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Johnattan García Ruiz

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Daniela Cepeda Cuadrado

Falsified medicines in Colombia – analysis from an anti-corruption perspective

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This research represents a first exploration exercise on the phenomenon of drug falsification in Colombia from an anti-corruption and transparency perspective. The study found that promote the commercialisation of illegitimate pharmaceutical products. Yet they operate reactively due to the absence of a regulatory framework that considers this phenomenon explicitly. This work identifies general areas in which the public and private sectors must strengthen their collaborative work to offer greater protection of the health and lives of citizens against the infiltration of falsified medicines, both in the legal and illegal – physical and virtual – markets.

Main points

- Colombia must recognise drug falsification as a problem of corruption, transparency and accountability that invites all actors, public and private, to take proactive action to counter this phenomenon.
- The country lacks reliable and standardised information to estimate the prevalence of drug falsification. This information gap prevents the government from proposing or justifying more significant investments to strengthen the institutional response to this critical public health problem.
- Inter-institutional strengthening and articulation are needed based on a modern public policy, with precise objectives, goals and responsibilities. This policy should adopt good practices and international terminologies to counter corruption related to the falsification of pharmaceutical products.
- E-commerce and the digital media advertising of falsified products constitute Colombian authorities' most significant challenge. The current regulatory framework does not give the government the ability to respond to the growing number of fake products marketed on the internet.

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In Colombia, different media have reported on multiple occasions the capture of criminal groups that traffic drugs produced in clandestine laboratories, those with altered expiration dates, or imported products without the marketing authorisation of the health authority. There are also known cases in which people from different health system organisations are complicit in the entry of this type of product into the supply chain. Likewise, more and more cases are being reported of products marketed on the internet or through social networks that do not comply with health standards.

The Chr Michelsen Institute's U4 Anti-Corruption Resource Centre and the United Kingdom Foreign, Commonwealth, and Development Office (FCDO), through the UK Embassy in Colombia, have commissioned this study, which aims to explore the phenomenon of drug falsification in the country and the influence acts of corruption have had on the proliferation of these products. This document proposes recommendations to Colombia's government, the private sector, civil society organisations, donor governments and international allies to work together to prevent the corruption that facilitates drug falsification in the country.

Methods

This research used four sources of information: (1) a PubMed and EBSCO Host literature review of scholarly articles published between 2011 and 2021; (2) a review of news published in digital media between January 2018 and August 2021 related to drug falsification; (3) six semi-structured interviews with experts and public officials; and (4) analysis of documents shared by the National Institute for Food and Drug Surveillance of Colombia (INVIMA).

Study relevance

Although multiple studies have been published in the last decade looking at the falsification of medicines in the world, few focus specifically on the impact of corruption on the purchase of medicines, their quality and, especially, on the risk of falsification. Within this category, the most relevant study is that of Sarah Steingrüber and Muktar Gadanya,[1] who recently explored the effect of corruption on the quality and integrity of medical products and their impact on the response to the Covid-19 global crisis.

This is the first document specifically focused on the corruption that promotes the falsification of medicines in Colombia. The study seeks to contribute to the growing

1. Steingrüber and Gadanya 2021.

literature that connects the anti-corruption perspective to the phenomenon of drug falsification. This research can also become a first step to promoting new strategies and collaborative actions to confront this phenomenon that threatens public health. It is expected that it could also become a guiding document for institutions or researchers from other countries interested in documenting the prevalence of falsified medicines in their territories.

Drug falsification: an act of corruption that affects global health

At least two billion people worldwide lack access to the medicines, vaccines or medical equipment they need, a gap that exposes them to purchasing and using falsified or substandard products.[2] Substandard and falsified medicines generate multiple adverse effects on public health, health systems and the economies of households, businesses and communities.[3]

However, unlike substandard drugs, which are substandard due to unintentional defects in manufacturing, transportation or storage, *falsified drugs are intended to corrupt the supply chain and mislead consumers for financial gain.* The latter involves criminal activity to which the health, police, immigration, tax and customs, and consumer protection authorities must respond.

Although there is great difficulty in quantifying the health and socio-economic effects of falsified medicines in the world, we know that this practice affects practically all types of medicines found on the market, both those that are low cost and treat common ailments, and those of high cost that are approved for highly complex diseases.[4] Furthermore, the available evidence shows that the falsification phenomenon occurs in low-income and high-income countries.[5]

Corruption directly and indirectly promotes drug falsification

Falsified medicines reach the market due to corrupt actions by legitimate actors or their omission to act against illegitimate actors. According to Steingrüber and

2. World Health Organization 2019.
3. World Health Organization 2017.
4. World Health Organization 2017.
5. Rahman et al. 2018; Ozawa et al. 2018.

Gadanya,[6] falsified medicines are affected by two types of corruption: (1) primary corruption, understood as an action that allows the manufacture or marketing of falsified medical products by legitimate and authorised actors in a regulated supply chain; and (2) secondary corruption, which occurs when the manufacture or sale of falsified medical products is facilitated by illegitimate actors such as criminal organisations or anyone who does not have market authorisation.[7]

Anti-corruption actions associated with this phenomenon can result in a very positive impact on public health and in reducing inequity in access to medicines and health services in all the countries where this phenomenon occurs.

Drug falsification in Colombia

The Colombian health system provides nearly 97% of the population with insurance that allows them to access many medicines co-financed by the same system and even fully financed, depending on the ability to pay.[8] In addition, the country has a robust pharmaceutical market that includes local manufacturers and national and international importers serving the growing demand for medicines. By 2020, the total value of the pharmaceutical market was 17 billion Colombian pesos (COP; approx. US$4,500 million), of which COP11 billion corresponded to the institutional channel (hospitals, health centres and other providers) and the remaining COP6 billion to the commercial channel (pharmacies and drugstores).[9] Despite having a solid health system, the country is no stranger to the phenomenon of drug falsification.

Steingrüber and Gadanya[10] propose nine different factors that allow falsified medicines: (i) supply chain disruption; (ii) product shortages; (iii) poor stock management; (iv) irrational and unauthorised use; (v) cost of medicines and manufacturing; (vi) misinformation and deception; (vii) limited regulatory capacity; (viii) legislation and policy; and (ix) challenges to national, regional and global coordination.

6. 2021.
7. In this study, the terms ‘primary corruption’ and ‘secondary corruption’ are used conceptually and not legally. As will be discussed later, in Colombia there is no crime of corruption, so the use of the term is not linked to a particular crime.
8. OECD 2015.
9. ANDI 2021.
10. 2021.

As the present document will explain in detail, the three most relevant factors for the Colombian case are misinformation, limited regulatory capacity, and legislation and policy. Colombia has no legal instrument defining a specific regulatory framework related to drug falsification. This regulatory vacuum, added to the growth of e-commerce, promotes an environment of primary and secondary corruption that facilitates falsified medicines in the Colombian market and limits the government's capacity to protect its citizens.

The institutional context against drug falsification in Colombia

The National Institute for Food and Drug Surveillance of Colombia (INVIMA) is the most significant entity in the government's response to drug falsification. INVIMA is the country's health authority: it is attached to the Ministry of Health and Social Protection and is responsible for exercising health surveillance and quality control for medicines. Among different actions, it is known for issuing health alerts that warn the public of products being marketed in the country in an altered or fraudulent manner. The entity can impose sanitary measures on establishments and products such as confiscations, destruction, freezing of products, partial, temporary or total closure of establishments, and cancellation of sanitary registrations.[11]

In 2014, INVIMA created the Immediate Reaction Unit Group (GURI), a multidisciplinary team in charge of preventing illegality, smuggling and corruption of products that are the responsibility of the institute. Since 2016, the GURI has been in charge of receiving and managing complaints about drug falsification in Colombia, coordinating its actions with other public institutions. Since 2018, it has managed the National Illegality and Contraband Observatory, a web tool that provides the public with related information about the entity's work and actions against altered or fraudulent products. The GURI and the Directorate of Medicines and Biological Products also monitor cases on digital platforms and in the media.

Nevertheless, in addition to INVIMA, Colombia counters drug falsification through other public and private entities with different powers to support and respond to this phenomenon.

The following table briefly summarises the most relevant entities and organisations and their relationship with action against falsified medicines:

11. Decree 780 of 2016.

Table of entities and organisations and their relationship with action against falsified medicines

Ministry of Health and Social Protection	The ministry is responsible for defining public health policy. It has a Directorate of Medicines and Technologies in Health, which directs pharmaceutical policy, medicines, devices, supplies and biomedical technology.
National Directorate of Taxes and Customs (DIAN)	DIAN oversees administration and control of tax, customs and foreign exchange obligations. It contains the Tax and Customs Police Management Division (POLFA), a department made up of members of the national police, to address its tax, exchange and customs work. It also carries out inspection, surveillance and control of the merchandise that enters the country.
Police and military forces	These forces comprise the national police and the military (the national army, air force and navy). Both the national police, through the POLFA and the Directorate of Criminal Investigation and Interpol (DIJIN), and the armed forces, carry out activities to deal with falsified medicines. They also coordinate actions with Interpol and Ameripol.
Attorney General's Office	This entity is responsible for investigating drug falsification and prosecuting the people involved before the judicial authorities. It also participates in joint operations through the Technical Investigation Corps (CTI) in its role as the judicial police.
Superintendence of Industry and Commerce (SIC)	It oversees consumer protection, including protection against risks to health. It can act against misleading advertising and monitors the responsibility of every producer to ensure the quality, suitability and safety of their products.
Departmental and municipal health secretariats	These entities conduct routine visits to commercial establishments, where they check that the medicines are offered in the manner established by law. In turn, they support the task of INVIMA and the national police in identifying products for which a health alert has been issued.
National Business Association of Colombia (ANDI)	ANDI brings together a large part of the private sector, especially leading companies from multiple industries. In 1998, the association created the Project Against Falsified Products and Falsified Trademarks as a cooperation mechanism between the public and private sectors to combat falsification, adulteration and smuggling.
Colombian Chamber of E-commerce (CCCE)	This organisation brings together and represents more than 300 e-commerce and internet companies. In 2016, the CCCE and INVIMA signed a cooperation agreement to deal with the marketing of altered or fraudulent products on virtual platforms, which also applies to the active surveillance of falsified medicines.
Corporación Punto Azul	This is a non-profit organisation created in 2010 by different pharmaceutical laboratories in the country. Its mission is to promote the proper management of waste from the Colombian pharmaceutical industry within the United Nations Sustainable Development Goals Framework.
Associations of manufacturers and importers of medicines and pharmacies	The Association of Pharmaceutical Industries in Colombia (ASINFAR), the Association of Pharmaceutical Research and Development Laboratories (AFIDRO) and the Colombian Association of Retail Druggists (ASOCOLDRO) have participated in different initiatives related to action against drug falsification in the country. However, they do not perform permanent or visible actions like the others.

Even though there are multiple public and private entities with different powers, Colombia has no specific regulatory framework to prevent the corruption that facilitates drug falsification in the country. Without a legal mandate, the country

does not have a common goal and cannot articulate specific functions and procedures to identify and reduce drug falsification. This lack of specific policies severely limits the capacity of the government to protect its citizens.

Falsified drugs' figures in Colombia

More than a billion units of medicines are sold each year in the country.[12] However, it is difficult to measure the risk of consumers being victims of fake medicines due to the challenges of availability of information that are experienced globally.

The literature review for this study did not find any academic article in which random or convenience sampling were used to estimate the prevalence of falsified medicines in the Colombian market. Only three articles mention samples collected in Colombia. Of these, two mention Colombia as the origin of the samples collected but do not refer to the results by country.[13] The third article, published in 2012, reviewed reports on anti-malarial drugs between 2006 and 2010 in Colombia. It found that, of 557 samples collected in that period, 46 (8.3%) failed the quality tests, 7 the disintegration test, and 39 failed visual and physical inspections.[14] Of this last group, 30 samples had expired and 9 had damage to the blister packaging.[15]

The National Illegality and Contraband Observatory of INVIMA is the nearest source of information on the phenomenon of drug falsification in Colombia. Although this tool does not provide useful information to estimate the prevalence of falsified medicines, it does offer valuable information to understand some characteristics of the health problem. For example, between 2018 and 2021, the observatory received 2,052 complaints of altered or fraudulent medicines and biological products. This indicator recognises drug quality problems in the Colombian market and that these should feature more prominently on the government agenda.

The observatory also provides valuable information on some types of medicines that are more likely to be altered or faked. By 2020, more than half of the complaints received corresponded to medicines sold via e-commerce. This confirms that the falsification phenomenon is migrating or spreading to virtual channels. The altered or fraudulent medications with the most reports sold via e-commerce were high-cost medications, cancer medications, contraceptive and fertility treatments, medications for hepatitis and HIV, and medications that claimed to provide benefits such as weight loss, improving intellectual capacity and 'fat burning', among others.

12. Technical Secretariat of the National Commission on Prices of Medicines and Medical Devices 2019.
13. Laserson et al. 2001; Hajjou et al. 2015.
14. Pribluda et al. 2012.
15. Ozawa et al. 2018.

Another source of relevant information from INVIMA is through its health alerts. Between 2018 and the first half of 2021, INVIMA published 339 health alerts for fraudulent medicines, including a wide range of products from dietary supplements and fat burners to vaccines and high-cost, specialised medicines. Alerts are issued due to complaints from citizens, manufacturers or importers or because of alerts from other health authorities.

According to INVIMA data, between 2017 and 2020, POLFA seized 8.5 million units of medication, 1.6 million dietary supplements, more than 300,000 herbal medicines, 72,000 sexual enhancers and 368 homeopathic medicines. In the case of medicines, 92% of the total (8 million units) were seized in 2020.

Drug falsification in the news

Given the lack of public information, this research performed a digital news analysis to understand a little more about the phenomenon of drug falsification in Colombia.

The study identified 172 news items published in 46 sources relating to falsified medicines in Colombia between January 2018 and August 2021. Fifty-five (55)% (94 items) of the news items were informative; that is, the outlet warned about some INVIMA warning or presented information about the dangers of consuming falsified medicines in general or in the case of a specific product. Forty-two (42)% (72) of the news items related to arrests and police operations, while only 3% (5) reported on monitoring judicial processes, and 1% (1) saw the issue feature in an opinion column.

Drug falsification is a topic of media interest. However, the attention paid to the arrests was greater than the media's monitoring of the judicial processes related to these cases of interest. This may be because there is not much public information available about falsification cases that the media can follow; consequently, this results in less pressure to make visible and punish organisations and individuals linked to corruption and falsification of medicines. It is also surprising that, in three years, only one opinion column has been written about this problem.

Falsified products

In most cases, the media does not specifically describe (in terms of the commercial name, pharmaceutical form, etc.) the falsified products about which the related complaints or arrests are made. In the news identified, products related to the following categories were described:

- Dietary supplements
- Treatments for anaemia
- Anti-inflammatories
- Fat burners

- Medicines for sexual development
- Antirheumatic drugs
- Diabetes treatments
- Products for fertility and assisted reproduction
- Medicines against infections
- Treatments for Covid-19
- Treatment of neonatal respiratory distress syndrome or hyaline membrane disease
- Hormones used for growth in children
- Cancer drugs
- Treatment as a 'ripener' of the uterine cervix
- Medications for arthritis and osteoarthritis
- Haemophilia medications
- Medications to treat opioid overdose and poisoning
- Medications for heart disease
- Treatments for diseases caused by parasites
- Anti-malarial drugs
- Treatments to increase intellectual capacity

The descriptions of the falsified products were very general. However, they did provide 'red flags' on product categories that may be at higher risk of falsification. This list also highlights the urgent need for the authorities to focus on combating the falsification or circulation of substandard quality medicines from a larger number of groups of medicines.

Illicit activities

The absence of products' health registration at INVIMA was the most frequently mentioned illicit activity (21%), followed by the marketing of expired medicines (17%), altered products (16%), altered packaging (8%), illegally imported products (8%) and falsified health records (7%). For the media and public opinion, the absence of a health registration is equivalent to an alarm signal that warns of a possibly falsified drug.

Distribution channels

The sale of this type of product was most reported from pharmacies and drugstores, followed by sales through social networks and online sales, as well as in health

centres. If digital channels are added, the most significant exposure to falsified medicines occurs in virtual channels. Diversity in distribution channels provides opportunities for criminal gangs and corrupt actors in the system to market falsified medicines, regardless of socio-economic status or whether they live in urban or rural areas. This reiterates the need to design and implement a comprehensive strategy against corruption that promotes and facilitates falsification.

On the other hand, it was observed that news about falsified drugs was presented in multiple cities in the country. Among the most mentioned in the selected news were Bogotá, Barranquilla, Bucaramanga, Medellín, Buenaventura, Cúcuta, Cali, Santa Marta, Manizales, Cartagena, Valledupar and Villavicencio. However, the information obtained was limited to digital news, which meant that the presence of falsified medicines in rural areas could not be ruled out.

Crimes related to acts of falsification

The main crimes mentioned in the news collected were *conspiracy to commit a crime* and *corruption of food, medical products or prophylactic material*. This shows that behind the acts of drug falsification, there are criminal networks that are being captured and prosecuted together. The high frequency of references to the crime of *usurpation of industrial property rights* indicates that, in many cases, imitations of legitimate products are being found. The appearance of the crime of *illegal alienation of medicines* reveals that, in many cases, medicines are being extracted from the legitimate distribution chain to resell on an illegal market.

Actors involved in drug falsification

Finally, the media study observed that 47% of the people involved and mentioned in the news operated through criminal gangs, while 27% worked individually. Seven (7)% of references involved employees of health insurance companies, 7% mentioned employees of pharmacies and drug stores, 6% spoke of employees of health providers, and 5% mentioned civil servants from administrative authorities or control entities.

This information highlights the importance of designing anti-corruption strategies in different institutions. When discussing corruption in the health sector, it is usual to associate the phenomenon with practices that are exclusive to the public sector. However, the corruption that facilitates or promotes drug falsification can also involve non-state actors, such as criminal organisations or individuals who have the power to access the drug distribution chain and abuse that power for their benefit.

Falsified medicines and digital commerce

Some factors that could contribute to the proliferation of falsified medicines in Colombia are the easy access by citizens to a vast range of information on the internet, the possibility of acquiring medicines subject to medical prescription without having such a prescription, lower prices, and convenience in the forms of delivery.

INVIMA and other actors identify possible cases of fraudulent drug marketing on the internet through requests, complaints, claims and reports from external entities or through the proactive monitoring carried out by the institute.

In 2016, INVIMA and online marketplace, Mercado Libre, signed an agreement to counteract and mitigate illegal and contraband sales of products marketed through e-commerce. As a result of this agreement, 3,413 publications associated with medications were removed from Mercado Libre between 2018 and 2020. INVIMA also signed an agreement with Facebook and Instagram, whereby 1,187 profiles associated with the sale of falsified medications were removed during the same period. The collaboration with the Superintendence of Industry and Commerce (SIC) made it possible to withdraw 209 publications about fraudulent medicines that did not comply with consumer protection regulations over the same period.

The proliferation of fraudulent drugs marketed over the internet represents a significant challenge for the government's response to the phenomenon. The number of publications promoting falsified or substandard-quality medicines on social networks exceeds the capacity of INVIMA or the SIC to remove them.

Conclusions

Colombia needs to recognise drug falsification as a corruption problem

Actions against drug falsification are not treated as actions to counter corruption, limiting the government's response to such a severe phenomenon to public health. Approaching the problem of drug falsification from the perspective of corruption can generate more attention from decision-makers, resources and alliances with other national and international organisations and institutions.

This approach would also make it possible to improve the response strategy, strengthening legitimate channels, while combating legal actors who abuse their

power to benefit from the sale and distribution of falsified medicines financially, and illegal actors who benefit from the proliferation of these products.

Colombia urgently requires a detailed diagnosis of the drug falsification phenomenon

There is a total absence of complete, reliable and standardised public information that allows an estimate of the prevalence of drug falsification in the country. Without sufficient information, the government cannot propose or justify more significant investments to strengthen the response to this problem, nor can it design better strategies to reduce consumer risk.

More information is also needed on the victims of falsified medicines. Currently, there is no clear profile of the most affected populations and what they require in terms of timely prevention and care interventions.

The greatest challenge to countering corruption that facilitates drug falsification is in e-commerce and advertising on digital media

E-commerce currently represents the most significant challenge in response to drug falsification in Colombia and the rest of the world. The current regulatory framework in Colombia does not respond to this need. Although a modification to Decree 334[16] of 2022 was recently approved, the new norm did not establish specific responsibilities of the competent entities, complaint handling mechanisms, nor clear sanctions for those who participate in the falsification of medicines.

Most cases of falsified products reported in the news were sold through digital channels, ranging from specialised trading platforms to instant messaging applications. INVIMA has advanced the necessary agreements to remove false advertising, but the speed and ease with which criminals operate are more significant than the institute's ability to respond to the illegal market.

Inter-institutional strengthening and articulation are needed based on a public policy with precise objectives, goals and responsibilities that adopt good international practices to counter falsification corruption.

There is collaborative work being carried out between different public and private institutions. However, without a legal framework that defines specific commitments, periodic joint planning and, ideally, a larger budget, the responses of each institution will continue to depend on the decisions of the administration in charge and not on government policy.

16. In March 2022, the national government issued Decree 334 of 2022, which updated the provisions on the renewal, modification and suspension of the sanitary registration of medicines. Regarding actions or powers to reduce primary or secondary corruption related to medical products, there were only two articles regulating the marketing of medicines through websites and digital platforms.

Nor did this study find significant participation of control bodies such as the Attorney General's Office, the Comptroller General's Office or the Ombudsman's Office, institutions that guarantee the protection of the constitutional rights of the Colombian population and the struggle against corruption that facilitates drug falsification in the country.

The need to generate collaboration with the private sector is also evident. There is a critical vulnerability among the different actors participating in the drug distribution chain, from producers and wholesale distributors to pharmacies/drug stores and health centres. The initiatives of different associations in the pharmaceutical sector show that eliminating falsified medicines is in their utmost interests.

15 recommendations to face the corruption that promotes falsified medicines in Colombia

Table of recommendations

For the national government	Adopt an anti-corruption, transparency and accountability approach in actions against drug falsification.
	Commission a study on the prevalence of falsified medicines in Colombia.
	Adopt international terminology agreed by the World Health Assembly on falsified and substandard medicines.
	Issue specific regulations related to the marketing of medicines over the internet.
	Implement an intersectoral technical group to counter drug falsification led by the Ministry of Health and Social Protection.
	Identify the support required by the judicial authorities to accelerate the prosecution of those responsible for drug falsification.
	Continue and strengthen citizen education activities on drug falsification.
	Implement an alert protocol for public purchases of possibly falsified medicines.
For the private sector	Implement corruption risk assessments in private sector organisations that may facilitate acts of corruption.
	Invest in new technologies to protect the distribution of medicines against falsified products.
For civil society organisations and academia	Strengthen the participation of organisations of patients affected or at risk, civil society organisations, and academia in studying the phenomenon of drug falsification and its response.
For donor governments and international allies	Support public sector entities in Colombia, offering technical cooperation opportunities and co-financing studies on the prevalence of falsified medicines in the country.
	Include anti-corruption and transparency actions in response to drug falsification within the activities and programmes to strengthen health systems.

	Collaborate with other international and regional organisations to develop global solutions incorporating transparency and an anti-corruption lens in responding to drug falsification.
	Position the fight against drug falsification as a relevant action to achieve the Sustainable Development Goals.

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About the author

Johnattan García Ruiz

Johnattan is an independent researcher and consultant in global health and health systems. He is a visiting scientist associated with the Takemi Program in International Health at the Harvard TH Chan School of Public Health. He has been a professor of law and global health at the Universidad de los Andes School of Law and a professor of global health at the Universidad del Rosario School of Medicine and Health Sciences in Colombia. He holds a law degree from Universidad de los Andes (Colombia), a Master's degree in Public Health (MPH) from Harvard University, and an MBA from the University of Oxford.

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