



# ILLEGITIMATE DRUGS

Information and Advice for Colombian  
Health Care Professionals

Start



# Instructions



This document can be navigated using the **sidebar menu** on the left of the screen. Please see below for a description of each section title and the main navigational buttons. All bevelled shapes throughout this interactive document **are clickable**.



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# What is an illegitimate drug?

Illegitimate medicines are “Illegal drugs not in accordance with accepted standards”.(1)\*

Origin	Characteristics	Types
Illegitimate drugs can result from criminal activity, mishandling, negligence, or a combination of the above. <b>In all cases, illegitimate drugs are potentially dangerous.</b> (2)	Illegitimate drugs can contain suboptimal (both higher or lower) concentrations of ingredients, contaminants or <b>poor quality ingredients.</b> (3)	There are two main categories of illegitimate drugs: <b>falsified</b> and <b>substandard.</b> (1)



(1) IOM (Institute of Medicine). 2013. Countering the problem of falsified and substandard drugs. Washington, DC: The National Academies Press.

(2) Binagwaho A, Bate R, Gasana M, Karema C, Mucyo Y, et al. (2013) Combatting Substandard and Falsified Medicines: A View from Rwanda. PLoS Med 10(7): e1001476. doi:10.1371/journal.pmed.1001476

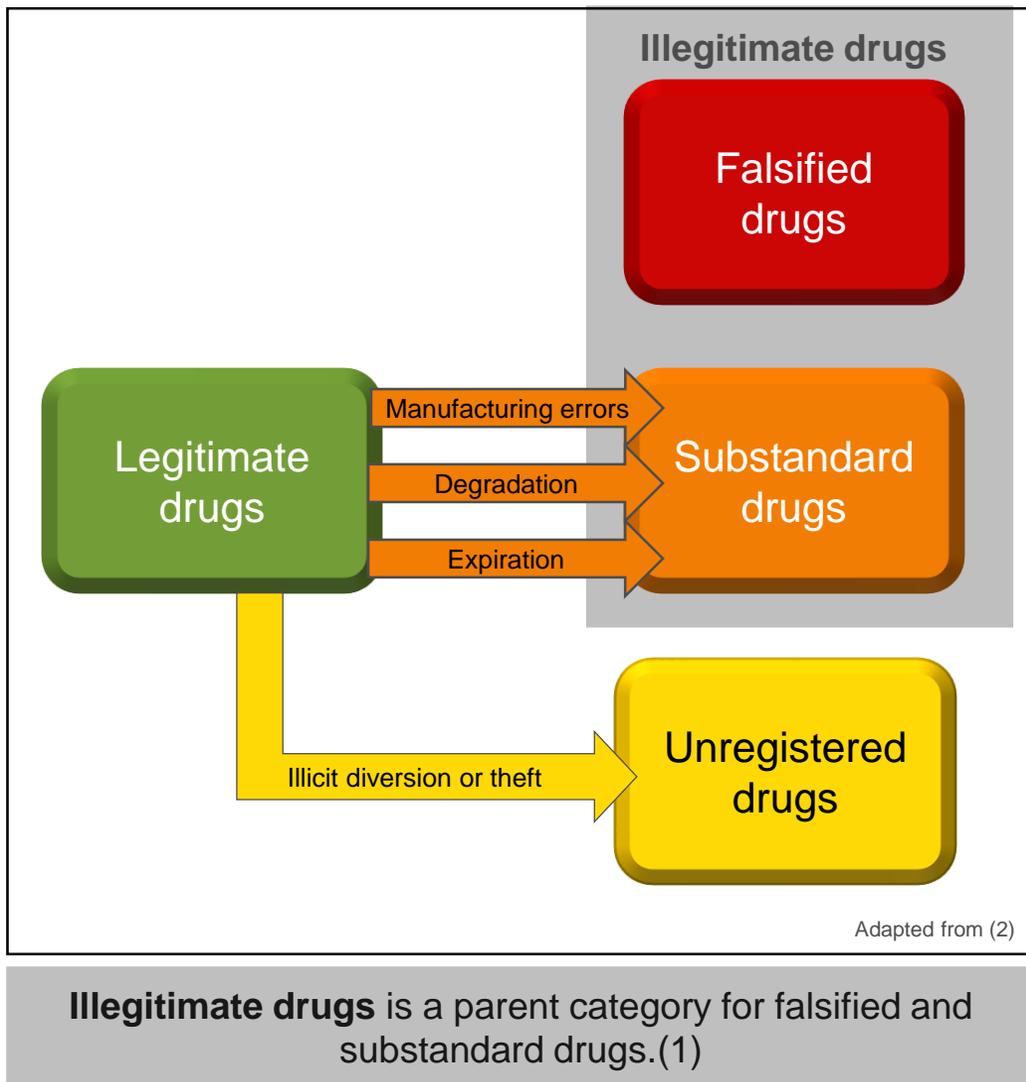
(3) Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Trop Med Int Health. 2008;13(8):1062-72.

\*This interactive PDF adopts the terminology suggested by the Institute of Medicine of the National Academies.(1)





# Illegitimate vs. Legitimate drugs



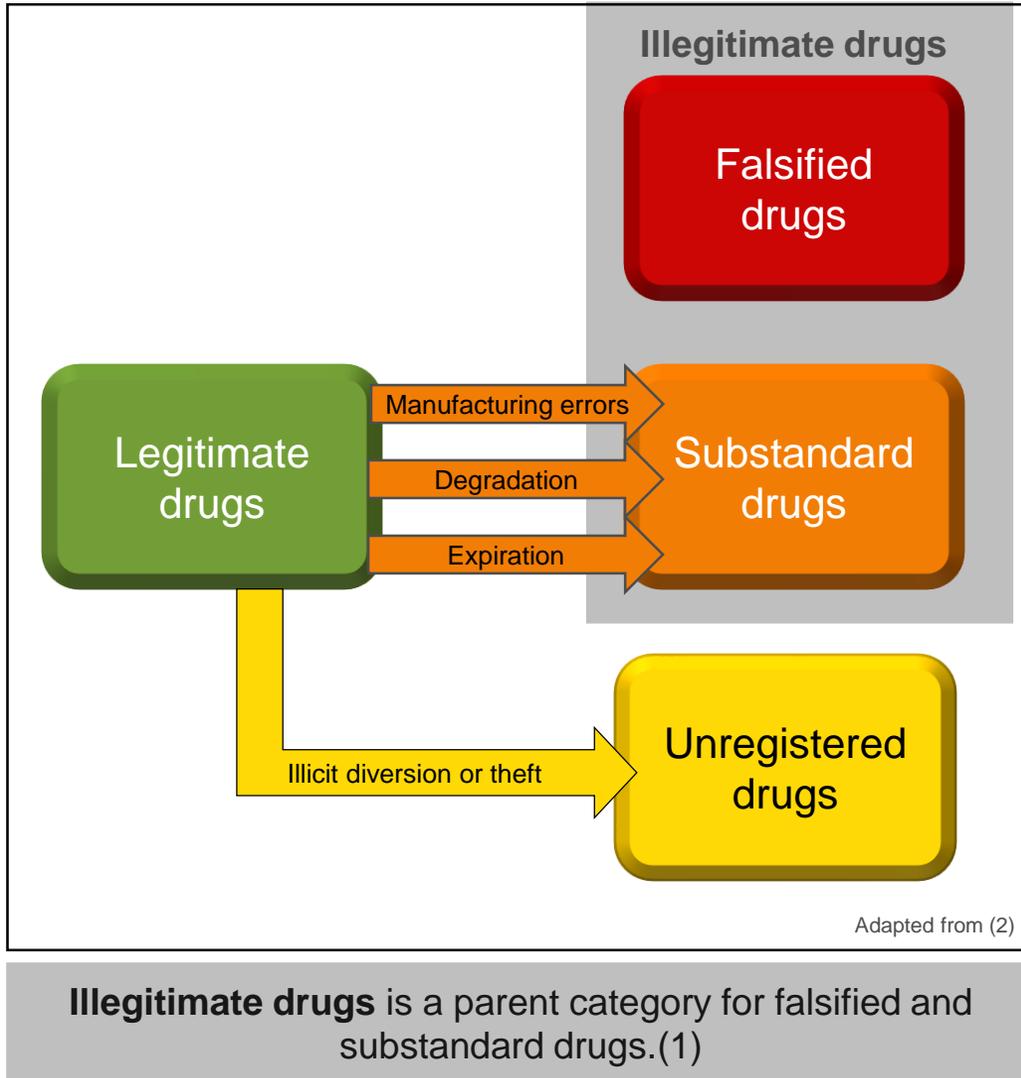
Click on the buttons to see the definitions here.

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(2) BMJ 2012;345:e7381





# Illegitimate vs. Legitimate drugs



Click on the buttons to see more definitions:

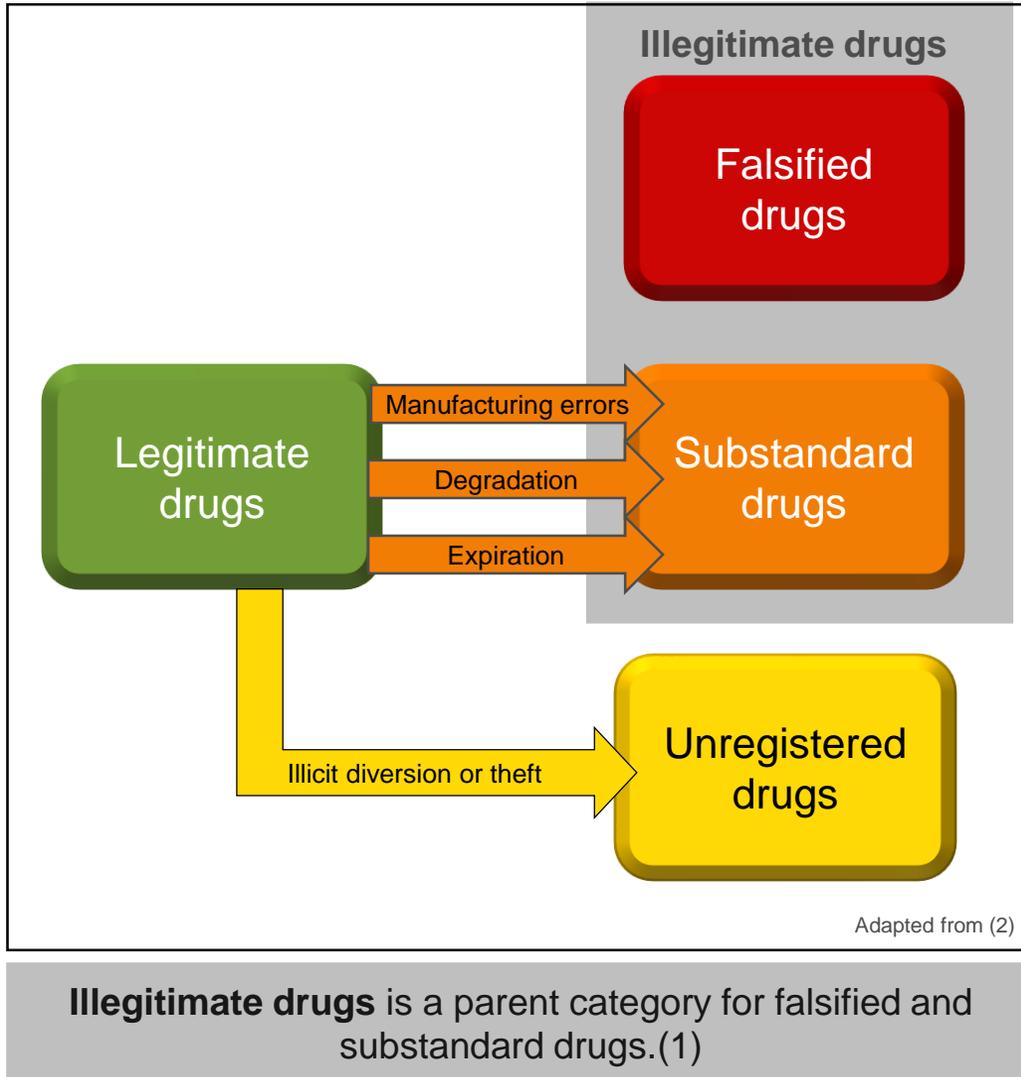
**Legitimate drugs** are approved by the regulatory authority and meet accepted standards.(1) They are safe for patients.

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(2) BMJ 2012;345:e7381





# Illegitimate vs. Legitimate drugs



Click on the buttons to see more definitions:

**Falsified drugs** carry a false representation of identity and/or source.(1) They are made with the wilful intention of misleading the patient.(2)

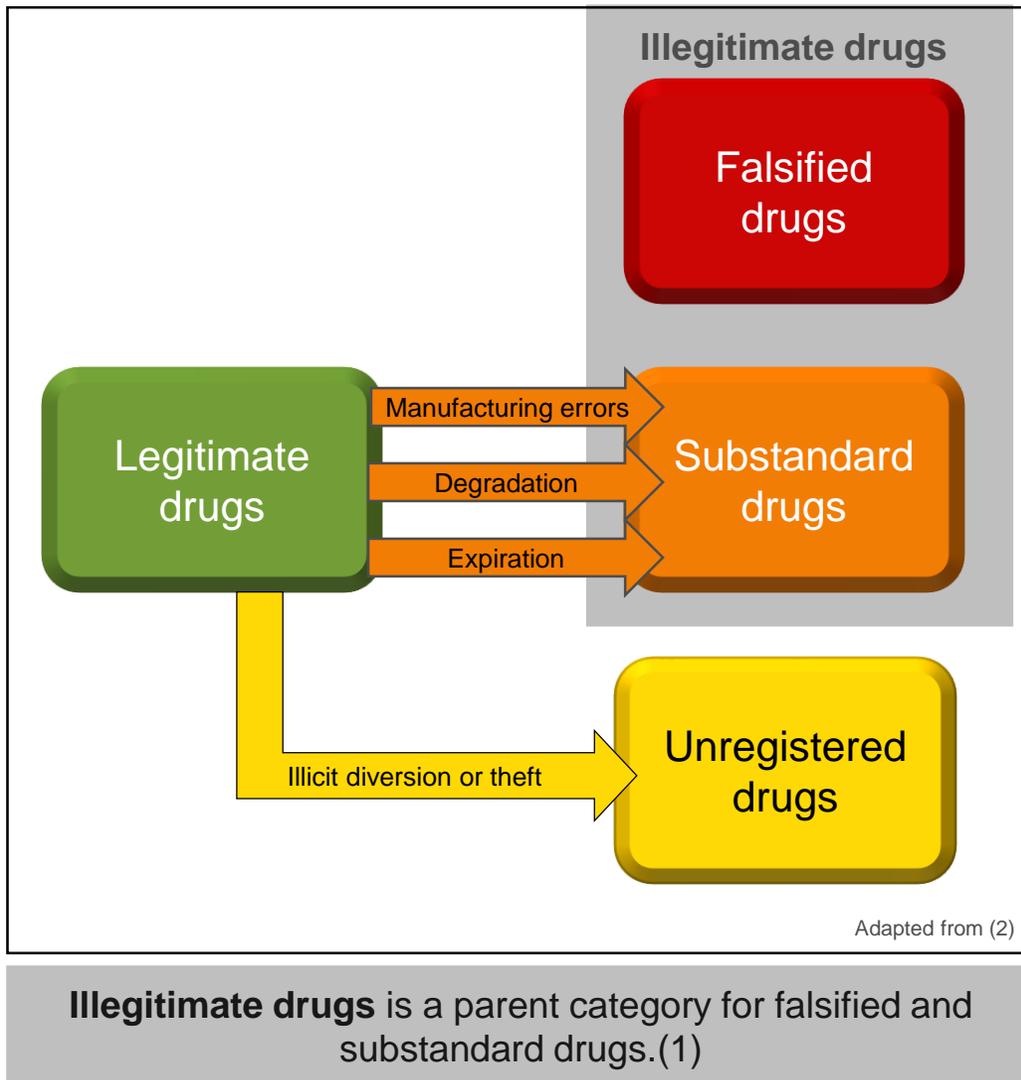
(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) BMJ 2012;345:e7381





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Click on the buttons to see more definitions:

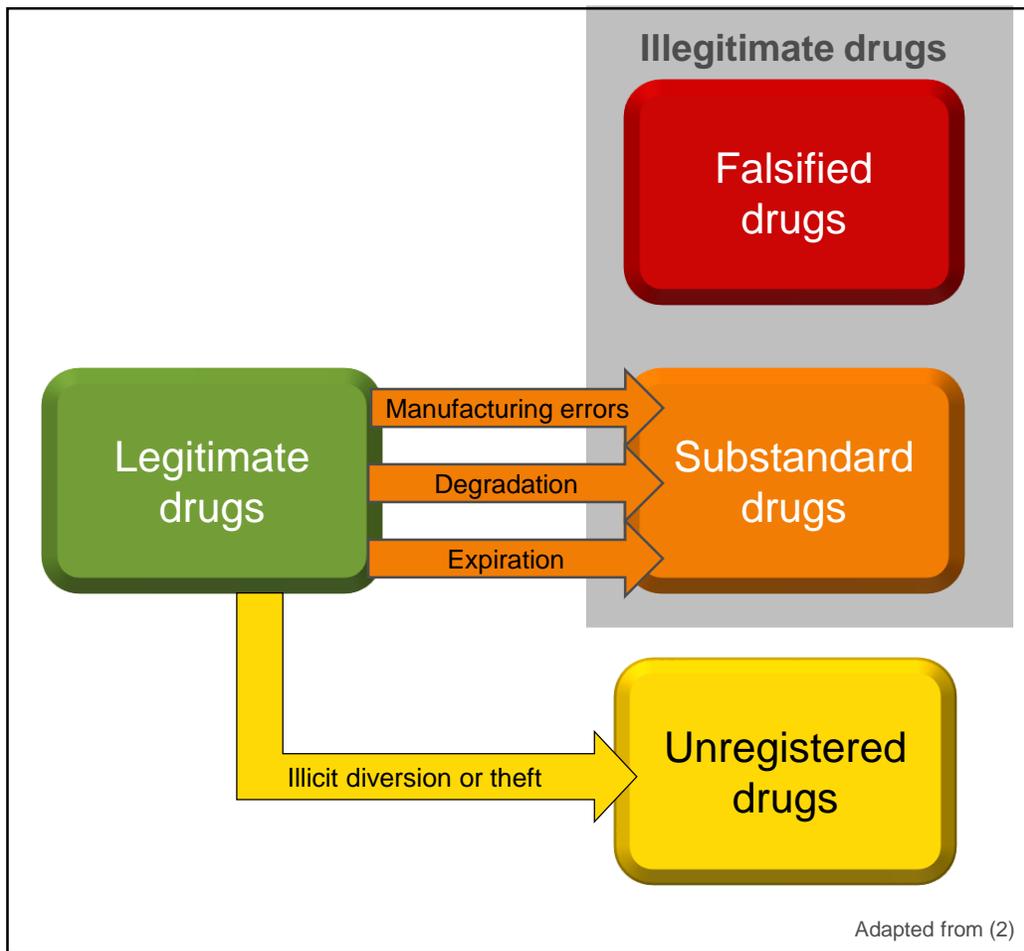
**Substandard drugs** don't meet the specifications given in the accepted pharmacopeia or in the manufacturer's dossier.(1) They result from unintentional manufacturing errors, degradation or expiration of legitimate drugs.(2)

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) BMJ 2012;345:e7381



# Illegitimate vs. Legitimate drugs



Adapted from (2)

**Illegitimate drugs** is a parent category for falsified and substandard drugs.(1)

Click on the buttons to see more definitions:

**Unregistered drugs** could meet accepted standards, but they are sold without the permission of the regulatory authority.(1) In some cases, they are sold after being stolen or illegally imported.(2)

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

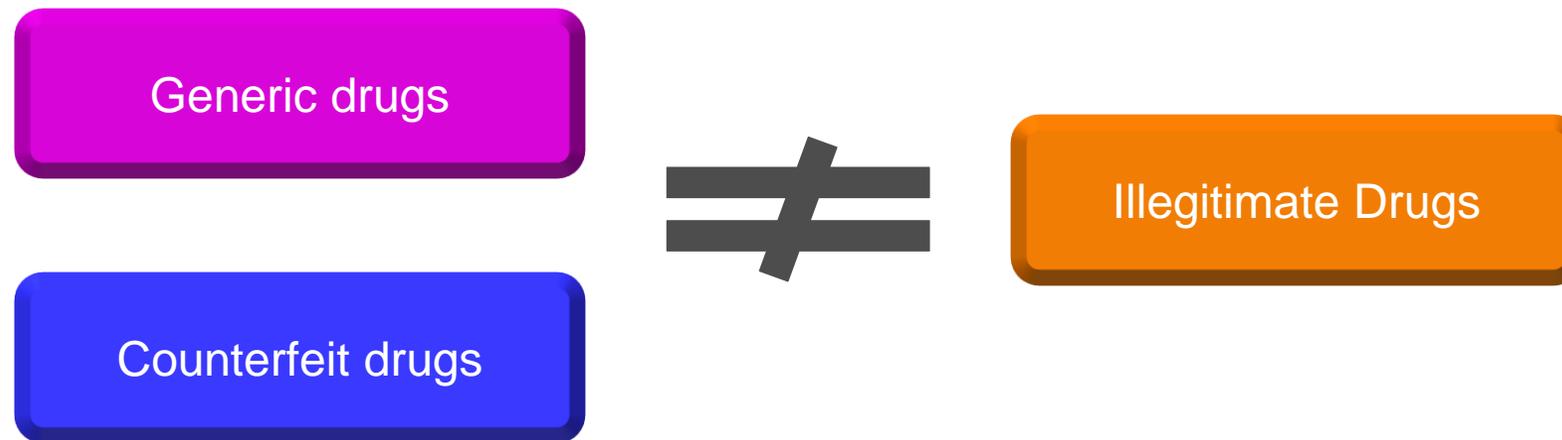
(2) BMJ 2012;345:e7381





# What is not an illegitimate drug?

- Neither **generic** nor **counterfeit** drugs are automatically illegitimate.
- Previous misconceptions about the difference between generic, counterfeit and illegitimate drugs have jeopardized the access of poor populations to quality, yet affordable, generic medicines.(1)



(1) Bate R, Attaran A. A counterfeit drug treaty: great idea, wrong implementation. *The Lancet*.376(9751):1446-8.  
(2) World Health Organization. Trade, foreign policy, diplomacy and health. Generic Drugs. <http://www.who.int/trade/glossary/story034/en/>  
(3) U.S. Food and Drug Administration. Understanding Generic Drugs. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm>

(4) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(5) *BMJ* 2012;345:e7381  
(6) Pharmaceutical Security Institute. <http://www.psi-inc.org/counterfeitSituation.cfm>





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- **Generic drugs** are not illegitimate per se. They are pharmaceutical products that are legally manufactured as bioequivalent copies of branded drugs for which a patent has expired.(2,3)
- Both branded and generic drugs could be affected by falsification, illegal diversion, theft and other violations, and thus become illegitimate drugs. (Click on the links to see the definitions)

(1) Bate R, Attaran A. A counterfeit drug treaty: great idea, wrong implementation. *The Lancet*.376(9751):1446-8.  
(2) World Health Organization. Trade, foreign policy, diplomacy and health. Generic Drugs. <http://www.who.int/trade/glossary/story034/en/>  
(3) U.S. Food and Drug Administration. Understanding Generic Drugs. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm>

(4) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(5) *BMJ* 2012;345:e7381  
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- **Generic drugs** are not illegitimate per se. They are pharmaceuticals that are identical to the original drug in terms of their chemical composition, strength, dosage form, and route of administration. They are produced by different manufacturers than the original drug, but they are approved by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). Generic drugs are often sold at a lower price than the original drug, which can make them more accessible to people who are unable to afford the original drug. However, generic drugs are not always of the same quality as the original drug, and they may be subject to counterfeiters. Therefore, it is important to purchase generic drugs from reputable sources and to check the expiration date and the packaging of the drug.

**Illegal diversion** of drugs occurs when medicines that were purchased (usually by the government or by charity organizations) for use in a specific population or geographical region are illegally taken to be sold elsewhere.(6)

(1) Bate R, Altaran A. A counterfeit drug treaty: great idea, wrong implementation. *The Lancet*. 376(9751):1446-8.  
(2) World Health Organization. Trade, foreign policy, diplomacy and health. *Generic Drugs*. <http://www.who.int/tradeflossary/story/034/en/>  
(3) U.S. Food and Drug Administration. Understanding Generic Drugs. [http://www.fda.gov/oc/press/2012/02/consumers\\_buying\\_generic\\_drugs\\_safety\\_understanding\\_generic\\_drugs\\_uem144356.html](http://www.fda.gov/oc/press/2012/02/consumers_buying_generic_drugs_safety_understanding_generic_drugs_uem144356.html)

(4) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(5) *BMJ* 2012;345:e7381  
(6) Pharmaceutical Security Institute. <http://www.psi-inc.org/about-the-institute/>



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- A **counterfeit drug** is defined as a drug that infringes on a registered trademark.(4)
- The term 'counterfeit drugs' has been previously used as a synonym of 'illegitimate drugs'; however, the Institute of Medicine (IOM) suggest to reserve that term to refer to intellectual property rights violations.(4)

(1) Bate R, Attaran A. A counterfeit drug treaty: great idea, wrong implementation. *The Lancet*.376(9751):1446-8.  
(2) World Health Organization. Trade, foreign policy, diplomacy and health. Generic Drugs. <http://www.who.int/trade/glossary/story034/en/>  
(3) U.S. Food and Drug Administration. Understanding Generic Drugs. <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm>

(4) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
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Generic drugs

**Illegitimate medicines** are “Illegal drugs not in accordance with accepted standards”.(1)

Counterfeit drugs



(1) Bate R, Attaran A. A counterfeit drug treaty: great idea, wrong implementation. *The Lancet*.376(9751):1446-8.  
(2) World Health Organization. Trade, foreign policy, diplomacy and health. Generic Drugs. <http://www.who.int/trade/glossary/story034/en/>  
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(4) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.  
(5) *BMJ* 2012;345:e7381  
(6) Pharmaceutical Security Institute. <http://www.psi-inc.org/counterfeitSituation.cfm>



# Magnitude of the problem



Illegitimate drugs are a global problem: they affected at least 124 countries in 2011.(1)



In some regions of Africa, Asia and Latin America, **more than 30% of medicines could be falsified.**(2)

The scale of the problem of substandard drugs is unknown as there are no definitive statistics available.(3)



Between 2005 and 2010, the worldwide sales of illegitimate medicines rose by 90%.(4)



The World Health Organization (WHO) has estimated that **more than 50%** of medicines purchased over the Internet are falsified.(3)

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT). 2006. Counterfeit Medicines: an update on estimates. <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf>

(3) Johnston A, Holt DW. Substandard drugs: a potential crisis for public health. *Br J Clin Pharmacol*. 2014;78(2):218-43.

(4) Center for Medicine in the Public Interest in the United States of America (USA).



# Illegitimate drugs in Colombia



Colombia is amongst the **top 10** countries in the world for offences involving medicines.(1)

In Colombia, there is **lack of official statistics** about the magnitude of the illegitimate drugs problem. The majority of available information comes from mass media.(3)

Headlines

A recent survey concluded that Colombian health care professionals are generally aware of illegitimate drugs problem; however, their **ability to identify and report** illegitimate drugs is poor.(2)

Survey

(1) IOM (Institute of Medicine). 2013. Table 3-2. Countering the problem of falsified and substandard drugs. Washington, DC: The National Academies Press.

(2) Mahecha MP, et al. Survey: Awareness of Colombian doctors and nurses about the problem of illegitimate drugs. (data unpublished).

(3) Foros Semana. Contrabando, falsificación: retos en materia sanitaria. ¿Cómo enfrentarlos?. [http://www.forossemana.com/cms\\_images/wp-content/uploads/2015/01/Relator%C3%ADa-del-foro-Contrabando-falsificaci%C3%B3n-retos-en-materia-sanitaria-c%C3%B3mo-enfrentarlos.pdf](http://www.forossemana.com/cms_images/wp-content/uploads/2015/01/Relator%C3%ADa-del-foro-Contrabando-falsificaci%C3%B3n-retos-en-materia-sanitaria-c%C3%B3mo-enfrentarlos.pdf).



Headlines in Colombia

# CAUTION!

Illegitimate drugs are a real problem in Colombia.

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# CAUTION!

NACIÓN | 2014/08/23 12:00

## Contrabando de medicamentos: negocio de alto costo

SEMANA le siguió la pista al tráfico de medicamentos entre Colombia y Venezuela. El negocio es multimillonario, puede afectar miles de vidas y no parece tener una solución a la vista.



<http://www.semana.com/nacion/articulo/contrabando-de-medicamentos-negocio-de-alto-costo/400145-3>





NACIÓN | 2014/03/07 00:00

## La droguería que vendía medicamentos falsos en Bogotá

Desmantelada fábrica y droguería que comercializaba medicamentos falsificados, cinco personas capturadas.



<http://www.semana.com/nacion/articulo/la-drogueria-que-vendia-medicamentos-falsos-en-bogota/379624-3>



Headlines in Colombia

# CAUTION!

Illegitimate drugs are a real problem in Colombia.



JUDICIAL 2 DIC 2015 - 3:31 PM

Medicamentos adulterados

## Desarticulan red que adulteraba medicamentos para el cáncer y el VIH

Se realizaron 31 allanamientos en Bogotá y 4 en Cúcuta.

<http://www.elespectador.com/noticias/judicial/desarticulan-red-adulteraba-medicamentos-el-cancer-y-el-articulo-603028>



Headlines in Colombia

# CAUTION!

Illegitimate drugs are a real problem in Colombia.



Jueves 26 de septiembre de 2013  ELTIEMPO.COM >

## Alarma por el lucrativo negocio de falsificar medicamentos

Autor: CARLOS F. FERNÁNDEZ Y SONIA PERILLA SANTAMARÍA.

<http://www.eltiempo.com/archivo/documento/CMS-13082423>



Headlines in Colombia

# CAUTION!

Illegitimate drugs are a real problem in Colombia.



NACIONAL 31 AGO 2015 - 1:20 PM

## En Santander incautan medicamentos vencidos evaluados en \$10 millones

Las incautaciones se presentaron en droguerías de los municipios de San Gil y Socorro.

Por: Redacción Nacional



<http://www.elespectador.com/noticias/nacional/santander-incautan-medicamentos-vencidos-avaluados-10-m-articulo-582858>

Headlines in Colombia

# CAUTION!

Illegitimate drugs are a real problem in Colombia.



NACIÓN | 2013/08/06 00:00

## La estafa que dejó un centenar de embarazadas en Arauca

Buscan justicia las mujeres afectadas por la distribución de anticonceptivos falsos.



Los anticonceptivos falsos provocaron el embarazo de casi 100 mujeres en Arauca. Foto: AP

<http://www.semana.com/nacion/articulo/la-estafa-dejo-centenar-embarazadas-arauca/353274-3>



# Survey

---

- In order to quantify Colombian HCPs awareness of the illegitimate drugs problem, an online survey was conducted.
- 53 Colombian doctors and nurses completed the survey.
- Click on the menu for further details.

- Demographic data
- Awareness about the problem
- Ability to identify illegitimate drugs
- Warning patients
- Conclusions



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- Demographic data
  - Professional background
  - Experience prescribing/administrating medicines
  - Health care facilities
- Awareness about the problem
- Ability to identify illegitimate drugs
- Warning patients
- Conclusions



# Survey

- In order to gain evidence concerning the awareness of Colombian health care professionals (HCPs) about the problem of illegitimate drugs, a survey was conducted.

- 53 Colombian doctors participated in the survey.

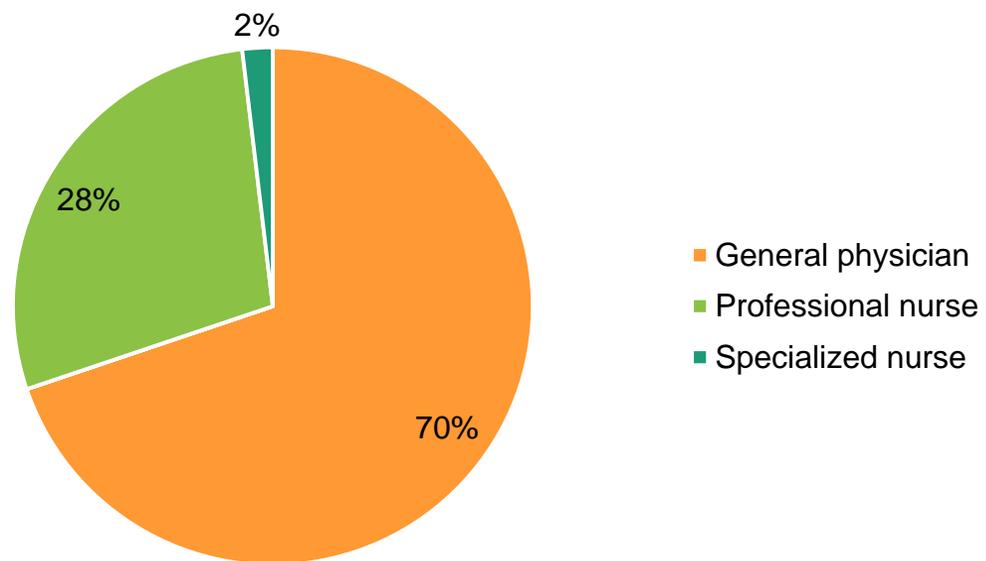
- Click on the menu for

Demographic data

Professional background



PROFESSIONAL BACKGROUND



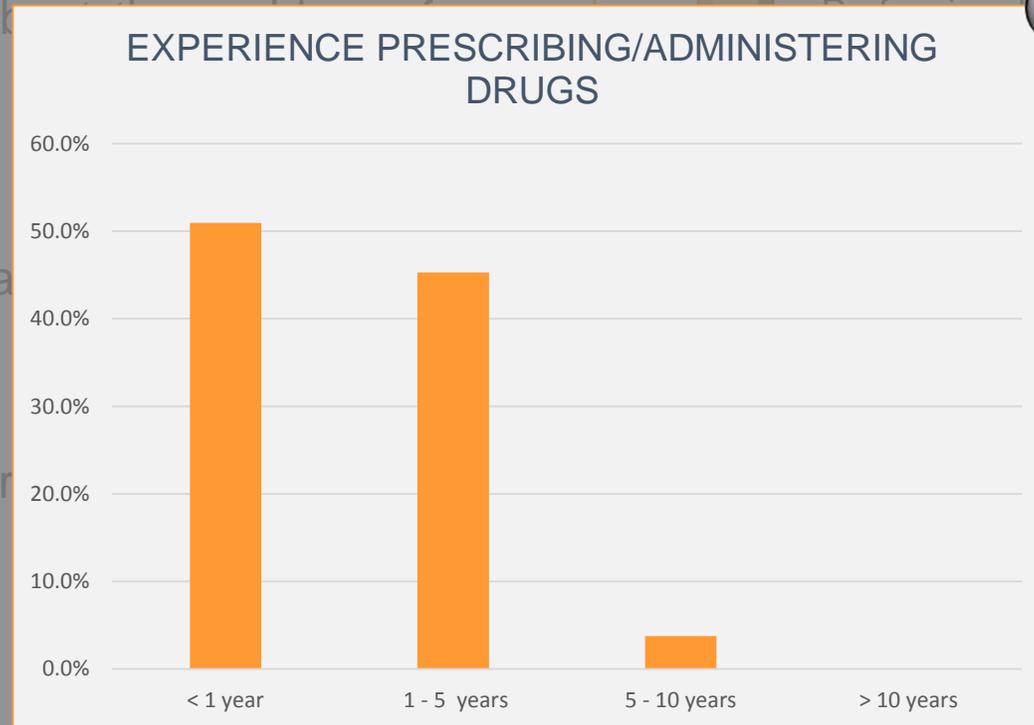


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Demographic data

Background

prescribing/administrating

facilities

about the problem

identify illegitimate drugs

patients





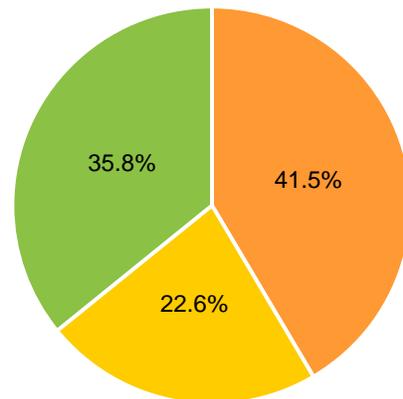
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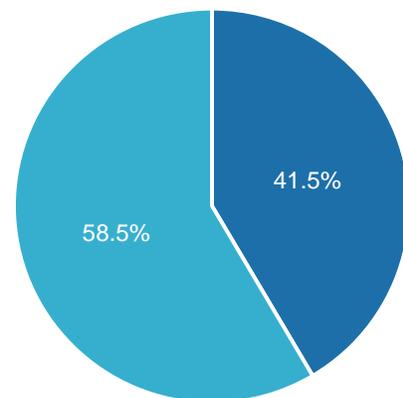
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### COMPLEXITY OF HEALTH CARE FACILITIES



■ Level I ■ Level II ■ Level III or IV

### TYPE OF HEALTH CARE FACILITIES



■ Public ■ Private

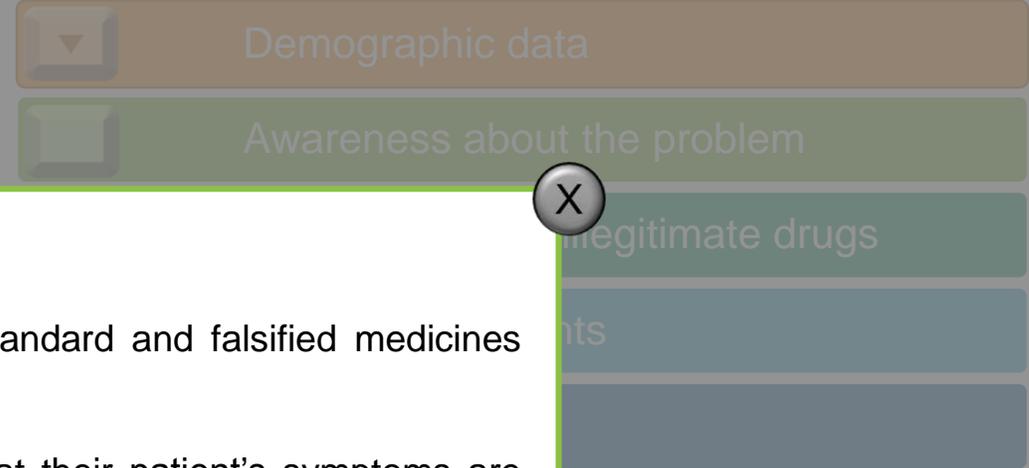


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- Click on the menu for f



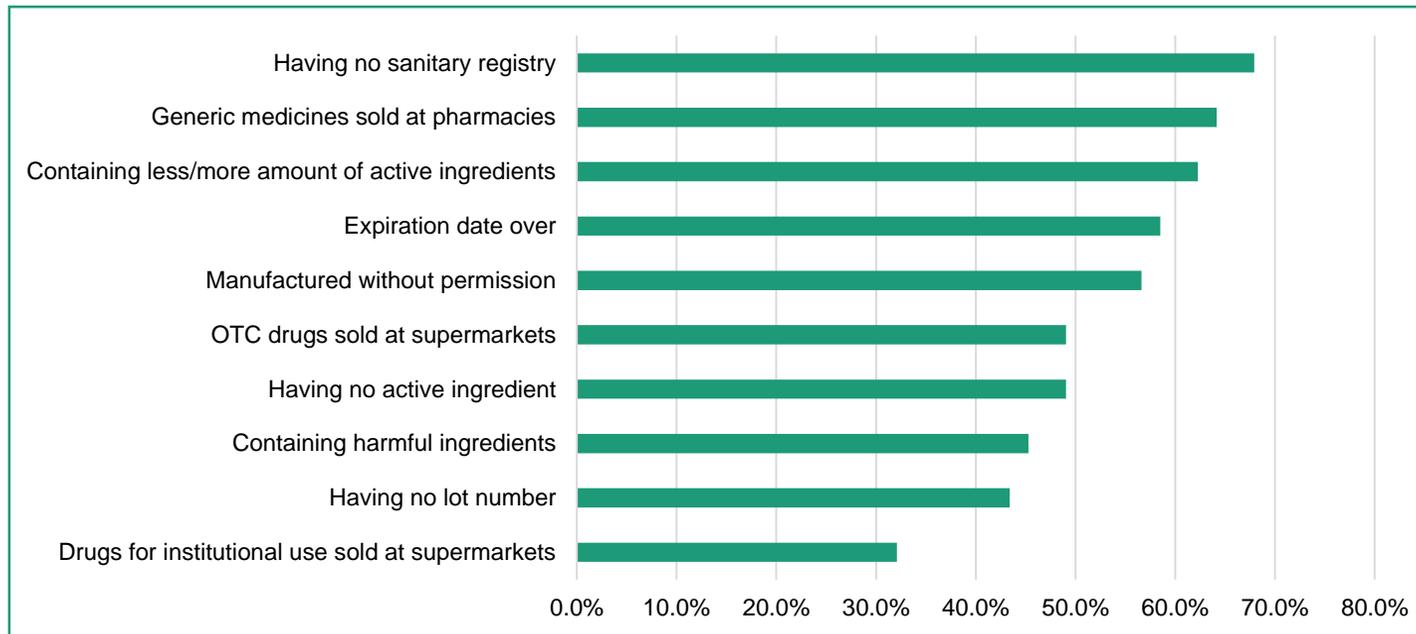
Of the surveyed HCPs:

- **9,4%** don't believe that substandard and falsified medicines are a problem in Colombia.
- **37.7%** have never thought that their patient's symptoms are secondary to the use of illegitimate drugs.
- **81%** don't know how to report an adverse event related to substandard/falsified drugs.

# Survey

- In order to assess the awareness of health professionals about illegitimate drugs, a survey was conducted.
- 53 Colombian health professionals participated in the survey.
- Click on the buttons to see the correct answers.

To test the ability of HCPs to identify illegitimate drugs, they were asked to mark which of the below statements correspond to falsified and substandard drugs. The following chart presents the % of correct answers for each description.



Click to see the correct answers

Legitimate drugs

Falsified/substandard drugs

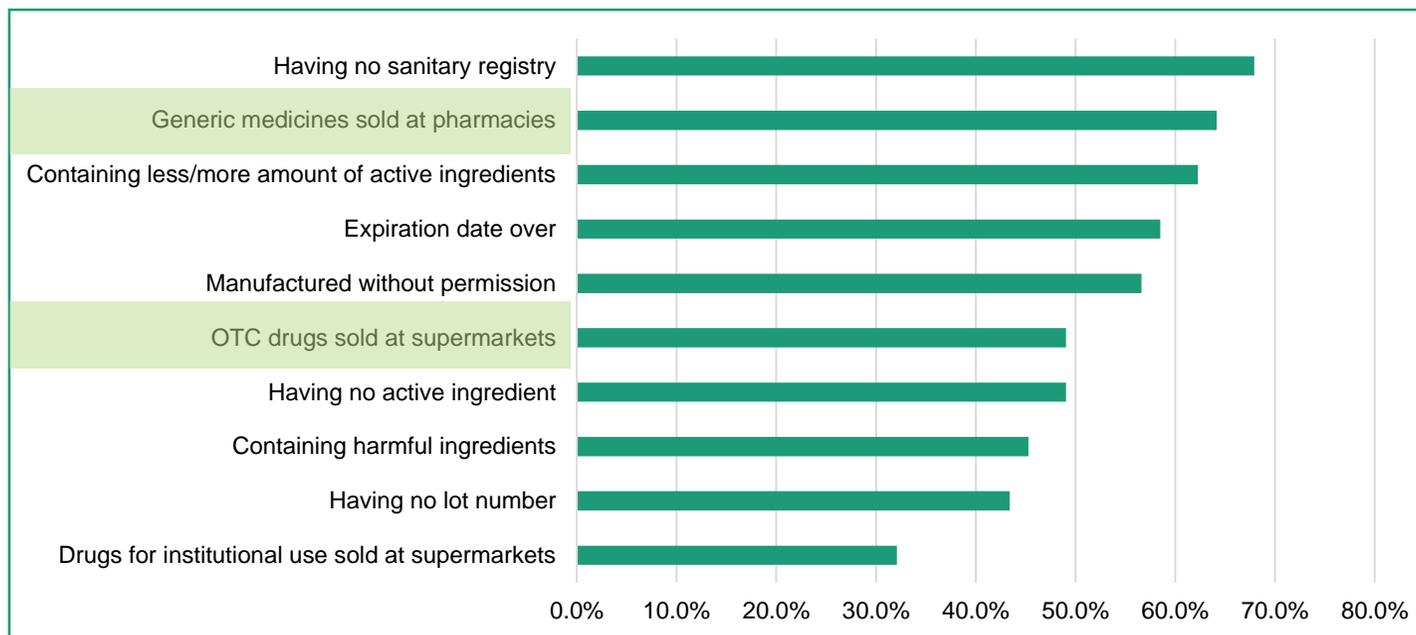
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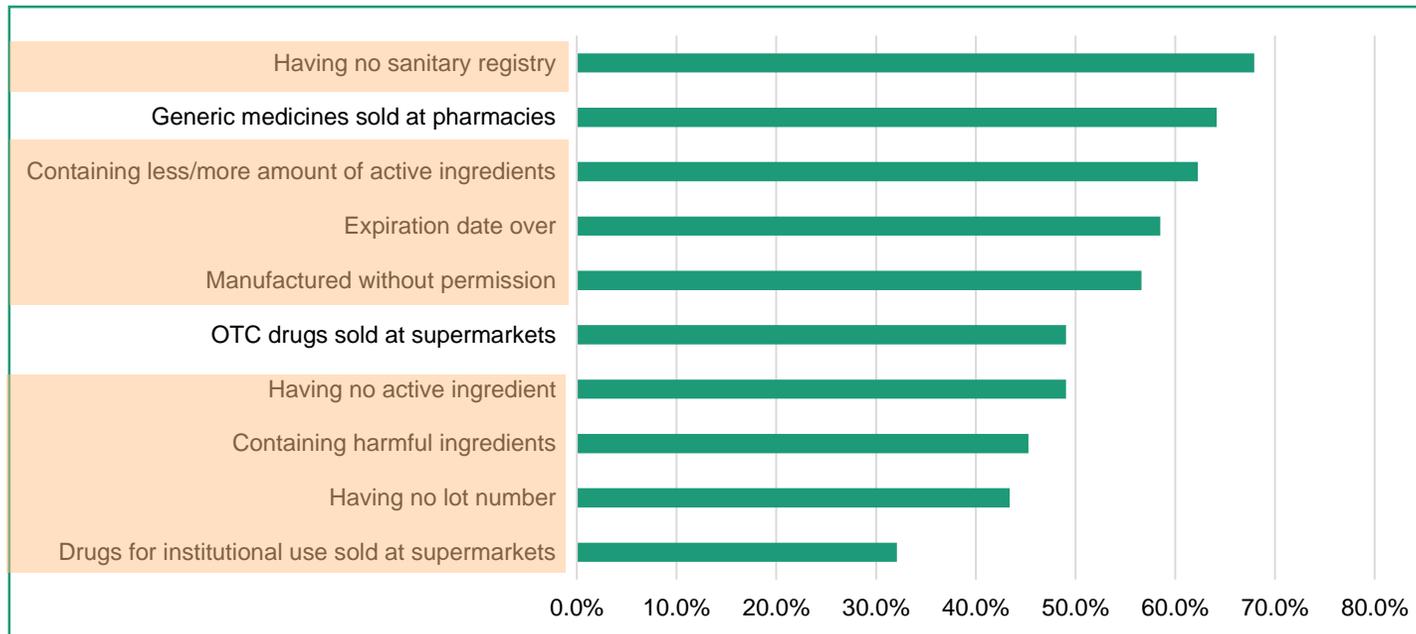
Legitimate drugs

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Click to see the correct answers

Legitimate  
drugs

Falsified/substandard  
drugs



# Survey

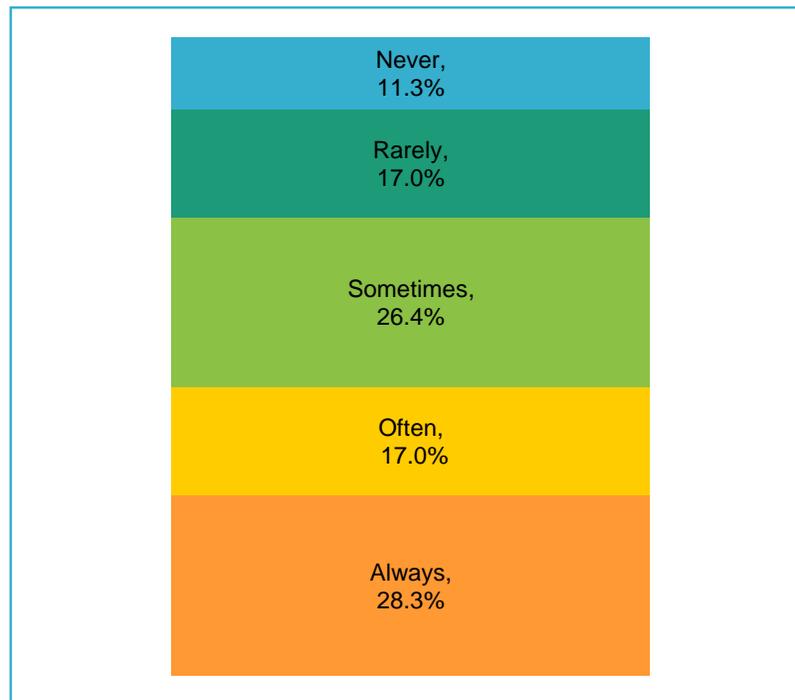


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- Click on the mer



The following chart shows the answers to the question:

## How often do you warn your patients against purchasing medicines from an unknown source?



- e problem
- itimate drugs



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- Click on the menu for more information.

- Demographic data
- About the problem
- Identify illegitimate drugs
- Patients

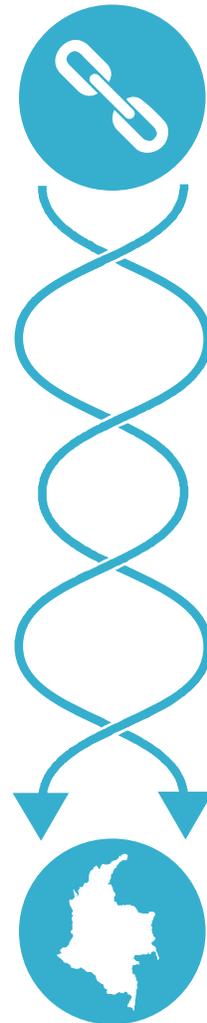
## Conclusions

- HCPs showed a **highly variable ability** to identify illegitimate drugs. The percentage of correct answers ranged between 33% and 68%.
- Around **4 out of 10** HCPs had never considered illegitimate drugs as a cause of their patient's symptoms.
- **More than 80%** of the surveyed HCPs didn't know how to report an adverse event related to substandard/falsified drugs.
- The above suggests that Colombian HCPs are generally aware of illegitimate drugs problem, however, **their ability to identify and report illegitimate drugs is low.**





# How can illegitimate drugs reach Colombian patients?



1

The pharmaceutical supply chain (PSC) is the means through which medicines are delivered to patients.(1)

2

Throughout the PSC, drugs change hands many times before reaching the patient. Every transaction is an opportunity for illegitimate products to infiltrate the market.(2)  
Compared to developed countries, developing countries have PSCs that are more vulnerable to illegitimate drugs.(2)

3

As a developing country, **Colombia is at high risk of being infiltrated by illegitimate drugs.**

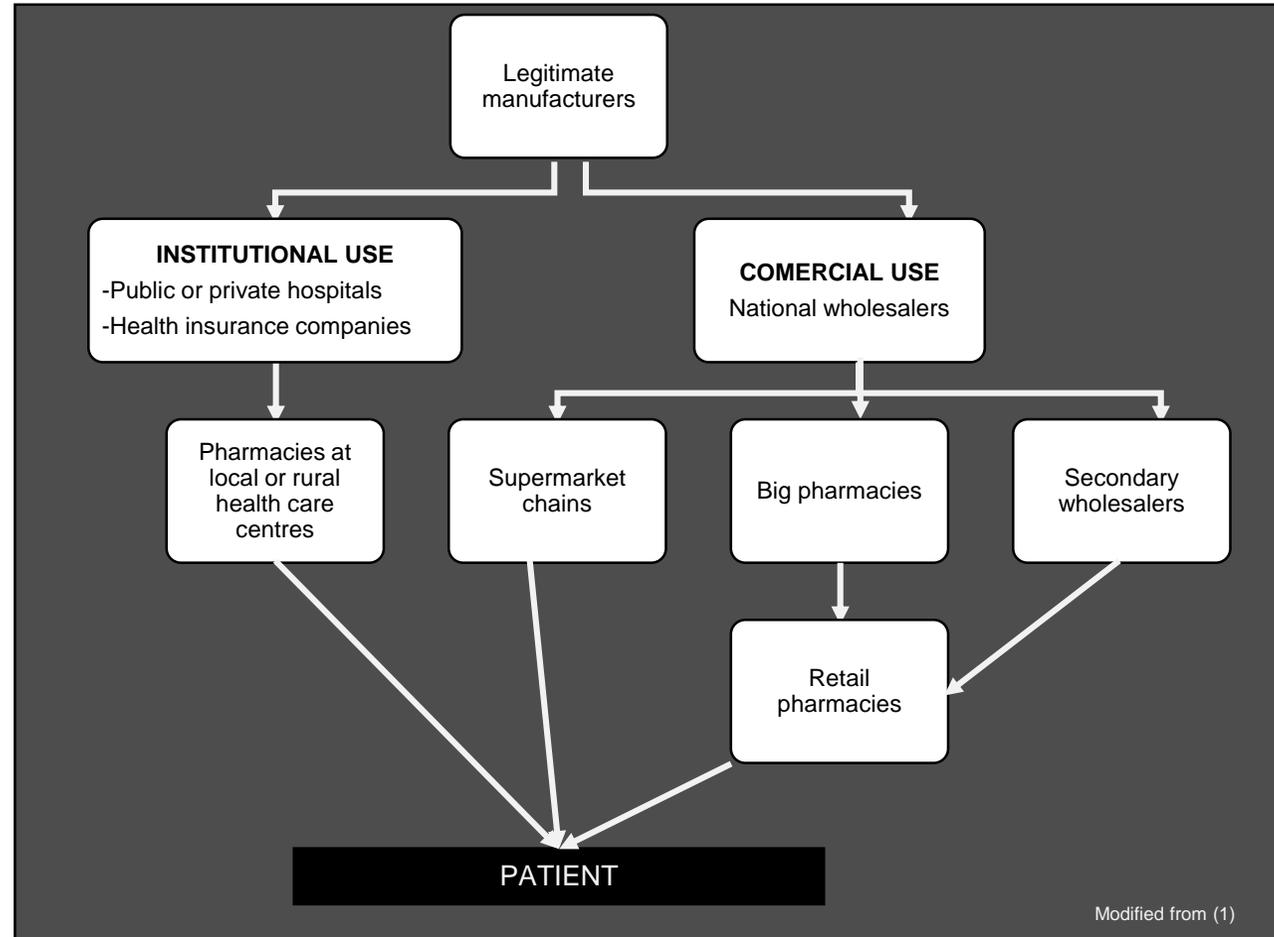
Colombian Supply Chain

(1) The Kaiser Family Foundation. Follow The Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain. <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/follow-the-pill-understanding-the-u-s-commercial-pharmaceutical-supply-chain-report.pdf>  
(2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

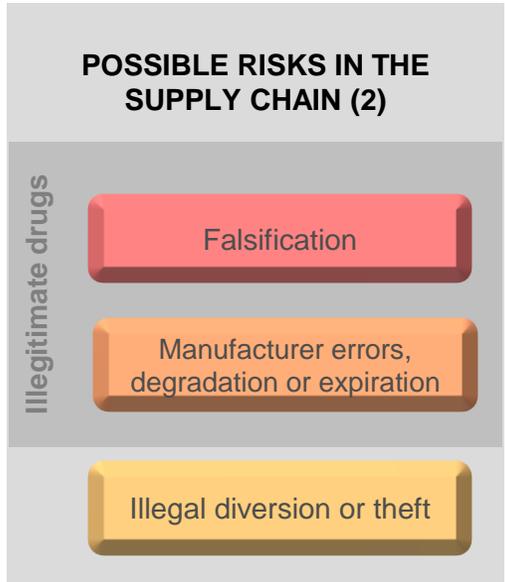




# Pharmaceutical Supply Chain in Colombia



## LEGITIMATE SUPPLY CHAIN (1)

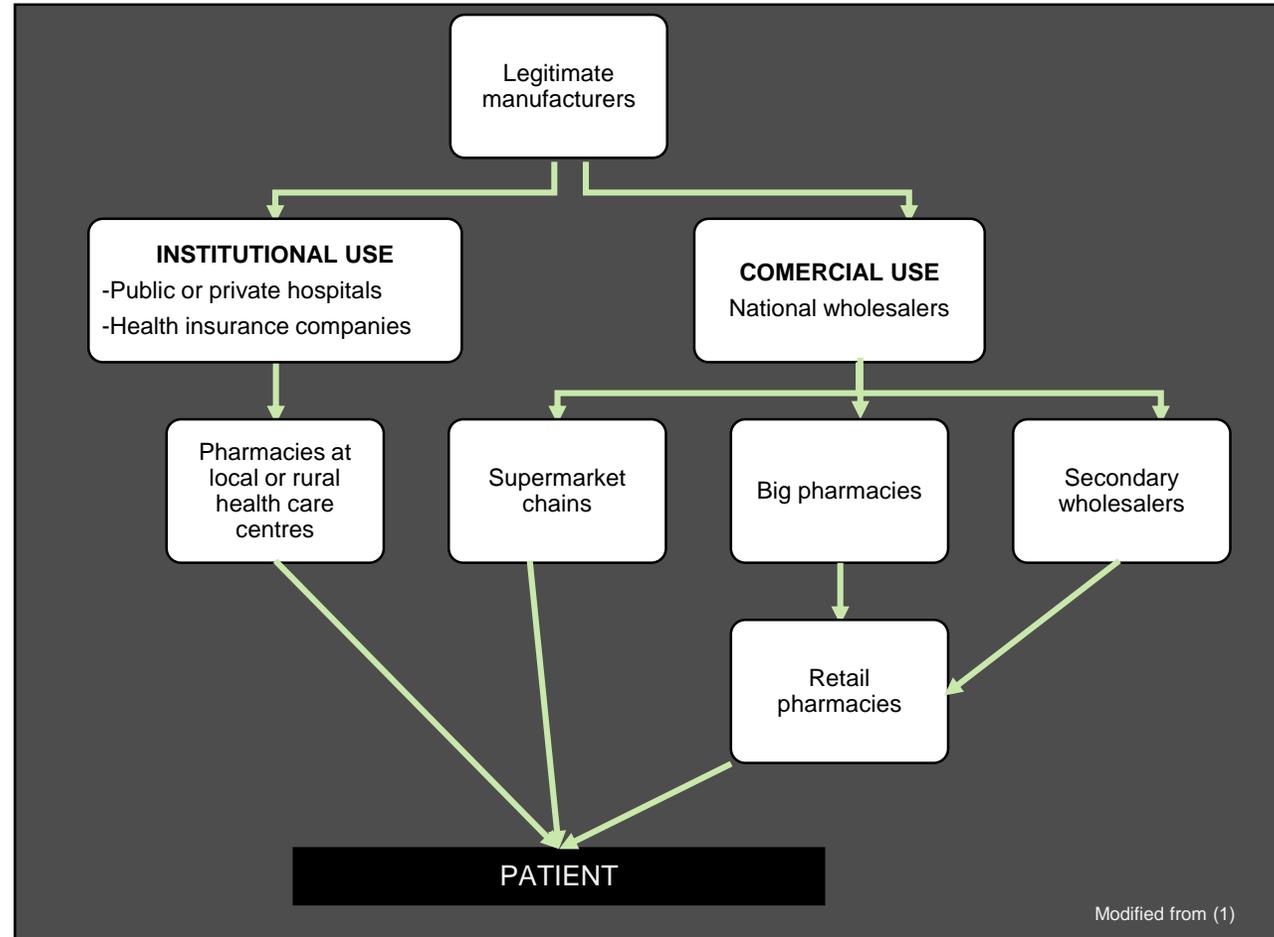


(1) Bustamante, A. Sector Farmacéutico Colombiano. Investigaciones Económicas. Corficolombiana. <http://www.corficolombiana.com.co/WebCorficolombiana/Repositorio/informes/archivo2262.pdf>  
(2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

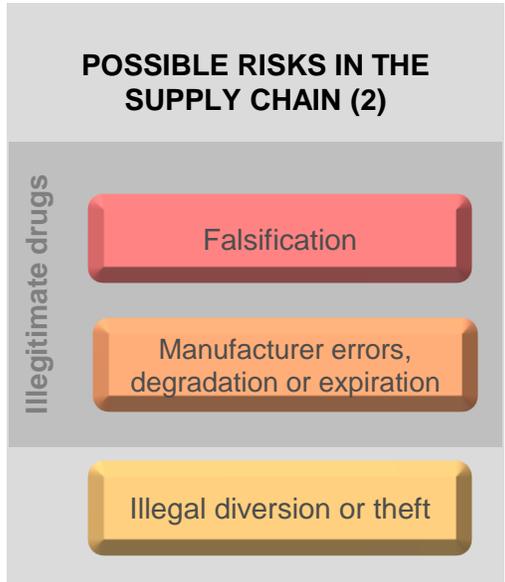




# Pharmaceutical Supply Chain in Colombia



## LEGITIMATE SUPPLY CHAIN (1)

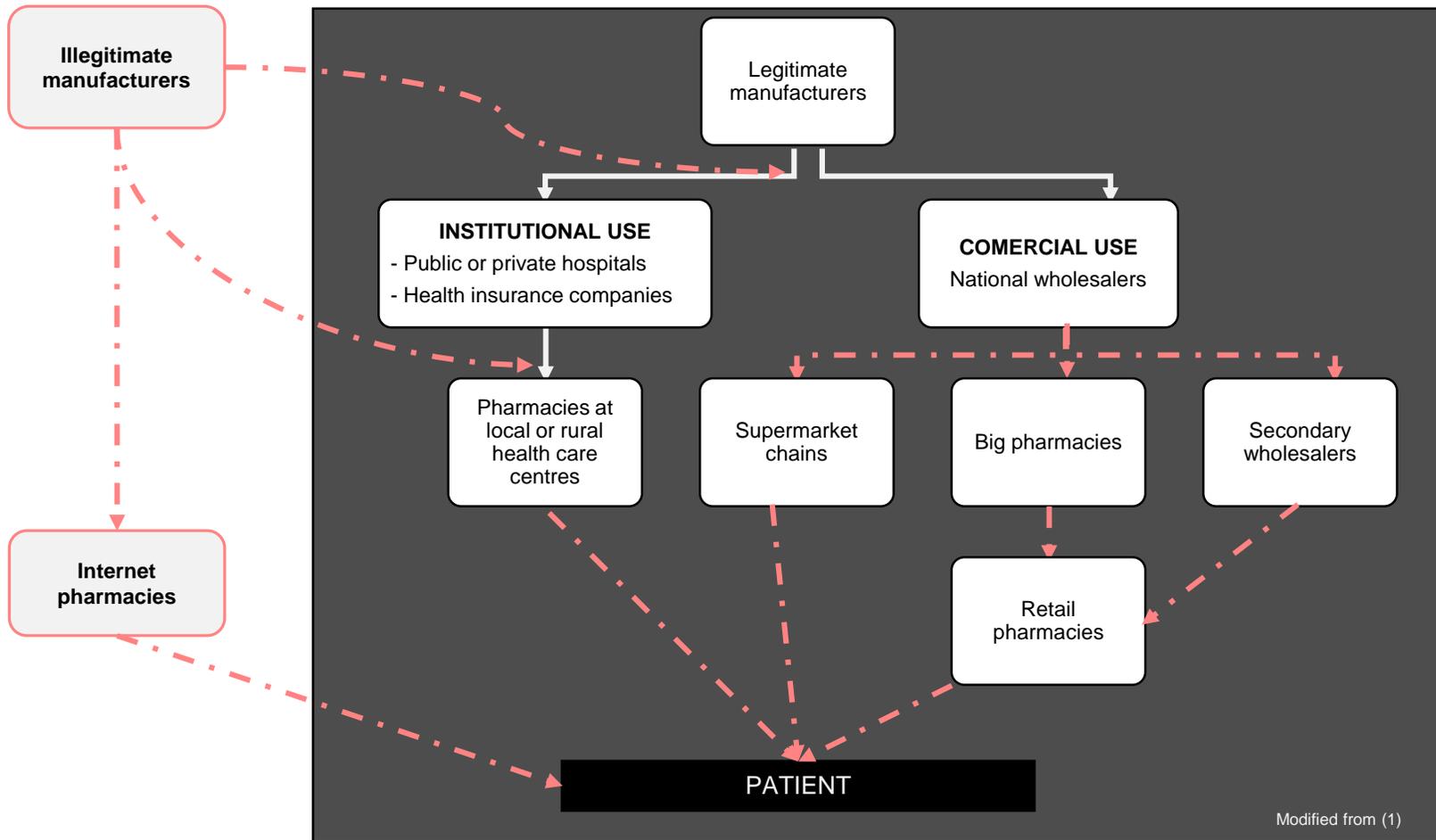


(1) Bustamante, A. Sector Farmacéutico Colombiano. Investigaciones Económicas. Corficolombiana. <http://www.corficolombiana.com.co/WebCorficolombiana/Repositorio/informes/archivo2262.pdf>  
(2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

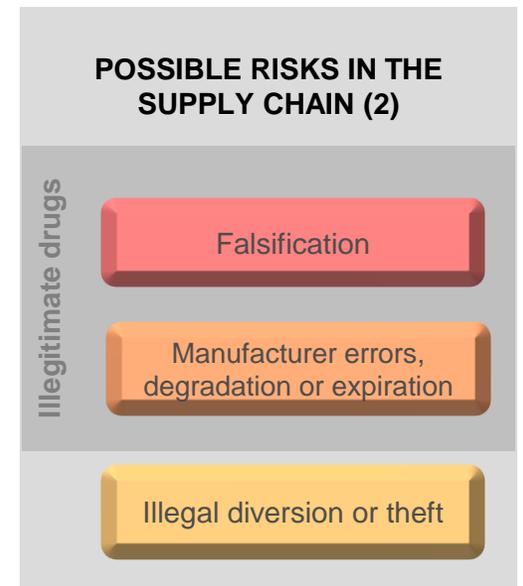




# Pharmaceutical Supply Chain in Colombia



## LEGITIMATE SUPPLY CHAIN (1)



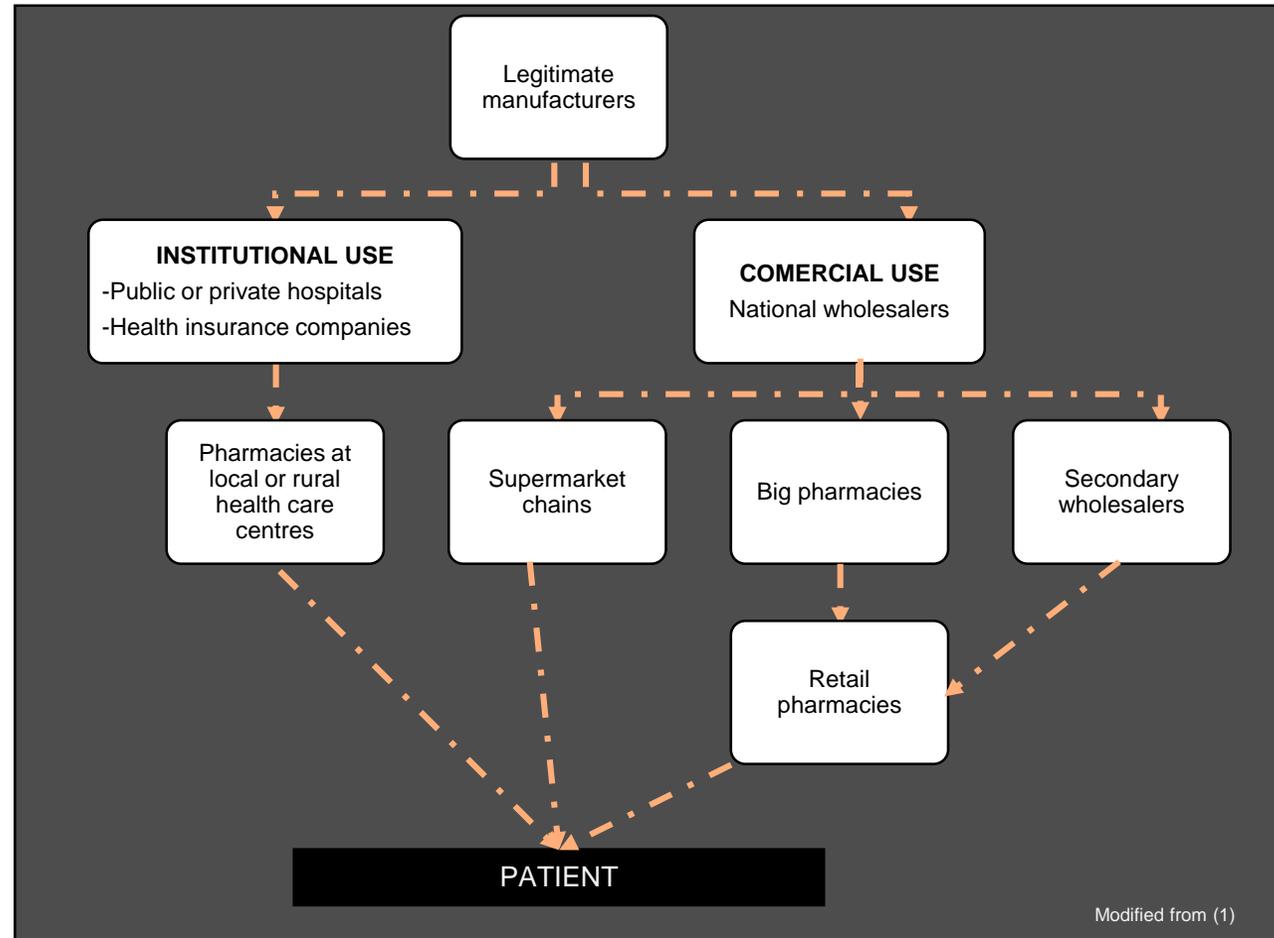
Modified from (1)

(1) Bustamante, A. Sector Farmacéutico Colombiano. Investigaciones Económicas. Corficolombiana. <http://www.corficolombiana.com.co/WebCorficolombiana/Repositorio/informes/archivo2262.pdf>  
(2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

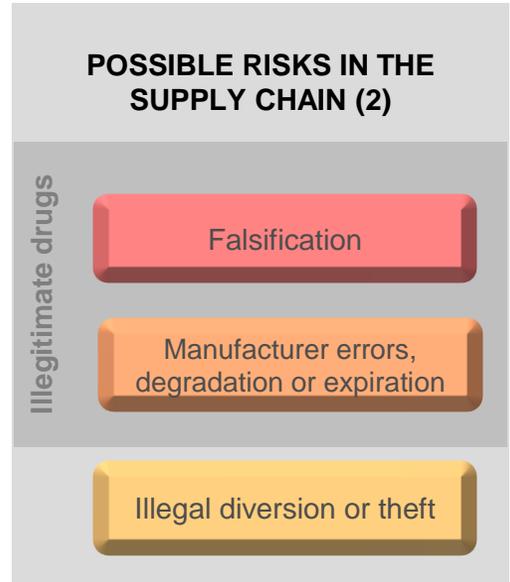




# Pharmaceutical Supply Chain in Colombia



## LEGITIMATE SUPPLY CHAIN (1)

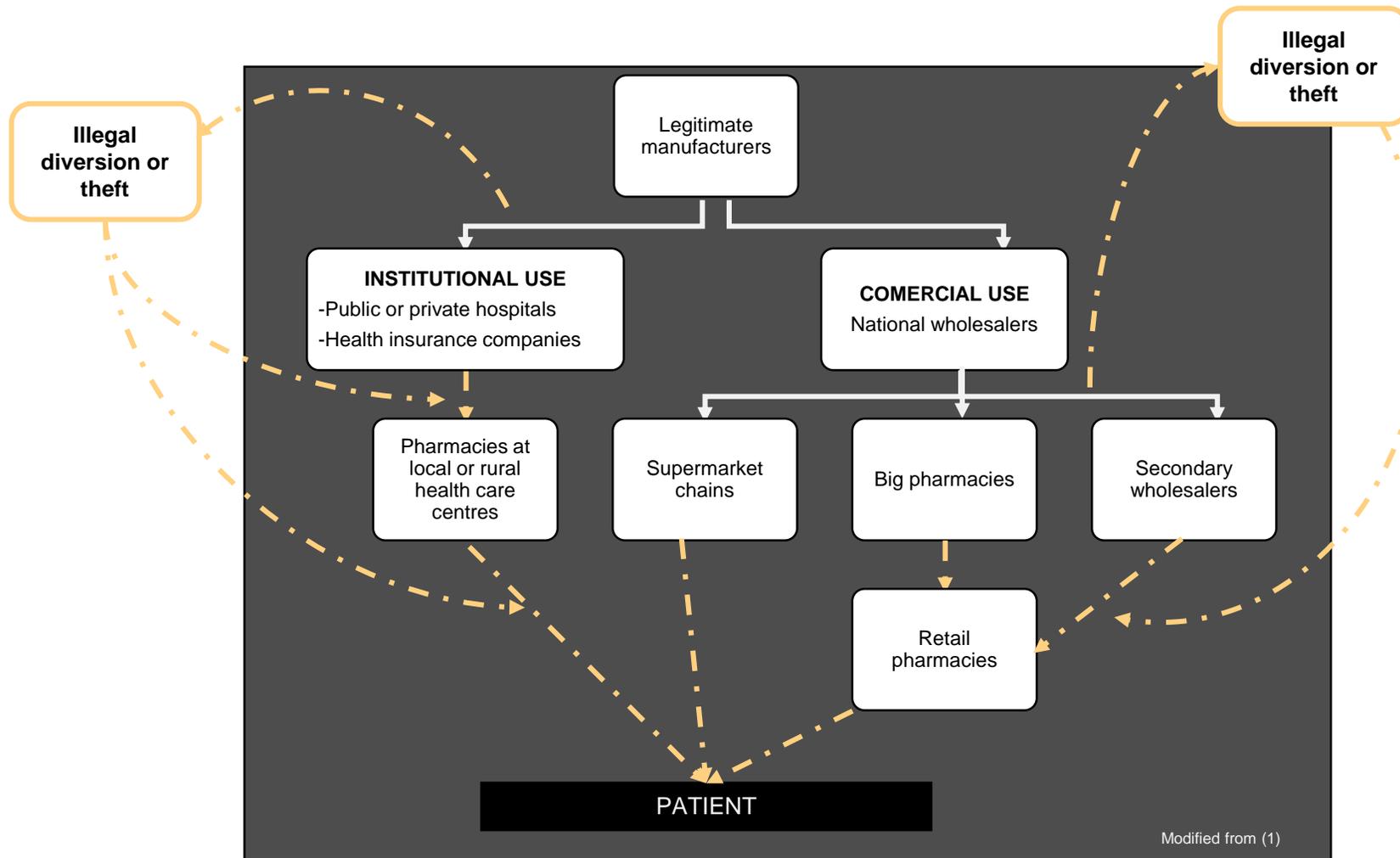


(1) Bustamante, A. Sector Farmacéutico Colombiano. Investigaciones Económicas. Corficolombiana. <http://www.corficolombiana.com.co/WebCorficolombiana/Repositorio/informes/archivo2262.pdf>  
(2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.





# Pharmaceutical Supply Chain in Colombia



## LEGITIMATE SUPPLY CHAIN (1)

### POSSIBLE RISKS IN THE SUPPLY CHAIN (2)

Illegitimate drugs

- Falsification
- Manufacturer errors, degradation or expiration
- Illegal diversion or theft

Modified from (1)

(1) Bustamante, A. Sector Farmacéutico Colombiano. Investigaciones Económicas. Corficolombiana. <http://www.corficolombiana.com.co/WebCorficolombiana/Repositorio/informes/archivo2262.pdf>  
 (2) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.



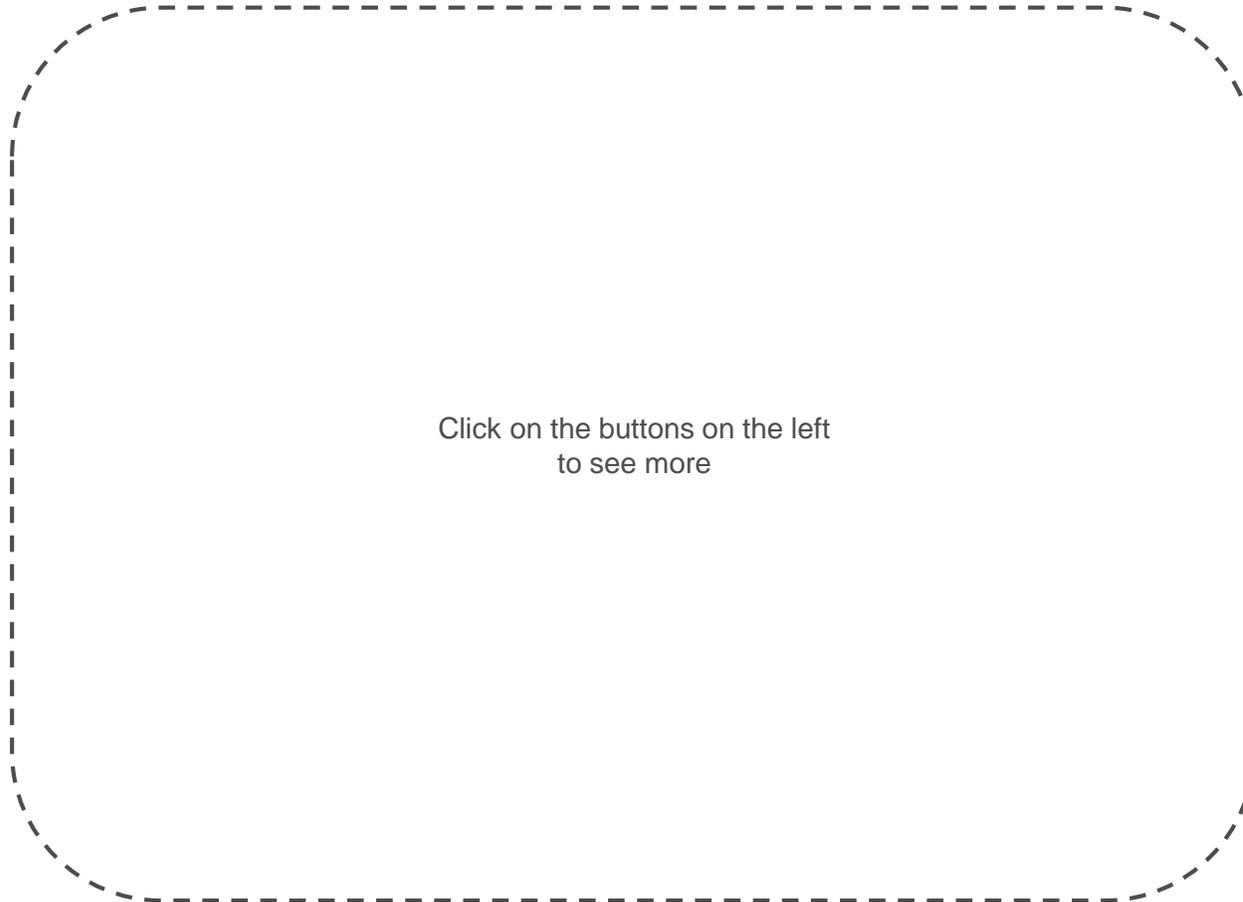
# Consequences of illegitimate drugs use

The use of illegitimate drugs has serious consequences from both health, economic and social perspectives.

Health  
issues

Economic  
issues

Social  
issues



(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Trop Med Int Health*. 2008;13(8):1062-72.





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issues

From a health perspective, illegitimate drugs can cause a wide spectrum of problems (2), for instance:

- Contamination can cause **fatal toxicity**.
- Lack of active ingredient can lead to **ineffective treatment** and **prolonged illness or death**.
- Under dosing of active ingredient promotes **drug resistance**.



(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Trop Med Int Health*. 2008;13(8):1062-72.





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The use of illegitimate drugs has serious consequences from both health, economic and social perspectives.

Health issues

Economic issues

Social issues

Illegitimate drugs use results in increased costs for the patient and for the health care system due to (1):

- Ineffective and prolonged **treatment**.
- Loss of **working** hours.
- Reduction of **antimicrobials'** lifespan.



(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

(2) Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Trop Med Int Health*. 2008;13(8):1062-72.





# Consequences of illegitimate drugs use

The use of illegitimate drugs has serious consequences from both health, economic and social perspectives.

Health  
issues

Economic  
issues

Social  
issues

Illegitimate drugs are problematic from a social perspective because (1):

- Consumers **lose confidence** in medicine, health care providers, and national regulatory agencies.
- The sale of falsified medicines funds **criminal activities** and conveys power to **corrupt officials**.

X

(1) IOM (Institute of Medicine). 2013. *Countering the problem of falsified and substandard drugs*. Washington, DC: The National Academies Press.

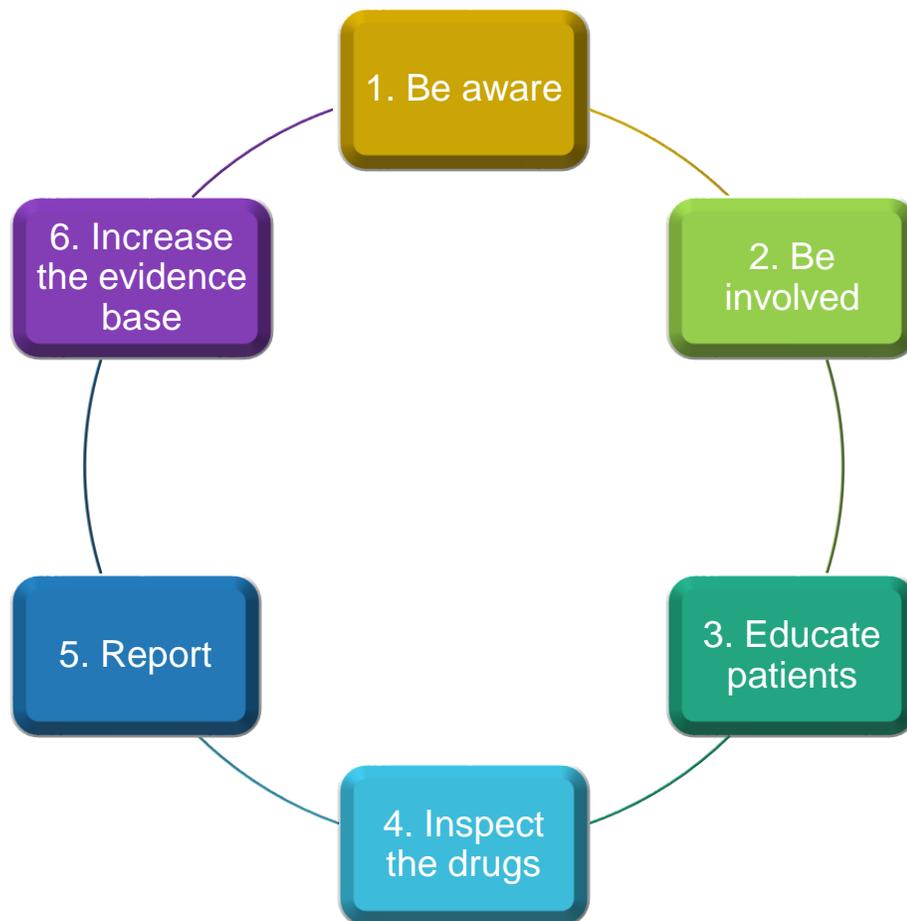
(2) Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Trop Med Int Health*. 2008;13(8):1062-72.



# What can doctors and nurses do to combat illegitimate drugs?



Health care providers can become key players in detecting and preventing the use of illegitimate drugs.





# 1. Be aware



If you observe or the patient reports that (1):

- The prescribed medicine has no effect or has an effect that is different to the expected outcome.
- The medicine packaging is not intact.
- The medicine has a different taste, consistency or appearance than usual.





## 2. Be involved in:

- National efforts to raise awareness and combat illegitimate drugs.(1)
- National monitoring and reporting systems.(1)
- Initiatives for appropriate legislation, drug regulation and law enforcement against illegitimate drugs.(1)
- Research into the most appropriate ways to tackle the issue of illegitimate drugs.



### 3. Educate patients to:

- **S**peak up if they have any queries about the medicine, the packaging, the expected health outcomes etc.;
- **A**sk questions about the medicine, its effects and possible side effects;
- **F**ind the facts about what the medicine should do (its expected health outcome);
- **E**valuate choices, understand the effect of the medicine and monitor effectiveness;
- **R**eport any lack of improvement in their health status, or unexpected or adverse events related to the medicine.<sup>(1)</sup>



(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf> .



## 4. Inspect the medicine



# Guide for doctors and nurses

- 1 THE CONTAINER
- 2 THE LABEL
- 3 TABLETS/CAPSULES

Click on this button to come back to this point



# 4. Inspect the medicine

## 1 THE CONTAINER

The container should (1):

- Protect the drug from the outside environment.
- Be appropriate for the drug inside.
- Be sealed.
- Have appropriate packing technology (e.g. holograms or barcodes).



Legitimate ciprofloxacin (left) and falsified ciprofloxacin (right) bought at pharmacies in Lagos, Nigeria. The falsified medicine was two-thirds talcum powder and contained no ciprofloxacin. (2)

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>

(2) The Lancet 2010 376, 1446-1448DOI: (10.1016/S0140-6736(10)61416-X)

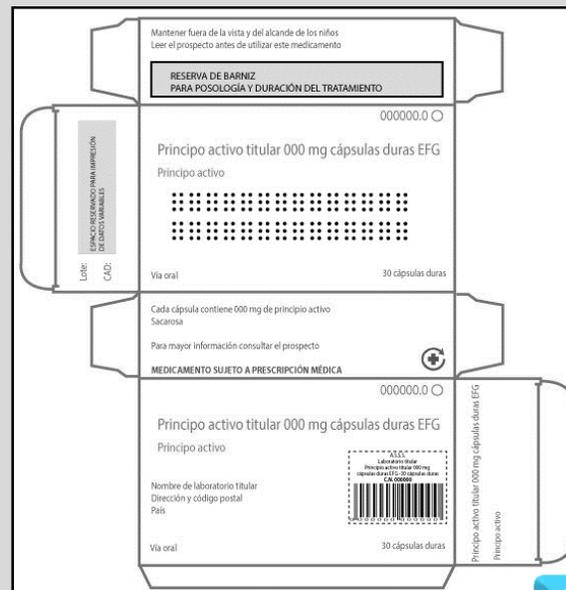


# 4. Inspect the medicine



## 2 THE LABEL

All information must be legible and indelible. Check that all the words are spelled correctly and the label and the container match (1):



Modified from (2)

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>

(2) <https://farmacondicionamiento.files.wordpress.com/2013/02/estuche-ejemplo.jpg>

# 4. Inspect the medicines

The diagram shows a medicine box with several labels and text. Blue arrows point from text labels on the left and right to specific parts of the box. The box contains the following text: 'Mantener fuera de la vista y del alcance de los niños. Leer el prospecto antes de utilizar este medicamento.'; 'RESERVA DE BARNIZ PARA POSOLOGÍA Y DURACIÓN DEL TRATAMIENTO'; '000000.0'; 'Principo activo titular 000 mg cápsulas duras EFG'; 'Principo activo'; 'Lote: CAD:'; 'Vía oral'; '30 cápsulas duras'; 'Cada cápsula contiene 000 mg de principio activo. Sacarosa.'; 'Para mayor información consultar el prospecto.'; 'MEDICAMENTO SUJETO A PRESCRIPCIÓN MÉDICA'; '000000.0'; 'Principo activo titular 000 mg cápsulas duras EFG'; 'Principo activo'; 'Nombre de laboratorio titular'; 'Dirección y código postal'; 'País'; 'Vía oral'; '30 cápsulas duras'; 'Principo activo titular 000 mg cápsulas duras EFG'; 'Principo activo'; and a barcode with 'ASIS' and 'Laboratorio titular' above it.

Labels on the left side:

- Dosage statement (if appropriate)
- The trade (brand) name
- The active ingredient name (scientific name/generic name)
- The date of manufacture and the expiry date
- The batch (or lot) number
- The manufacturer's full address

Labels on the right side:

- Storage information
- The medicine strength (mg/unit)
- The dosage form (e.g., tablet / capsule)
- The manufacturer's name and logo
- The number of units per container
- The sanitary registry number

# 4. Inspect the medicine

## 3 TABLETS/CAPSULES

All the tables/capsules should be (1):

- Uniform in shape, size, colour and texture.
- Free of breaks, cracks, splits or pinholes.
- Free of embedded surface spots and foreign particle contamination.
- Filled (no empty capsules should be present).
- Smell the same as the original.



Lipitor®. Falsified pills (left), legitimate pills (right). (2)

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>

(2) <http://www.pbs.org/wgbh/nova/next/wp-content/uploads/2013/08/lipitor-pills-1024x576.jpg>



# 5. Report illegitimate drugs in Colombia

By reporting adverse events, health care professionals can contribute to detect and prevent the use of falsified and substandard drugs.(1) Follow the recommendations below to effectively report an adverse event potentially related to illegitimate drugs:

-  Always report adverse events to the national regulatory authority (INVIMA).
-  Notify the authorities.
-  Inform your colleagues that there is a possibility of an illegitimate drug having entered the health care facility.

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>  
(2) Convenio por la legalidad de Medicamentos. <https://www.afidro.org/wp-content/uploads/Convenio-por-la-legalidad-de-los-medicamentos.pdf>





## 5. Report illegitimate drugs in Colombia



By reporting adverse events, health care professionals can contribute to detect and prevent the use of falsified and substandard drugs.(1) Follow the recommendations below to effectively report an adverse event potentially related to illegitimate drugs:



Always notify adverse events to the national regulatory authority

- Report all adverse events related to medicines (even if you think that the involved medicine is legitimate).
- Click [here](#) to learn how to notify adverse events in Colombia.

Report to authorities.



Inform your colleagues that there is a possibility of an illegitimate drug having entered the health care facility.

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>  
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# 5. Report illegitimate drugs in Colombia



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División de Seguridad de Medicamentos  
Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA  
Tel: (1) 2948700 Ext. 3915

Dirección de Impuestos y Aduanas Nacionales DIAN  
Línea Nacional: 018000 129 080  
Bogotá (1) 6079832 – 6079847 – 6079849  
Buzón: [denuncias@dian.gov.co](mailto:denuncias@dian.gov.co)

Unidad Anticorrupción y Delitos contra la Propiedad Intelectual  
Fiscalía General de la Nación  
Tel: 5958510 Ext. 218

Convenio por la Legalidad de Medicamentos  
Transversal 27ª No. 53B-13 – Tel: 3126542 Ext. 119  
[convenio.legalidadmedicamentos@asocoldro.com](mailto:convenio.legalidadmedicamentos@asocoldro.com)

drug having entered the health care facility.

(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>  
(2) Convenio por la legalidad de Medicamentos. <https://www.afidro.org/wp-content/uploads/Conevnio-por-la-legalidad-de-los-medicamentos.pdf>



# 5. Report illegitimate drugs in Colombia



By reporting adverse events, health care professionals can contribute to detect and prevent the use of falsified and substandard drugs.(1) Follow the recommendations below to effectively report an adverse event potentially related to illegitimate drugs:



Always notify adverse events to the national regulatory authority (INVIMA).

Informing your colleagues could help prevent additional illegitimate drug-related adverse events from occurring.

Report to authorities.



Inform your colleagues that there is a possibility of an illegitimate drug having entered the health care facility.



(1) International Council of Nurses. NURSES FOR PATIENT SAFETY: TARGETING COUNTERFEIT AND SUBSTANDARD MEDICINES. <http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf>  
(2) Convenio por la legalidad de Medicamentos. <https://www.afidro.org/wp-content/uploads/Convenio-por-la-legalidad-de-los-medicamentos.pdf>





# 6. Increase the evidence base

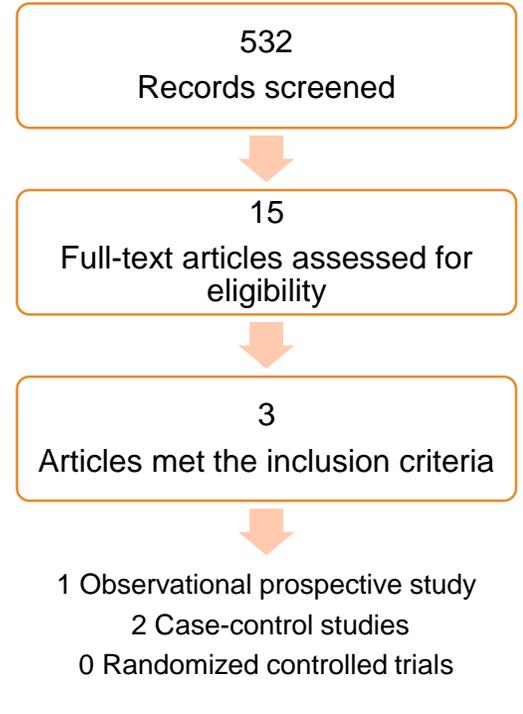
## Background:

- There is insufficient evidence regarding effective interventions to prevent and detect the use of illegitimate drugs.(1)

## Methodology:

- In order to explore the evidence in Latin America and the Caribbean countries, a systematic literature review was conducted.(2)
- In order to encompass Latin American literature the search was performed in international and Latin American electronic databases.

## Review Process:



## Main conclusion:

Randomized controlled trials are needed to more accurately evaluate the effectiveness of different interventions to prevent and detect the use of illegitimate drugs in Latin America and the Caribbean.

(1) El-Jardali F, Akl EA, Fadlallah R, et al. Interventions to combat or prevent drug counterfeiting: a systematic review. *BMJ Open* 2015;5:e006290. doi:10.1136/bmjopen-2014-006290  
 (2) Mahecha MP, et al. Data unpublished.



# 6. Increase the evidence base

## Background:

- There is insufficient evidence on the effectiveness of interventions to prevent and detect the use of illegitimate drugs in Latin America and the Caribbean.

## Methodology:

- In order to explore the available scientific evidence regarding effective interventions to prevent and detect the use of illegitimate drugs in Latin America and the Caribbean, a systematic literature review was conducted.
- With the objective of identifying the available scientific evidence on the effectiveness of interventions to prevent and detect the use of illegitimate drugs in Latin America and the Caribbean, a systematic literature review was conducted.

## Main conclusions:

Randomized controlled trials and observational studies are needed to evaluate the effectiveness of interventions to prevent and detect the use of illegitimate drugs in Latin America and the Caribbean.

## Illegitimate drugs in Latin America and the Caribbean: Systematic Literature Review (2)\*

### Preliminary conclusions:

- The available scientific evidence regarding effective interventions to prevent and detect the use of illegitimate drugs in Latin America is **scant and based primarily on observational studies**.
- The available evidence suggests that:
  - The implementation of drug quality monitoring programs (that include in-field visual and physical inspection as well as laboratory analyses) could help to improve the quality of drugs in the public sector.
  - Reporting and studying adverse event outbreaks through case-control studies could help to detect the contamination of medicines and to prevent new cases of toxicity or death.

\*For more information concerning the systematic literature review, please contact: Maria Mahecha ([illegitimatedrugslatam@gmail.com](mailto:illegitimatedrugslatam@gmail.com))



# Links to related content

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You can find more information regarding illegitimate drugs and additional resources for health care professionals in the following links:

- <http://www.iracm.com/flip/brochures/ukint/mobile/#p=1>
- <http://www.iracm.com/flip1506/mobile/#p=8>
- <http://www.iracm.com/elearnlanding/sp/>
- <http://fightthefakes.org/>