

**International Federation
of Pharmaceutical
Manufacturers & Associations**



Counterfeit Medicines: how to fight a public health threat?

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IFPMA**

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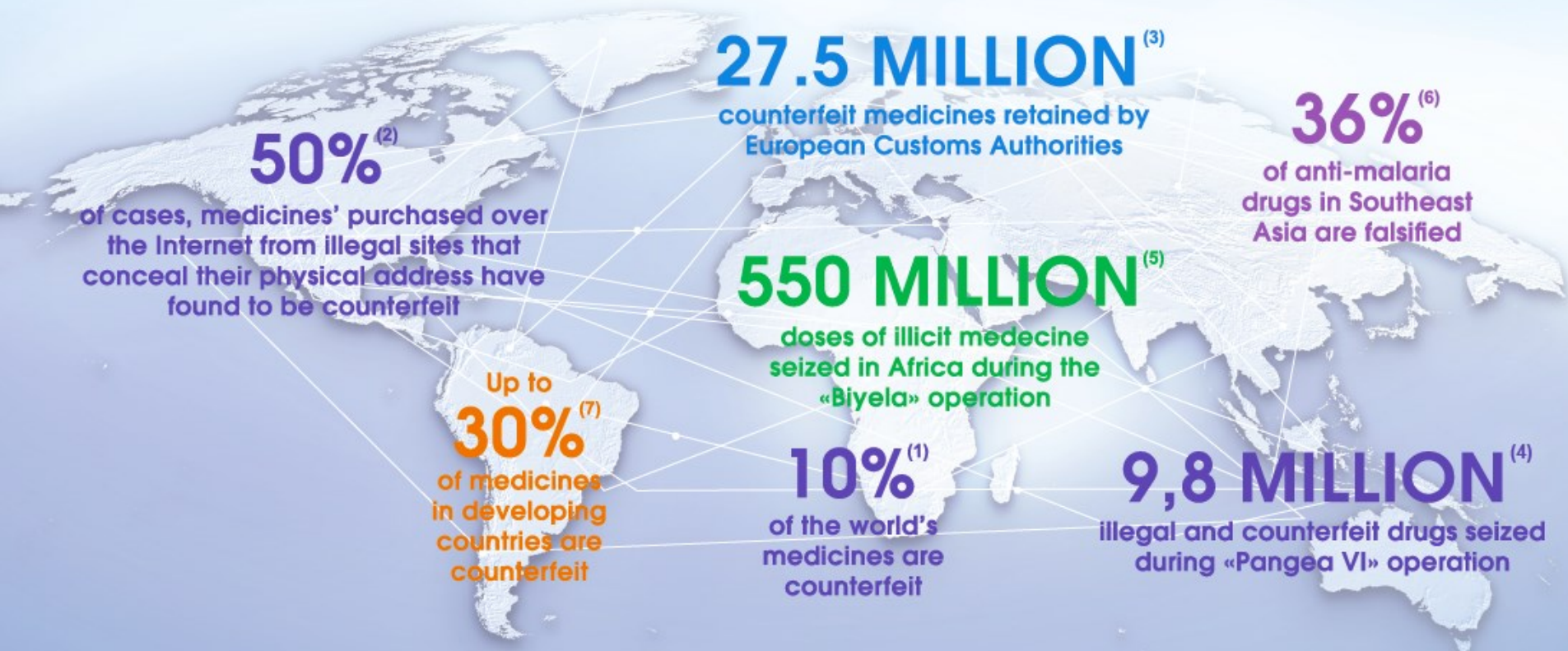
“Combating Counterfeit and Substandard ICT Devices”



“The IFPMA advocates policies that encourage discovery of and access to life-saving and life-enhancing medicines to improve the health of people everywhere”

A public health threat

PHARMACEUTICAL COUNTERFEITING, THE VISIBLE PART OF THE ICEBERG



A highly profitable crime

**SAME PACKAGING,
SAME SHAPE
AND SAME COLOR...**

BUT FAKES!



SPEAK UP ABOUT FAKE MEDICINES

www.fightthefakes.org

PILLS THAT DO NOT ACTUALLY
CONTAIN WHAT WE THINK THEY DO

- * no active ingredient
- * wrong ingredient
- * wrong dose
- * dangerous substances



...and that are concocted in unsanitary and unregulated conditions, like in garages, warehouses or shacks.

- * Can mimic **brand-name** or **generic** prescription or **over-the-counter** medicines.
- * From antibiotics to pain medications... **More than 500 fake versions of pharmaceutical products** are currently circulating.¹
- * **Over 50% of medicines** purchased from **illegal websites** that hide their physical address are fake.²
- * **Most of fake medicines** penetrating the legitimate medicine supply chain are knock offs of **lifesaving medicines**.

A DANGER
BUSINESS
PUTS PATIE
LIVES AT RI



\$75/\$200 BILLION



Highly profitable crime that could
be worth between \$75 billion and
\$200 billion a year.⁶

15%



15% of medicine
circulation world-wide
may be fake.⁴

Each year, fake medicines
may account for up to 30% of
medicines in circulation.

medicines.⁵

\$200 billion a year.⁶

patients into
deceitful

EVERY YEAR.³

BILLION



crime that could
\$75 billion and

\$200 billion a year.⁶



A crime against patients

- Fake medicines pose global public health risks leading to **resistance** to treatment, illness, disability and even **death**
- Fake medicines undermine patients' **trust in health systems** and their governments, and in providers
- Patients, Governments, Health Professionals and Manufacturers, are **all affected**

10 key principles

IFPMA'S 10 PRINCIPLES ON COUNTERFEIT MEDICINES



1 COUNTERFEITING IS A CRIME!

By deliberately and deceitfully attempting to pass themselves off as something that they are not, namely genuine approved medicines, counterfeit medicines pose a global public health risk that can lead to resistance to treatment, illness, disability and even death.



2 COUNTERFEITERS DO NOT DISCRIMINATE BETWEEN MEDICINES

They can be falsified versions of patented medicines, generic medicines or over-the-counter medicines and exist in all therapeutic areas (even traditional medicine). They range from medicines with no active ingredients to those with dangerous adulterations.



3 PATENTS HAVE NOTHING TO DO WITH FAKE MEDICINES

Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the production of falsified versions of genuine approved medicines.



4 COUNTERFEIT AND SUBSTANDARD MEDICINES ARE NOT THE SAME

A medicine which is approved and legally manufactured but does not meet all quality criteria is substandard, and may pose a significant health risk but should not be regarded as counterfeit. However, all counterfeits are, by their nature, illegal and therefore substandard.



5 FAKE AND ILLEGAL MEDICINES ARE NOT THE SAME

A medicine that is authorized for marketing by one regulatory authority but not by another should not be regarded as counterfeit on these grounds alone in the latter's territory.



6 EMPOWER REGULATORS

While the incidence of counterfeit medicines occurs in both developed and developing countries, the problem is more prevalent in countries where regulatory oversight and enforcement are weak.



7 COUNTERFEIT MEDICINES TRADE MUST BE STOPPED

Countries should be encouraged to adopt measures that will stop trade in medicines that do not contain the ingredients that they purport to contain.



8 COUNTERFEIT MEDICINES ARE EVERYBODY'S BUSINESS

Public and private organizations; national regulatory and enforcement agencies; health professionals; patients; research-based and generic pharmaceutical manufacturers; drug distributors, wholesalers and retailers: all play a role in preventing counterfeits from reaching patients.



9 GLOBAL COOPERATION IS NEEDED

Because counterfeiting does not recognize borders, new mechanisms that bring together the expertise of medicines regulatory agencies, enforcement agencies, healthcare providers and the private sector in a unique global platform should be supported.



10 WHO GLOBAL COORDINATION IS NECESSARY

Patients need to be protected worldwide. As the leader on global health matters, and particularly with respect to threats to public health in developing countries, the World Health Organization has a key role to play. Strong coordination among international organizations is needed to ensure that all aspects of this problem are adequately addressed.



A multistakeholder issue



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Governments

Regional
Organizations

WHO

Academics

UNODC

Healthcare
Professionals

OECD

Patients
Organizations

WIPO

NGOs

WCO

Pharma
industry

Interpol

R&D Pharmaceutical industry engagement: a multi-pronged approach



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Public Affairs and
Communication

Regulatory
and
Enforcement

Policy
Research and
Data
Collection

Pharmaceutical
Security
Institute

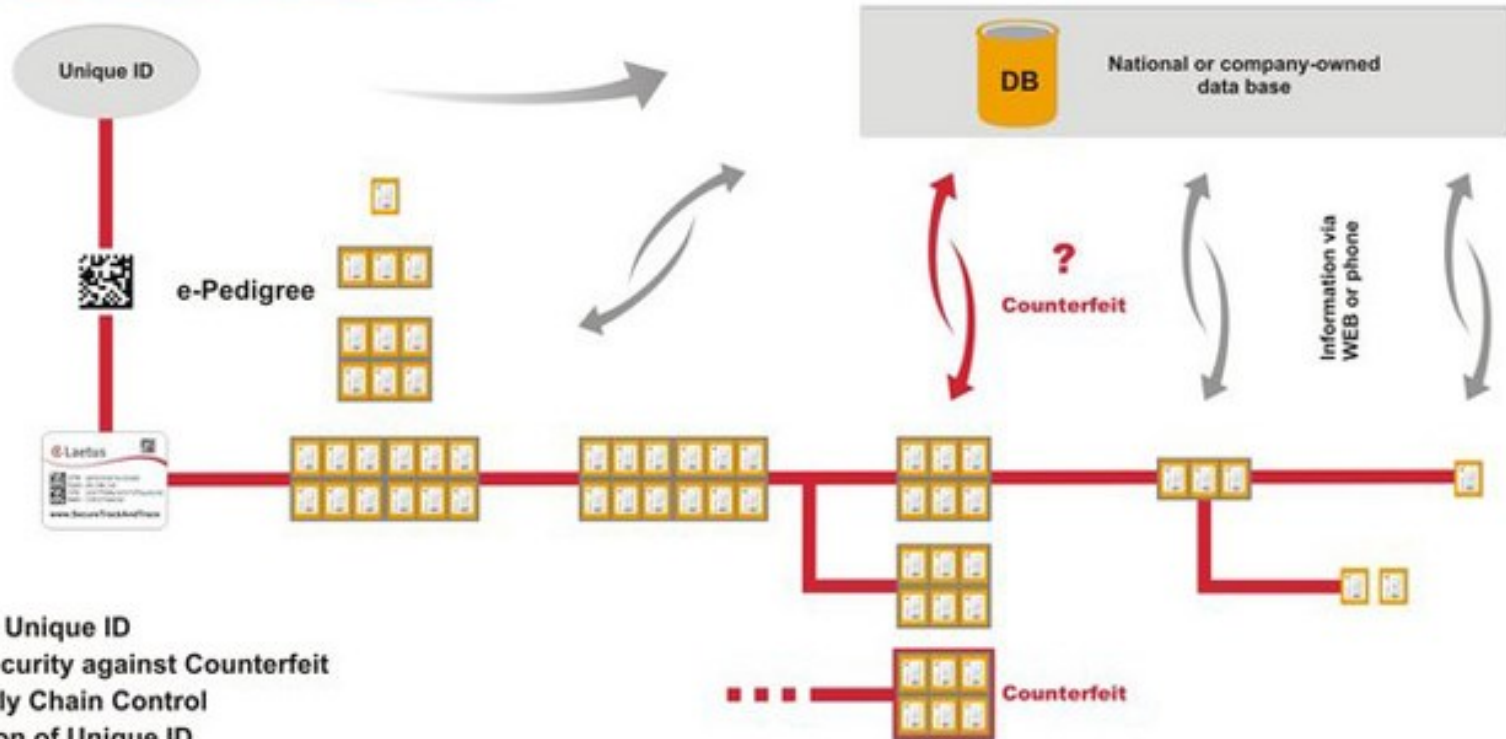


Can technology prevent pharmaceutical crime?



- No single solution
- A holistic approach
- Tight control throughout the global supply chain
- Constant updating of tactical countermeasures
- Tougher legislation and deterrent custodial sentencing
- Coordination and cooperation

Secure Track & Trace



- Worldwide Unique ID
- Highest Security against Counterfeit
- Total Supply Chain Control
- Combination of Unique ID and Supply Chain Location



Pharma manufacturer
Aggregation



Wholesaler
Splitting



Retailer
Splitting



Hospital
Splitting



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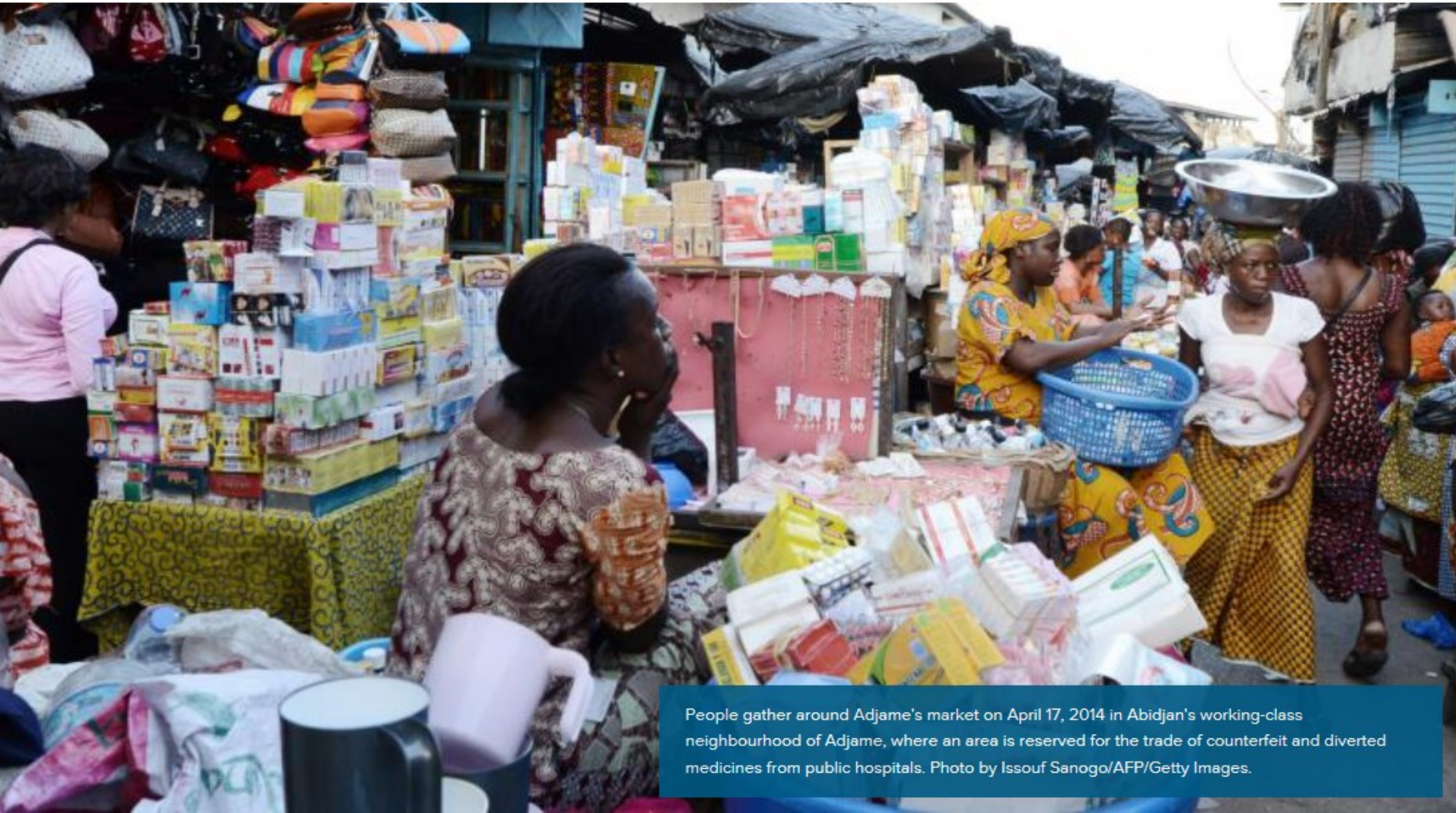
Track and trace or 'point-of-dispense'

- *EFPIA: "Track and trace provides the same basic functions as a 'point-of-dispense' Verification System, but requires greater logistical capabilities throughout the supply chain in order to track full product location and product movements"*

The reality of some markets...

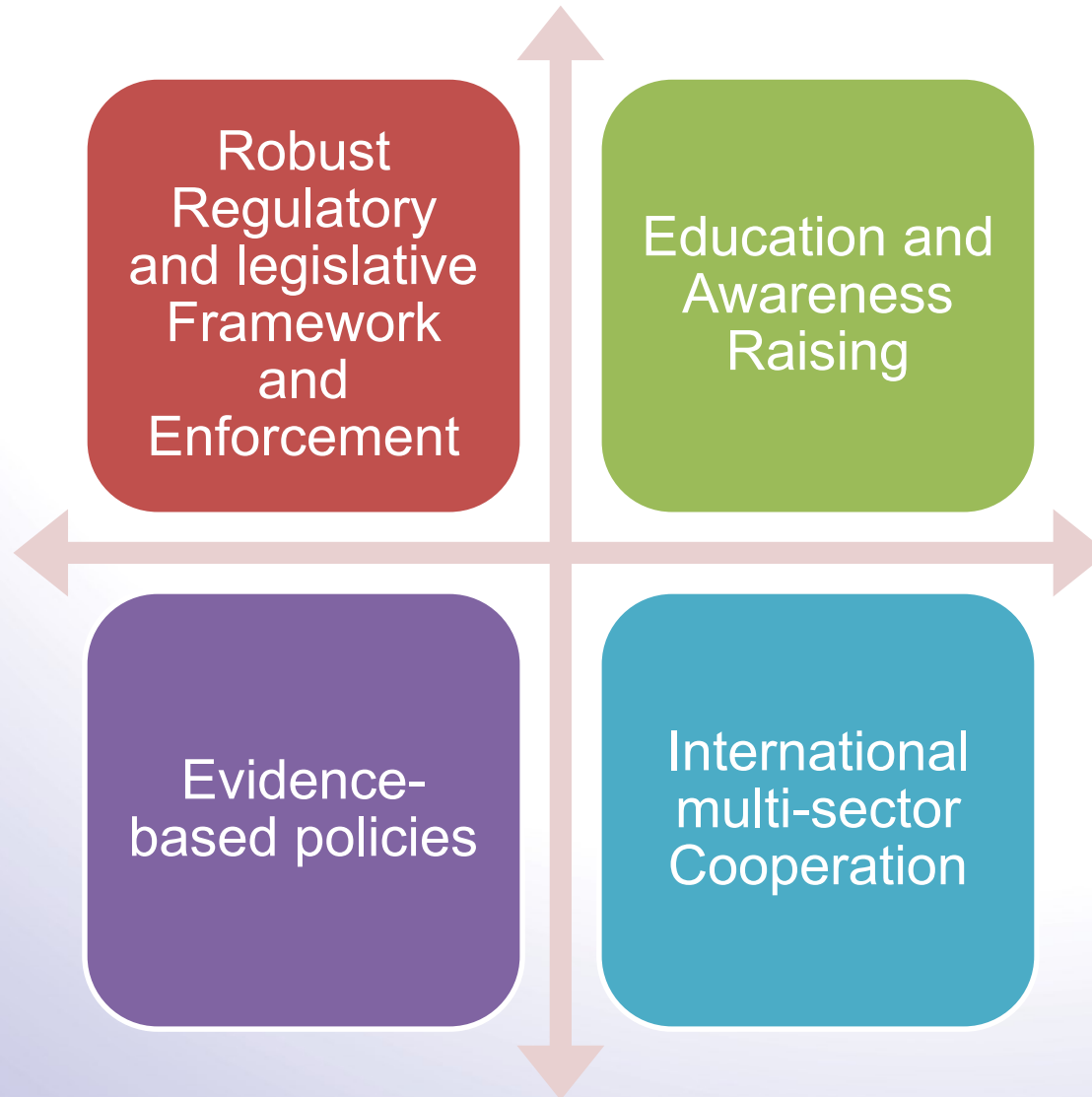


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People gather around Adjame's market on April 17, 2014 in Abidjan's working-class neighbourhood of Adjame, where an area is reserved for the trade of counterfeit and diverted medicines from public hospitals. Photo by Issouf Sanogo/AFP/Getty Images.

Challenges





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Thank you