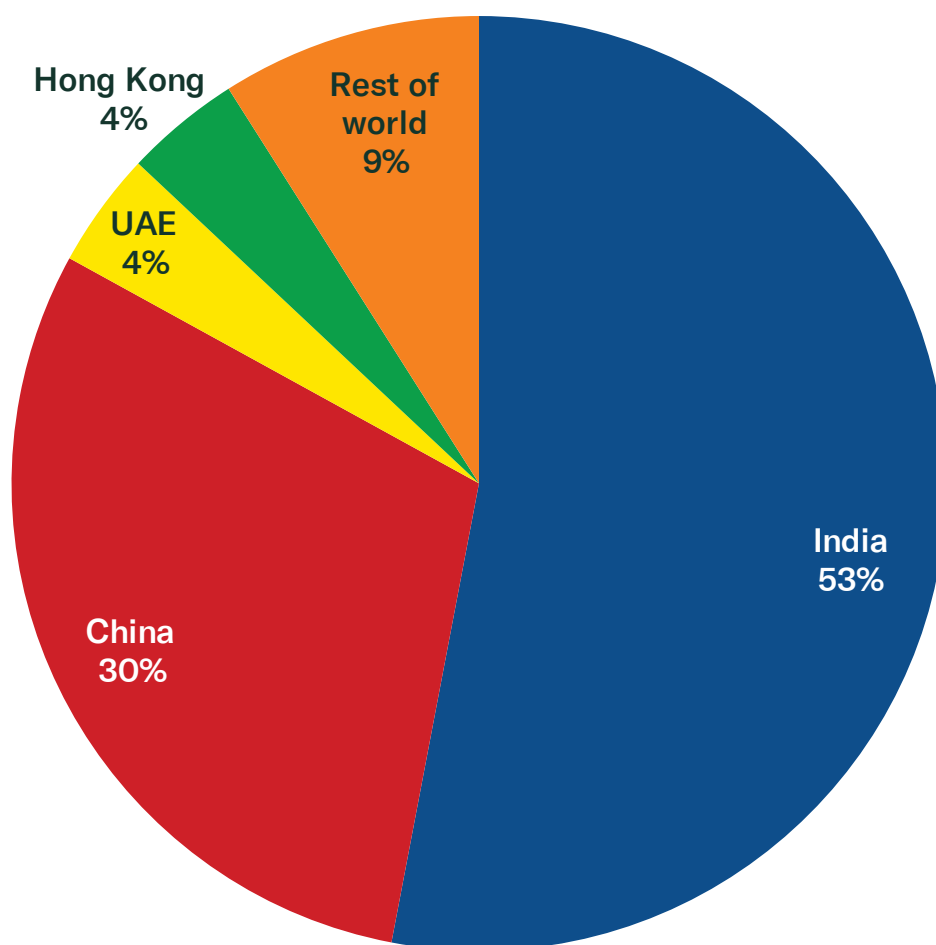
Nigeria, Kenya, and Ghana all have a high domestic prevalence of unsafe and illicit medicines as measured in the academic literature and compared to the average

level in low- and middle-income economies as found by the WHO. With respect to the results from the pharmaceutical-specific GTRIC-e, the *Trade in Unsafe Medicines Index* finds that China and India have a high

propensity of exporting and contributing to the international trade in unsafe and illicit medicines. And these are not empty models. The raw descriptive data upon which these estimates are based tell the same story.

Figure 6 shows the provenance of economies with the largest share of the total seized value of counterfeit pharmaceutical products and medicines worldwide in 2016 as found by the OECD and the EUIPO.²⁴

Figure 6. % of Share of the Total Seized Value of Counterfeit Pharmaceutical Products and Medicines Worldwide in 2016



As seen in Figure 6, the latest available data on the global seized value of counterfeit and illicit medicines shows how two economies—India

and China (including, Hong Kong)—are together the source for the vast majority of these unsafe and illicit

products. Significantly, this share has remained constant over the past decade.

Factor 4: Regulatory Control and Licensing of Parallel Imported Medicinal Products

Figure 7. Factor 4 Results

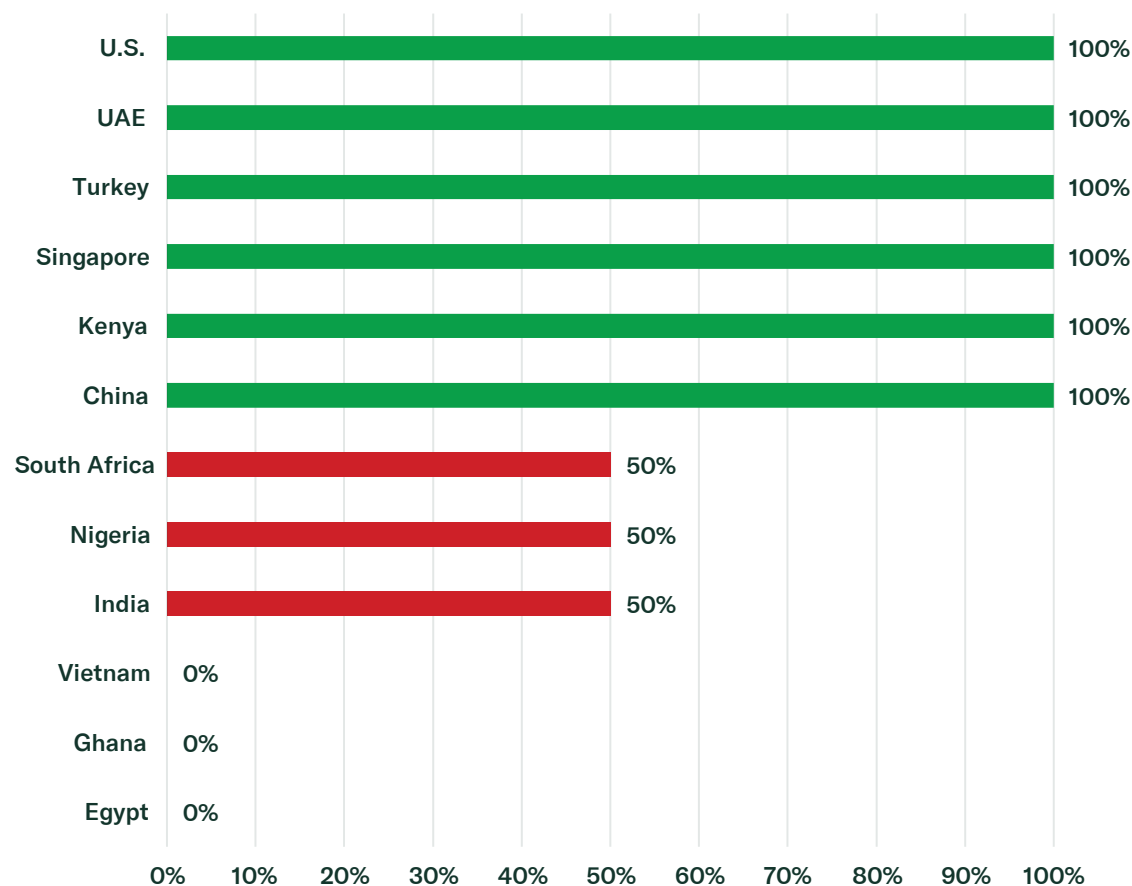


Figure 7 shows that economies by and large do fairly well on this factor. Half the sampled economies achieve a full score of 100%, suggesting they have in place de jure regulatory standards and sanitary registration requirements that sufficiently mandate full safety and quality inspection requirements for all products imported. This includes those products manufactured in a third economy and imported by someone other than the manufacturer or original seller.

Nevertheless, it is worth noting that Factor 4 does not measure the de facto application of these practices and standards nor the extent to which they are actively implemented and enforced. It only measures their availability in primary or secondary legislation. For example, comparing the achieved score on Factor 4 with that of Factor 3 for Kenya and Nigeria suggests that there is a clear discrepancy between the legal and regulatory environment and the facts on the ground.

Both economies have a high level of estimated national prevalence of unsafe and illicit medicines, much of which will have been imported.

This, in turn, calls into question the effectiveness of the existing legal framework. Other economies such as Ghana have high prevalence rates of unsafe and illicit medicines. Unlike Nigeria and Kenya, however, there are no equivalent regulatory standards and sanitary registration requirements for imported products.



Recommendations

The Trade in Unsafe Medicines Index demonstrates a pressing need at the national and international levels to effectively address this significant public health challenge.

This report makes three key findings.

Key Finding 1:

The world is failing to effectively tackle the trade in unsafe and illicit medicines both at the level of effective regulatory frameworks and their application.

The Trade in Unsafe Medicines Index shows how few economies are in a position to effectively fight the trade in unsafe and illicit medicines.

All but 1 of the 12 economies included in the *Trade in Unsafe Medicines Index* have significant weaknesses as captured in one of the

four factors assessed. The fact that the overall average score on the *Trade in Unsafe Medicines Index* is less than 50% illustrates this. Eight out of the 12 economies included—that is, two-thirds of the sample—achieve a score of 45% or less. Almost half the sample achieve a score of around 25% or less.

The results also strongly suggest that not enough is being done to deter and prevent this trade in these economies. Given the major public health threat that the trade in unsafe and illicit medicines poses to patients around the world, this poor performance is alarming.

Key Finding 2:

Sub-Saharan Africa is a case in point for the global challenge of unsafe and illicit medicines.

The Trade in Unsafe Medicines Index includes five economies from the African continent. None of these economies achieve a score of over 50%. As measured by Factor 3, the sample of African economies suffer the most from the trade in unsafe and illicit medicines through either

high domestic prevalence rates of these medicines or a high propensity to contribute to the international trade of these medicines. These economies also score low on Factors 1 and 4, which measure the strength and availability of existing IP enforcement and drug regulatory standards relating

to parallel imports. These findings highlight the public safety issue that unsafe and illicit medicines present in these African economies and for the broader Global South as these networks metastasize and find weaknesses in other regions.

In addition to reforms targeting the specific factors covered in the *Trade in Unsafe Medicines Index*, there are

other policy areas that could be strengthened. Examples include health system infrastructure, pharmaceutical

distribution and supply chain standards for drugs, and pharmacovigilance.

Key Finding 3:

The trade in unsafe and illicit medicines is a transnational problem that requires more sustained policy action in economies all over the world.

The latest available data from the OECD on the global seized value of counterfeit and illicit medicines shows how India and China (including, Hong Kong) are together the enduring source for a large proportion of global unsafe and illicit medicines. However, the results of the *Trade in Unsafe Medicines Index* also show how unsafe and illicit medicines risks rarely stay

local. These types of goods are transshipped through other economies such as Singapore, Egypt, and the UAE, where their dangers also manifest and fan out further via transportation nodes.

These three economies achieved OECD GTRIC-e high scores of 0.66, 0.84, and 0.95, respectively, suggesting a high propensity

to be a provenance for the distribution of unsafe and illicit medicines. All these economies—China, India, Singapore, Egypt, and the UAE—should do significantly more to limit the trade of unsafe and illicit medicines. Greater enforcement efforts in these economies would significantly reduce levels of unsafe and illicit medicines globally.

Index Recommendations

All parties in the development, production, sale, shipping, border clearance, and administration of medicines must play an active role in the protection of patients and healthcare systems from unsafe and illicit medicines.

- Customs agencies should have the authority to identify, seize, and destroy unsafe and illicit pharmaceuticals and related manufacturing equipment without undue burdens. These authorities must be implemented consistently and effectively. Further, these enforcers should implement risk-based approaches for greater enforcement accuracy, collaborate with other law enforcement agencies and pharmaceutical regulators, and engage rights holders to verify product authenticity at borders and in transit.

- Policymakers and regulators should require checks for product authenticity and quality at borders and other checkpoints, meaningfully penalize offenders, and enact targeted rules that address fraud and uphold secure supply chain standards.
- Lawmakers should ensure that legal frameworks provide meaningful criminal penalties, civil remedies, and ex officio authority for police and customs officials to seize suspected counterfeit goods. Appropriators should ensure adequate and enduring funding for enforcement authorities. They should also incentivize enforcers to partner with the private sector to strengthen supply chain integrity. IP rights legal regimes should be crafted and maintained to protect and enforce rights holders' IP and improve

transparency among rights holders, customs, and other law enforcement actors.

- E-commerce marketplaces should implement and support multi-stakeholder systems that screen and authenticate vendors, ban repeat offenders, provide clear consumer information, address shipping and fulfillment center risks, share information with rights holders, and engage the Internet Corporation for Assigned Names and Numbers (ICANN) to remove and de-platform bad actors and websites.

The pharmaceutical industry should support proactive enforcement, share expertise with regulators and law enforcement, and educate policymakers, healthcare providers, and patients about the risks from counterfeit and illicit medicines.

Additional Issues

Issues not accounted for in this report's analysis, but merit future consideration include the following:

Underreporting of counterfeit and substandard medications

- There is a lack of healthcare providers (HCP) awareness in developed countries regarding counterfeit and substandard medicines. Many HCPs do not suspect that medications themselves could be a problem in patient care. Thus, HCPs often do not alert authorities to these issues despite the availability of existing sophisticated reporting systems. In addition, U.S. HCPs procure medications increasingly from internet pharmacies. This includes directing patients to internet pharmacies because of this same lack of understanding. The National Association of Boards of Pharmacy (NABP)²⁵ and Johns Hopkins University's Bloomberg School of Health²⁶ have reported on this topic.

Online marketplaces

- Online marketplaces continue to proliferate and present a massive and growing risk for the movement of illicit and unsafe medicines. These venues evade comprehensive measurement; therefore, it is difficult to adequately analyze them and their effect on facilitating access to HCPs for these dangerous materials.

Endnotes

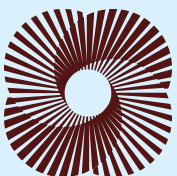


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Notes



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