
WHO's work to combat substandard-falsified medical products

“World Together Against Substandard and Falsified Medical Products”

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Global surveillance and monitoring system

WHO Regulation and Prequalification



What is the problem, why it exists and how to solve it

WHO working definitions

Unregistered

Medical products that have not undergone evaluation and/or approval by the NRA for the market in which they are distributed or used, subject to conditions under national regulation and legislation.

Substandard

Also called 'out of specification', these are authorized medical products that fail to meet either their quality standards or their specifications, or both. e.g. manufacturing error

Falsified

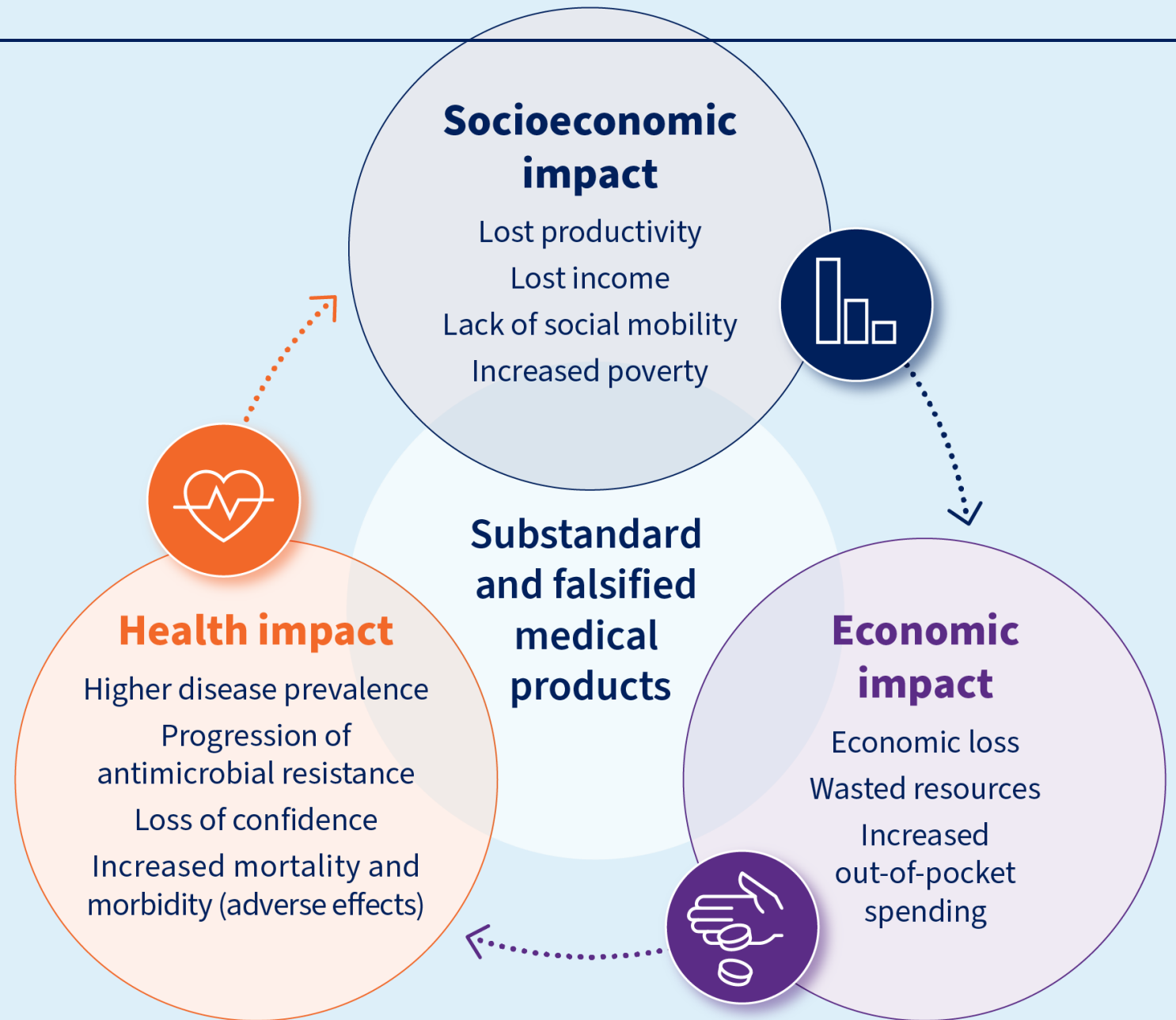
Medical products that **deliberately/fraudulently** misrepresent their identity, composition or source. Intellectual property rights considerations do not fall within this definition.

✓ "*Identity*" refers to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

✓ "*Composition*" refers to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRA.

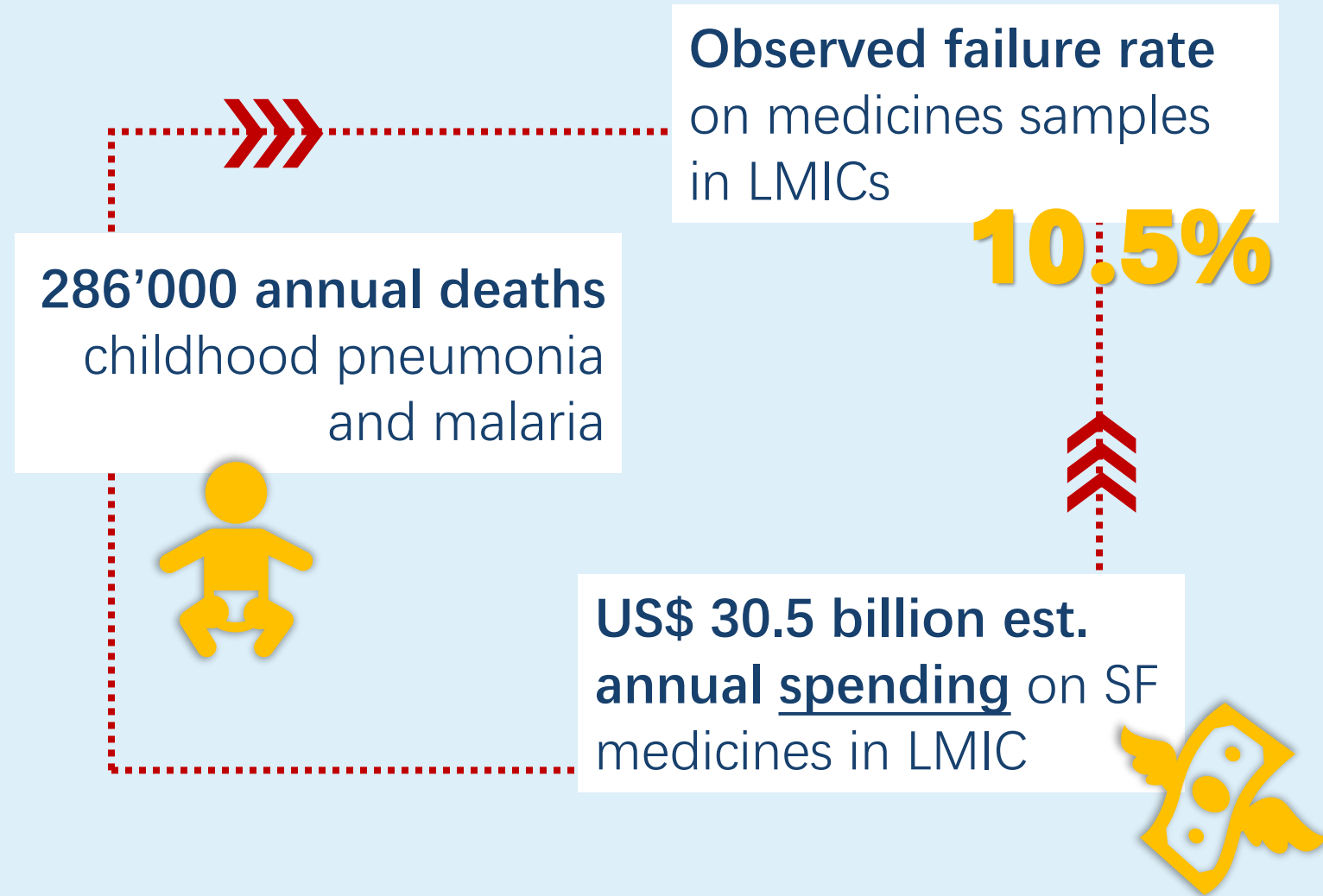
✓ "*Source*" refers to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Impact of substandard and falsified medical products

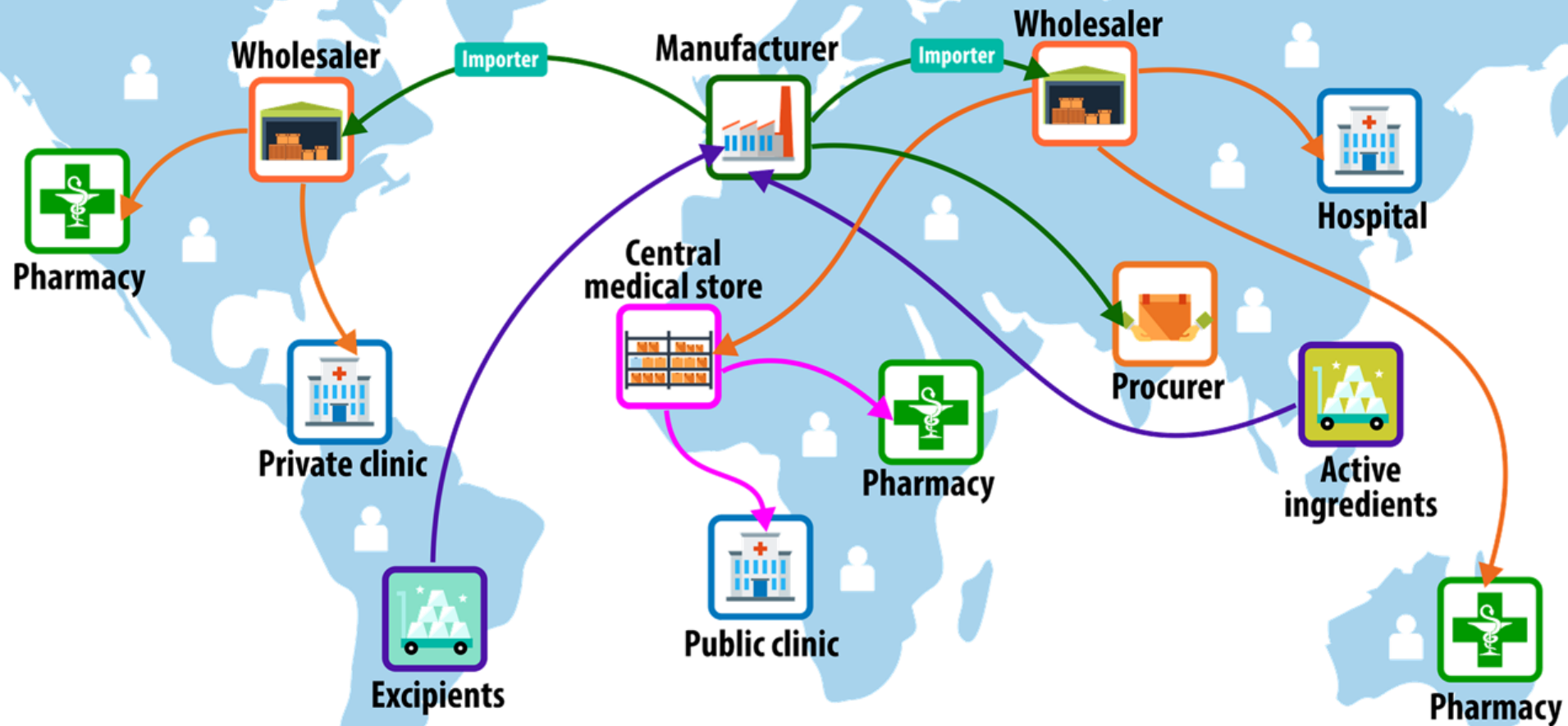


Impact models (2017)

- Children under 5
- sub-Saharan Africa
- Pneumonia or malaria



Globalized markets, heterogeneous systems



Medical product life cycle

multiple stakeholders contribute to ensuring quality, safety and access

Legislation



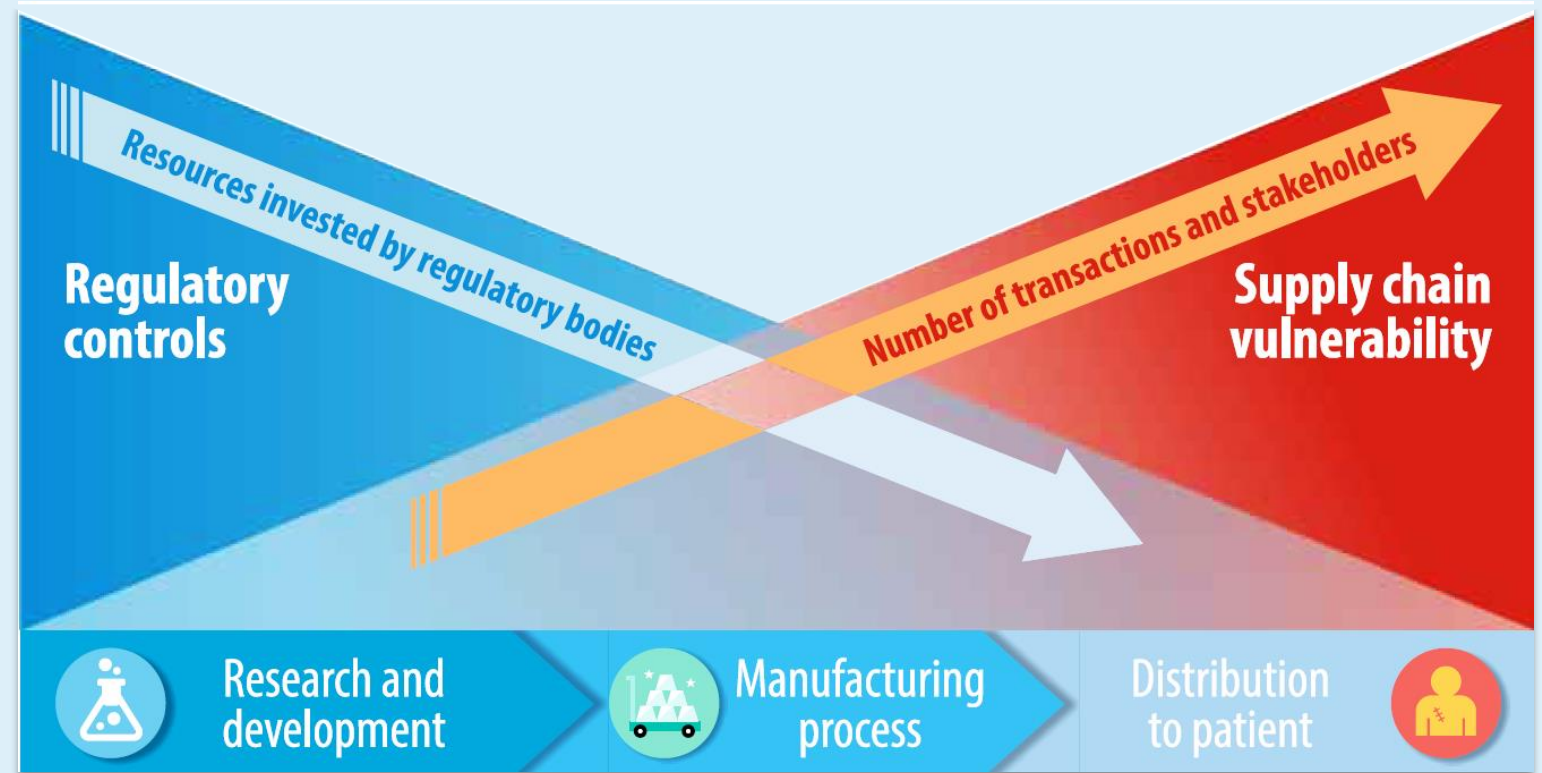
Regulation



Governance

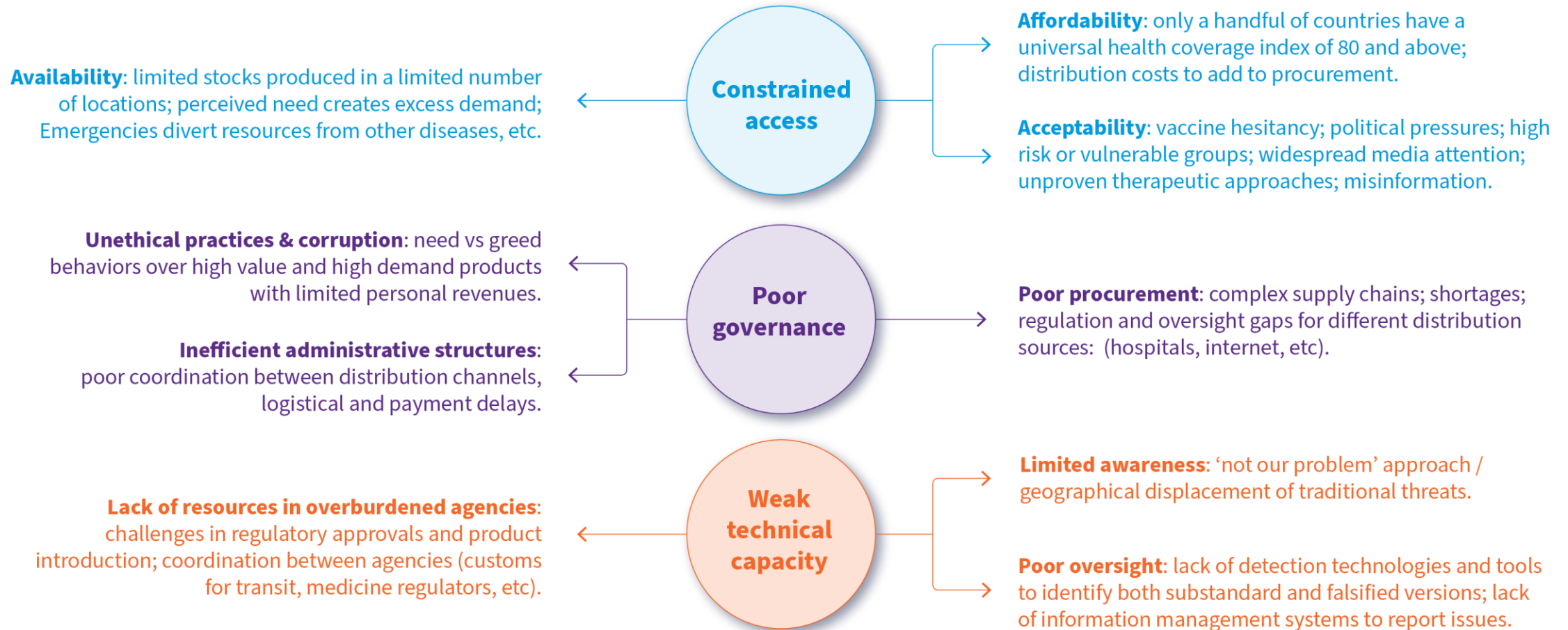


Monitoring

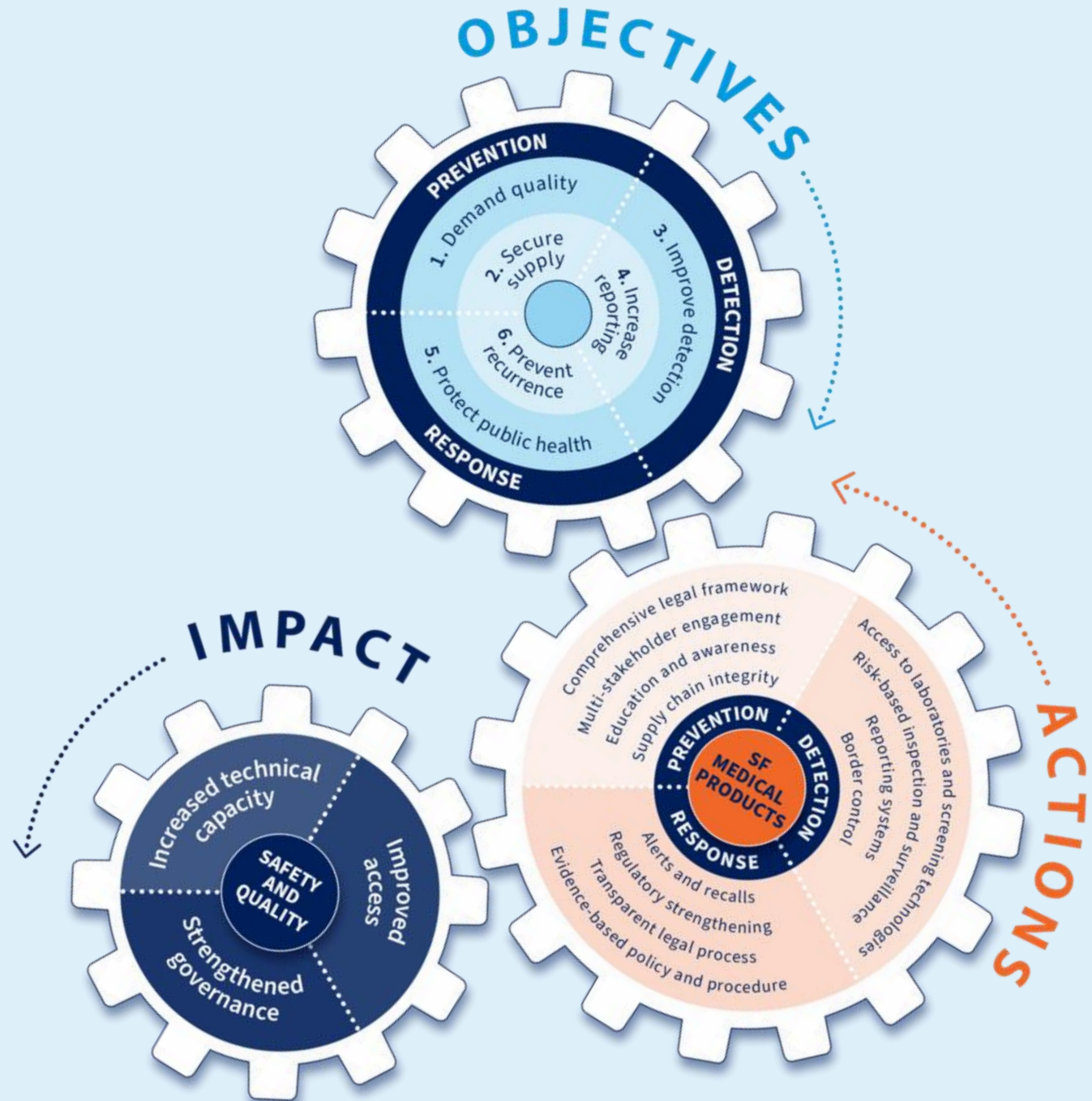


The last mile is the most vulnerable: hence the need for continued detection. Unethical and corruption practices can occur throughout the supply chain

Driving forces



Framework of action for SF medical Products



Demand quality & Secure supply

(contributes to prevention)
e.g., due diligence, seizure operations,
enforce legal provisions, etc.



Build capacity and harness synergies

(contributes to response)
e.g., training, field screening equipment,
etc.



Develop joint intelligence base

(contributes to detection)
e.g., exchange data & analytics,
interagency collaboration, etc.

Prevent-detect-respond strategy

PREVENTION

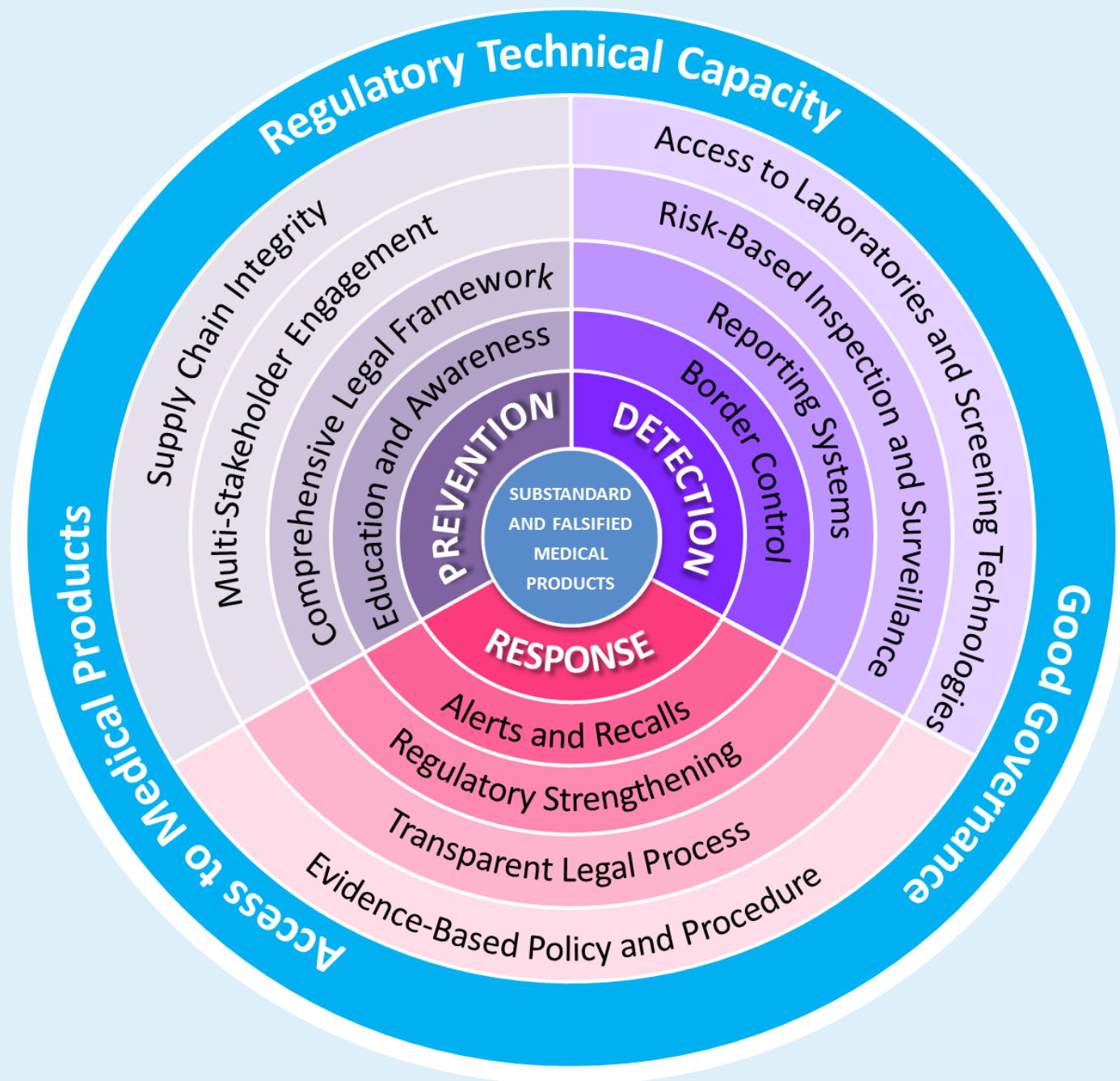
- Demand and require quality at all supply chain levels
- Ensure the safety and security of the supply chain

DETECTION

- Increase sensitivity and specificity of detection
- Facilitate reporting and accelerate information feedback systems

RESPONSE

- Protect the health of citizens
- Identify and implement corrective actions to avoid recurrence (regulatory, judicial actions)

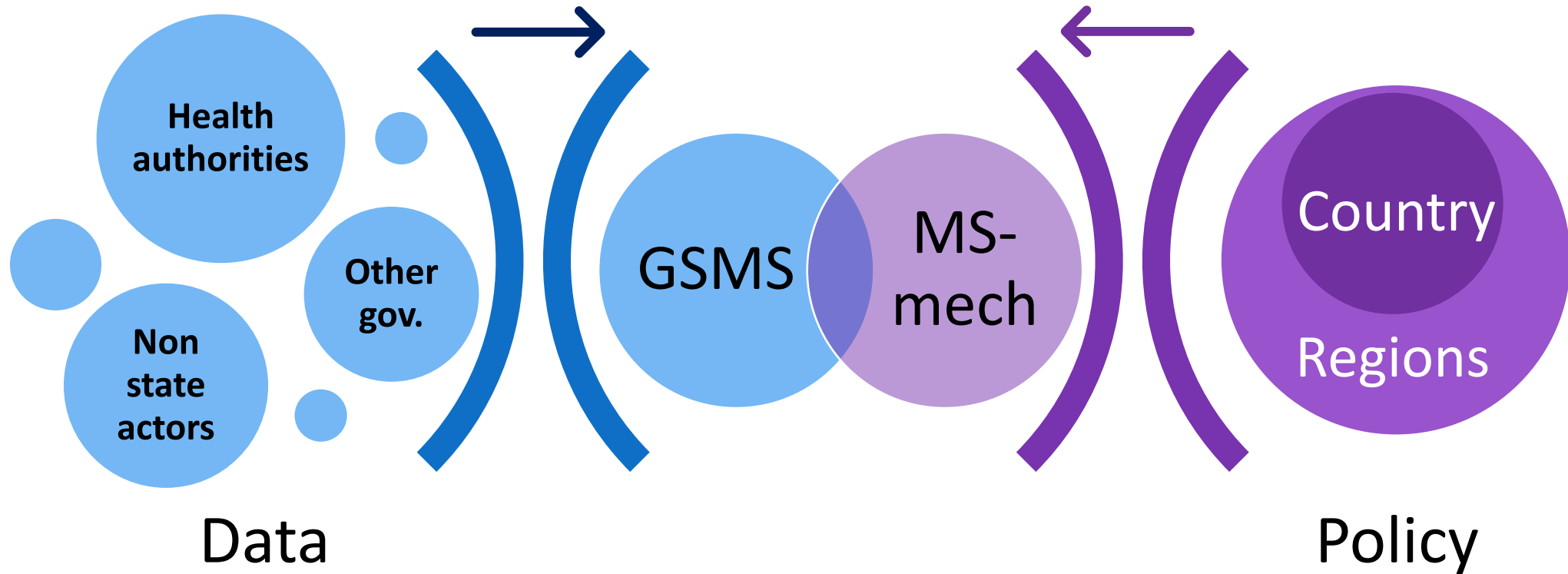




World Health
Organization

WHO dual approach

How WHO addresses SFMP



Global Surveillance and Monitoring System (GSMS)

Technical initiative to gather evidence, understand the scope, scale and harm, and support regulatory systems. Countries collaborate with GSMS through designated focal points, supplying data and receiving support. Launched in 2010.

Member State Mechanism (MSmech)

Political forum where countries shape global policy and advocate for systemic change. Countries participate through official representation in MS-mech meetings and working groups. Launched in 2012.

Purpose of the MS-mech (*Member State Mechanism – or ‘the Mech’*)

- Public health focus by collaborative leverage of evidence



Range of services provided by the GSMS



Market control

Field missions

e-Course

Toolkits

Global alerts

Threat assessments

Watch lists

Thematic analysis



Service accessible
via the GSMS portal

New Portal



Focus group discussions Jan-Feb 2024

Design rounds Q1-Q3 2024

Migration to new platform

Key improvements:

- ✓ Machine reading PIC/S RAN
- ✓ Receipt form
- ✓ Standardize ingredients
- ✓ Repository
- ✓ Medical device reporting
- ✓ Expanded search tool
- ✓ Useful tools + communications



The screenshots show the WHO GSMS portal V4.8 interface. The top navigation bar includes links for 'Submit a report', 'Submit a medical device report', 'Historic reports', 'Search medical products', 'Resources', 'FAQs', and 'English'. The main content area displays a list of products under 'Product Name', a pie chart for 'Statistics' showing 'Total Suspect Products By Region', a 'Training modules' section with links to access different modules, and a 'Preview videos' section featuring a video titled 'Leadership insight: the importance of training'.

World Health Organization
Global Surveillance and Monitoring System (GSMS) for Substandard-Falsified medical products (SFMP)

Product report to the WHO GSMS portal

<https://gsms.who.int>

1. Date of report to WHO portal	2. Date of incident
3. Reporter's reference	4. Reporter's organization World Health Organization
Product name	
5. Name of reporting person Pernette Bourdillon Esteve	
6. Product Type Medicine	7. Supply chain type Regulated
8. Country of discovery Switzerland	9. Distribution level Business-to-business
10. Discovered by Pharmacists	11. Action by organization for this specific product Public statement
12. Incident subject to regulatory action or investigation? Law enforcement action	13. Product authorized in country of discovery? No
14. Stated manufacturer or marketing authorization holder	15. Packaging language
16. Quantities discovered	17. Expiry date
18. Batch number	19. Manufacturing date
20. Active ingredient	21. Pharmaceutical form
22. Therapeutic indication of the product	23. Dosage strength
24. Other uses	25. Quantities discovered
26. Type of screening or analysis undertaken	27. Results of Analysis - Product
28. Assistance required from WHO?	29. Results of Analysis - Packaging
30. Adverse Reaction or harm caused?	31. Estimated number of patients affected?
32. Reporters Comments	33. WHO incident number: INC-89365-RZUO

DISCLAIMER: This document is the receipt of a report submitted to the GSMS portal. If any of the above information appears incorrect, please contact rapidalert@who.int. One document is generated for each product record: incidents with multiple products will generate multiple documents. You are free to share the document with relevant stakeholders, however, please note that in no event shall WHO be liable for damages arising from its use.

GSMS services (some)




Training toolkit (normative WHO guidance)


Content

- ✓ Competency framework
- ✓ Curriculum guide
- ✓ Trainer guide
- ✓ Technical resources


Target audience




Training organizations, academia, public health institutions



Students in biomedical sciences (pharmacy, medicine, nursing, etc.),




Practicing healthcare professionals



Authorities dealing with quality and safety of medical products

Access




Trainer's Toolkit


on substandard and falsified medical products

Overview


Welcome to the Training Toolkit on Substandard and Falsified Medical Products (SFMP) !




Download the handouts




Trainer's Toolkit Overview




Competency Framework




Identifying suspect SFMP for healthcare professionals



Characteristics of websites like



SFMP incident management



Prioritization and risk parameters

More information

Sign up if you want to download the full-resolution version of the toolkit and receive updates about the publication

[Sign up](#)

[FAQs](#)

Competency Framework

The **Competency framework** outlines the essential competencies required to effectively combat SFMPs. It is aligned with WHO's PDR strategy and includes specific and cross-cutting competency domains. The framework serves as a basis for curriculum development, ensuring that training programs address the required knowledge, skills, and attitudes.

2.1 Competency framework overview

The toolkit is organized to address the needs of three levels of health personnel: health service providers, health management personnel, and regulators and policy-makers. Each level requires different sets of skills and knowledge. The framework is designed to be flexible and adaptable, allowing trainers to tailor the competencies to the specific needs and contexts of their learners.

2.2 Specific competency domains

The prevention domain focuses on securing the production, procurement, distribution, and use of medical products to prevent SFMPs. The detection domain covers the identification and reporting of SFMPs throughout the supply chain. The response domain outlines the competencies needed for assessing and mitigating risks associated with SFMPs, including patient management and regulatory actions.

2.3 Cross-cutting competency domains

The cross-cutting domains of communication, collaboration, leadership, and research are explained, emphasizing their importance in a comprehensive approach to combating SFMPs.

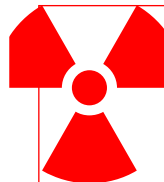
2.4 Link with the curriculum guide

Alignment between the competency framework and the curriculum guide ensures a structured approach to combating SFMPs. This linkage helps trainers design and deliver effective training programmes that meet the specific needs of their learners.

WHO Global Medical Product Alerts



Objective is to **support the regulatory RESPONSE**: increased vigilance will help remove the SFMP from market. It empowers member States to request WHO support and is part of the intelligence cycle.



HIGH RISK: Evidence suggests that the SFMP represents a **genuine and significant risk** to public health in a wide geographic region, and/or additional adequate steps are needed remove the product from the supply chain



CURRENT THREAT: Report is **recent**, and/or the product is likely in **current circulation**, and/or there have been previous recent signals / notifications of the same product.



RELIABLE INFORMATION: WHO **established the veracity and accuracy of the report**. Relevant stakeholders may be informed and/or consulted about the alert content before publication.

Medical Product Alert No. 4/2023 Substandard (contaminated) syrup medicines identified in WHO Region of the Western Pacific

Alert Summary

This WHO Medical Product Alert refers to a batch of substandard (contaminated) GUAIFENESIN SYRUP TG SYRUP identified in the Marshall Islands and Micronesia (Federated States of) and reported to WHO on 6 April 2023.

Guaifenesin is an expectorant used to relieve chest congestion and the symptoms of cough.

Samples of the GUAIFENESIN SYRUP TG SYRUP from the Marshall Islands were analysed by quality control laboratories of the Therapeutic Goods Administration (TGA) of Australia. The analysis found that the product contained unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.

The stated manufacturer of the affected product is QP PHARMACHEM LTD (Punjab, India). The stated marketer of the product is TRILLIUM PHARMA (Haryana, India). To date, neither the stated manufacturer nor the marketer have provided guarantees to WHO on the safety and quality of these products.

The product referenced in this Alert may have marketing authorizations in other countries in the Western Pacific region. It may have also been distributed, through informal markets, to other countries or regions.

Please refer to the [Annex](#) of this Alert for full details of the affected products.

WHO has previously published three Alerts on other contaminated liquid dosage medicines. Please see [Medical Product Alert N°6/2022](#), [Medical Product Alert N°7/2022](#) and [Medical Product Alert N°1/2023](#).

Risks

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal.

The substandard product referenced in this Alert is unsafe and its use, especially in children, may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

Advice to regulatory authorities and the public

If you have the affected product, WHO recommends that you do not use it. If you, or someone you know, has, or may have used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by these products. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities are advised to immediately notify WHO if these substandard products are discovered in their respective country.

Threat assessment example of nitazenes

- Difficult to detect
- Increased risk to health
- Mitigation requires behaviour change and information sharing


Threat Assessment n°1 of 2025 urged health authorities to:

- ✓ Sensitize emergency responders, health-care professionals and poison control centres
- ✓ Inform the general public, vulnerable populations, and support communities of the increased hazard
- ✓ Coordinate with law enforcement.

- **Initial RnD:** Developed in the 1950s as alternatives to traditional pain medications like morphine.
- **No approval:** never approved for medical use, due to safety concerns.
- **Multiple analogues:** each with unique properties (isonitazene, metonitazene, and flunitazene, etc.).
- **Intention:** Nitazenes intentionally added to falsified medicines to increase their potency.
- **Signal detection:** Increase in GSMS reports of falsified medicines contaminated with nitazenes
- **Key collaborative response:** Stronger surveillance and better coordination with law enforcement

Target market surveillance requests: watch lists

- ✓ Product previously reported
- ✓ Product likely to be available across one or more WHO Regions (wide distribution)
- ✓ Product previously referenced in a WHO global alert
- ✓ Request that information on the product is further disseminated

 World Health Organization

February 2025

Targeted Market Surveillance list: Quarter 1 - 2025

Global Surveillance and Monitoring System for substandard and falsified (SF) medical products

DISCLAIMER: The information in this document is only for use by national regulatory authorities (NRAs). It is not intended for the public, nor should it be shared beyond the GSMS network of focal points. NRAs are requested to conduct market surveillance for the medical products listed below.

All reasonable precautions have been taken by WHO to verify the information below. However, this document is distributed without warranty of any kind, expressed or implied. Responsibility for interpretation and use lies with the reader. In no event shall WHO be liable for damages arising from use of this document.

Products have been referenced in this issue because:

1. The product has been previously reported to the [WHO GSMS database](#) AND
2. The product is likely to be available across one or more WHO Region(s) AND
3. The product has previously appeared or may appear on a [WHO Medical Product Alert](#) AND
4. The reporter has requested that information on the product is further disseminated.

Notify WHO if you detect any of these products or have additional information

Please increase surveillance when dealing with these products or when considering importation. This may be done by using the [GSMS Portal notification tool](#) or by email rapidalert@who.int.

It is important to obtain photographs, samples for laboratory analysis, and inform the public. Please refer to the WHO guidance on how to take photographs of SF medical products. For more information, see the Aide-Mémoire for guidance on handling incidents of SF medical products. Both documents are available on the GSMS Portal at <https://sfreport.who.int/>.

This issue references 16 products which, at this stage, have been detected in a predominantly reported to the GSMS between late October 2024 and late January 2025. Please consult the GSMS Portal search tool for additional photographs.

Widespread attention is required in all WHO regions, regardless of where the products are detected. Please share reports to the GSMS if you are aware of products referenced in this issue to remove these products from circulation to prevent potential public harm.

- 1 GLOBAL TRENDS.....
- 2 WHO REGION FOR AFRICA
- 3 WHO REGION FOR THE AMERICAS
- 4 WHO EASTERN MEDITERRANEAN REGION
- 5 WHO EUROPEAN REGION
- 6 WHO WESTERN PACIFIC REGION

TMS_Q1-2025 | Incidents and SF medical products

 World Health Organization

February 2025


2 WHO Region for Africa

2.1 FALSIFIED ANTIBIOTICS DETECTED IN CAMEROON AND CENTRAL AFRICA REPUBLIC

Since October 2024, WHO received five different notifications of falsified antibiotics identified in Cameroon and the Central African Republic, circulating at patient level. Thin layer chromatography screening did not detect any active pharmaceutical ingredient in any of the sampled products.

HOW TO DETECT: Two products claim to contain amoxicillin (Amoxy Capsules, Healmoxy Capsules), another claims to contain Amoxicilline + Cloxacilline (Zoneclox), and the last product claims to contain Ampicillin (Petsow Starnicillin).

Declared active ingredient	Amoxicillin	
Product Name	Amoxy Capsules 500mg	Healmoxy Capsules 500mg
Stated Manufacturer	Yangzhou No. 3 Pharmaceutical Co. Ltd.	Maxheal Pharmaceuticals Ltd
Batch Number	A023683	AO23683
Expiry Date	27-Jan	26-Jun
Available photograph		

Product Name	Zoneclox	Petsow Starnicillin Ampicillin Capsule BP
Declared active ingredient	Amoxicillin + Cloxacillin	Ampicillin
Stated Manufacturer	By Northwest pharmaceutical China, For Zee Pharmaceutical LTD Nigeria	Petsow Laboratories LTD
Batch Number	2205018	23612
Expiry Date	May-26	1/1/2027
Available photograph		

International cooperation against SF medical products

PREVENT ↔

DETECT ↔

RESPOND

Secure quality & supply

(e.g. seizure operations, enforce legal provisions, etc.)

Intelligence base

(e.g. exchange data & analytics, interagency collaboration, etc.)

Build capacity

(e.g. training, field screening equipment, etc.)

WHO does WHAT :

Examples of different stakeholders playing different roles when managing incidents of SF medical products

NATIONAL focal points

- Health authorities (ministry, regulators, quality control laboratories, etc.)
- Law enforcement (customs, police, etc.)
- Judiciary (prosecutors, judges, etc.)
- Civil society (community representatives, health workforce, etc.)
- Private sector (manufacturer, authorization holder, distributor, importer, etc.)

REGIONAL networks



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



GLOBAL systems



World Health Organization



INTERPOL



World Customs Organization
Organisation mondiale des douanes



THE WORLD BANK



UNODC
United Nations Office on Drugs and Crime



UNOPS

Thank you

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Incidents and SF medical products (ISF) ; Global surveillance and monitoring system (GSMS)

Regulation and Safety – WHO - rapidalert@who.int