WHO’s work to combat substandard-falsified medical products

“World Together Against Substandard and Falsified Medical Products”

Belgrade, 14 October 2025

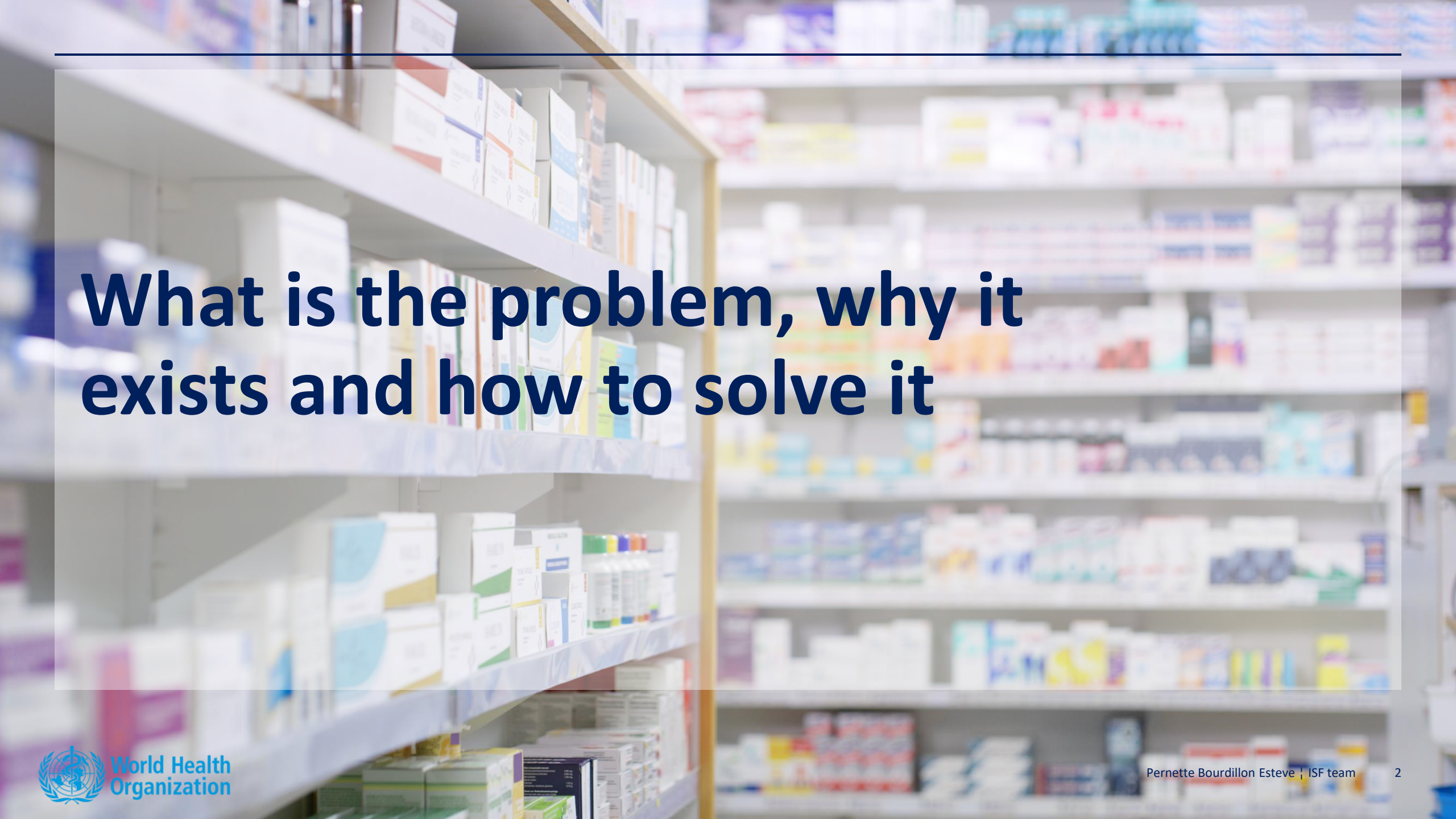
Rasmus Gjesing, *MSc Pharm, MSc HPPF*

Regional Adviser, Access to Medicines and Health Products, WHO European Region

Global surveillance and monitoring system

WHO Regulation and Prequalification

World Health Organization



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

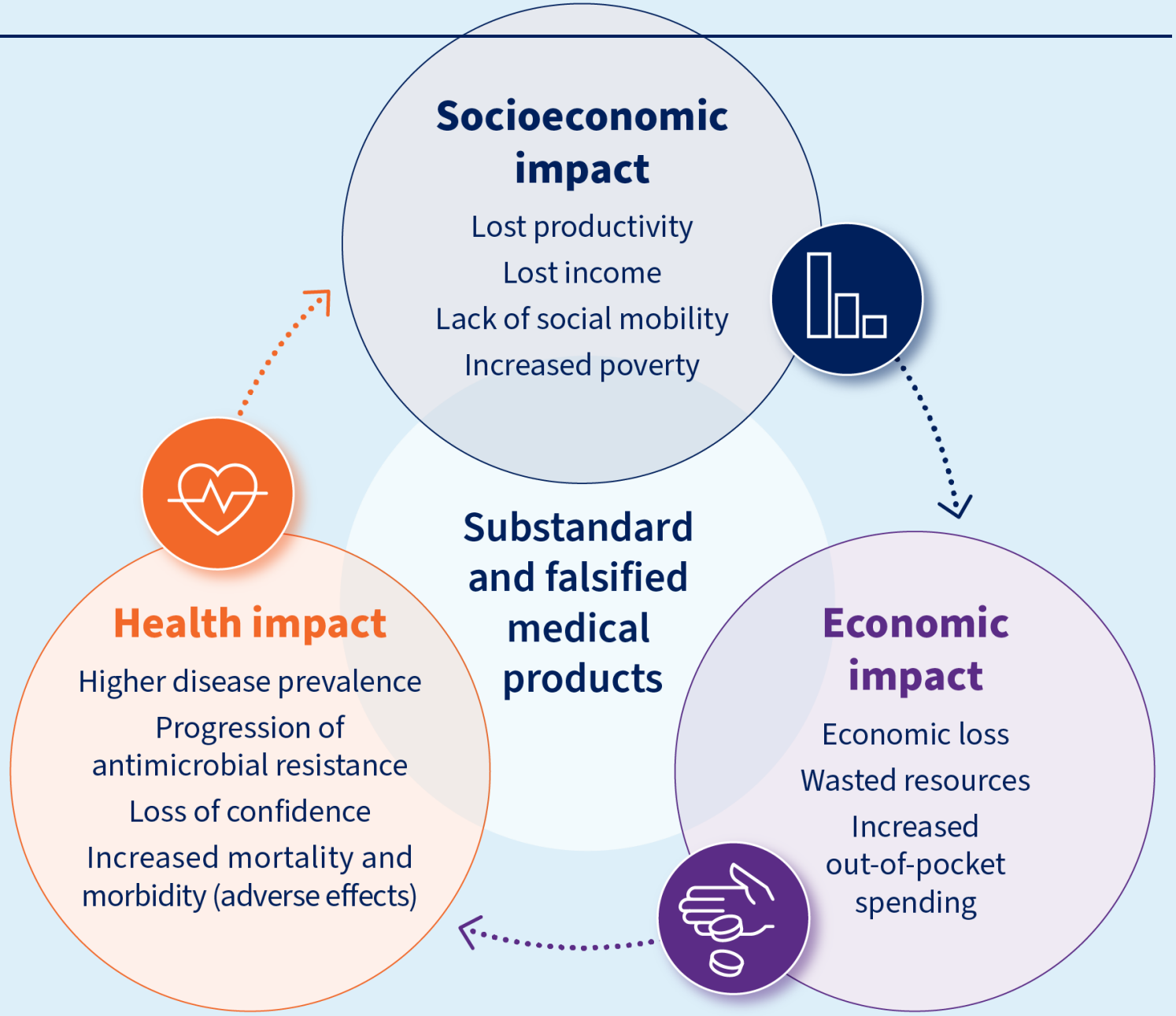
Falsified

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.

World Health Organization

Impact of substandard and falsified medical products



World Health Organization

Impact models (2017)

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

Observed failure rate on medicines samples in LMICs

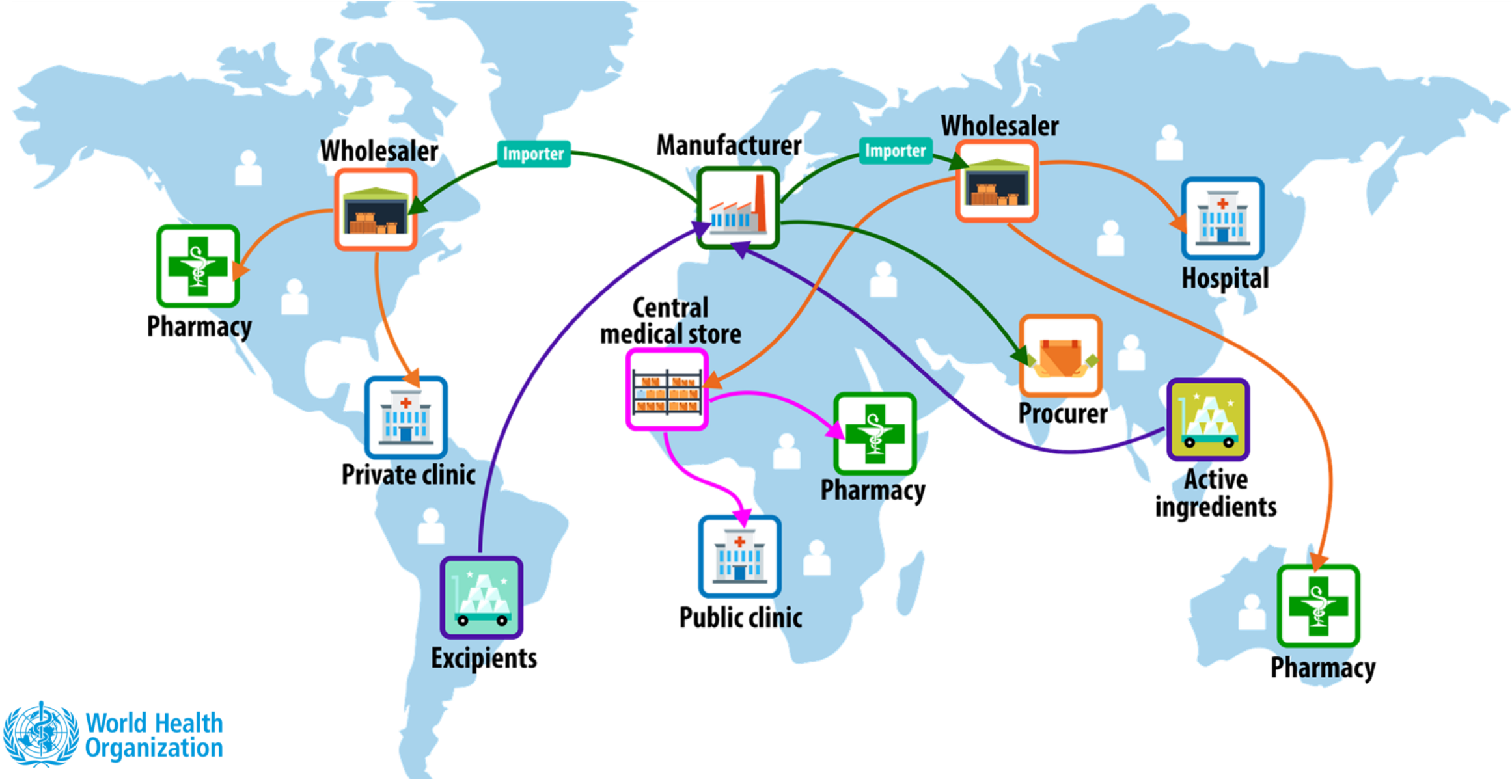
10.5%

286’000 annual deaths childhood pneumonia and malaria

US$ 30.5 billion est. annual spending on SF medicines in LMIC

World Health Organization

Globalized markets, heterogeneous systems



World Health Organization

Medical product life cycle

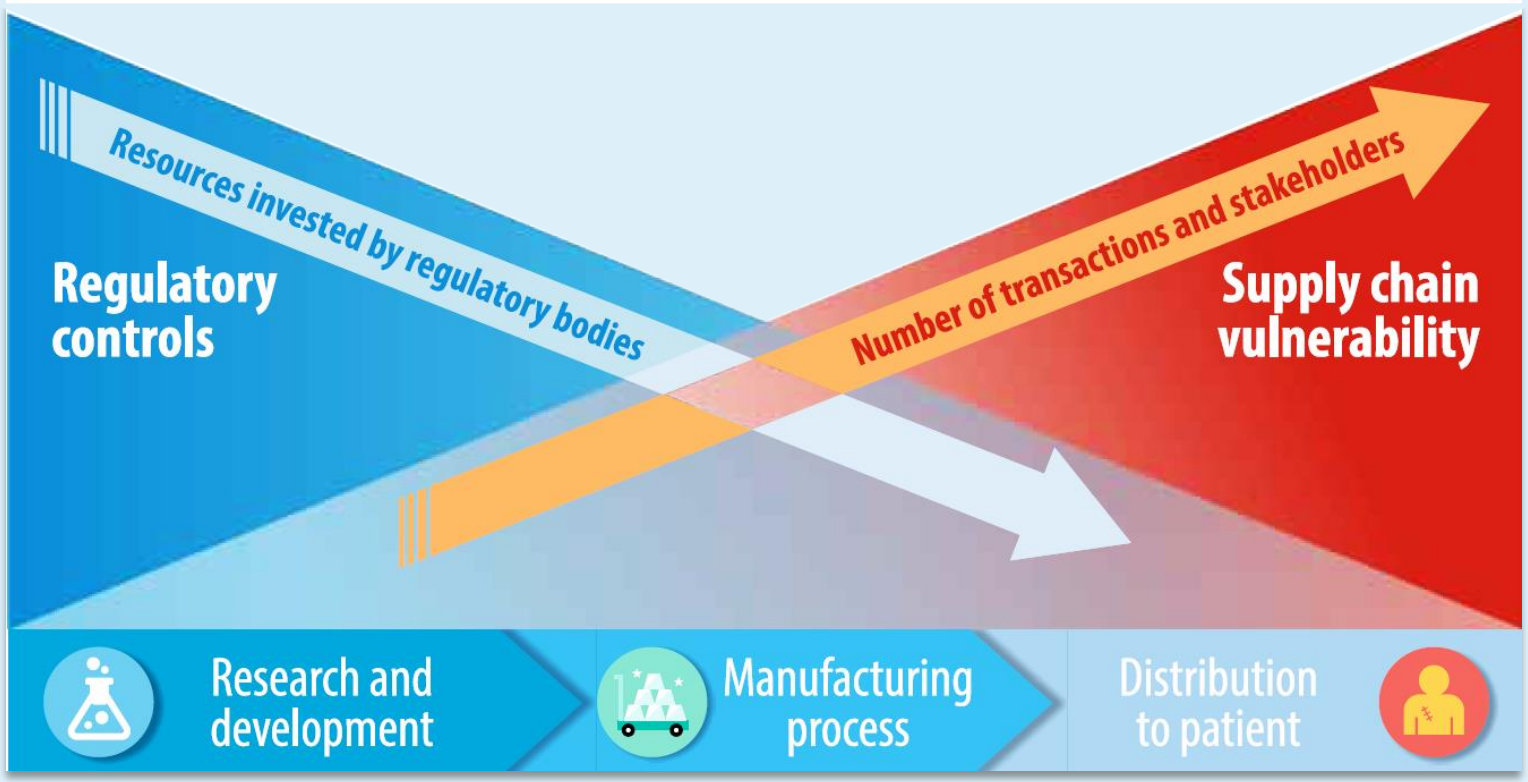
multiple stakeholders contribute to ensuring quality, safety and access

Legislation

Regulation

Governance

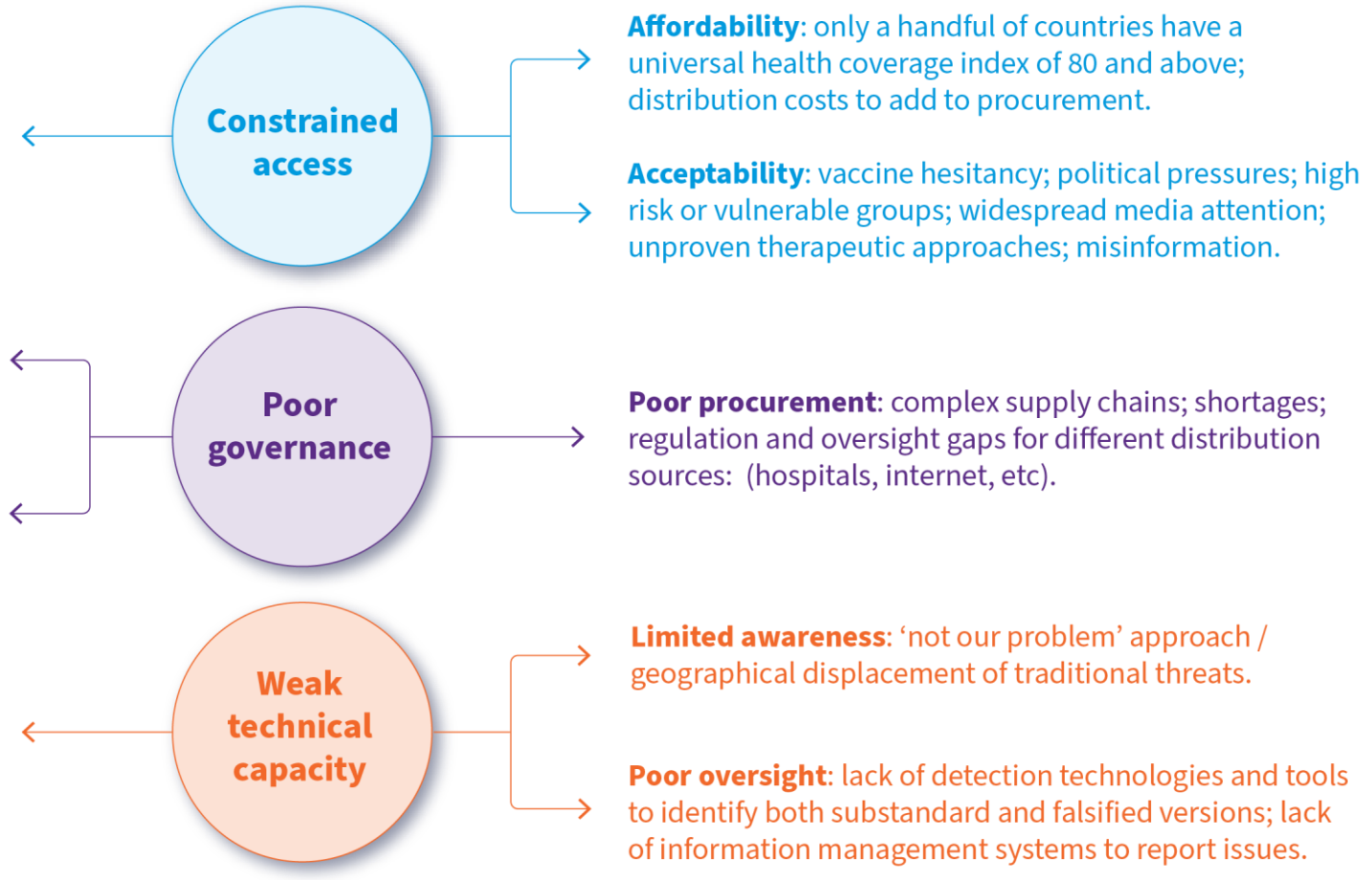
Monitoring



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

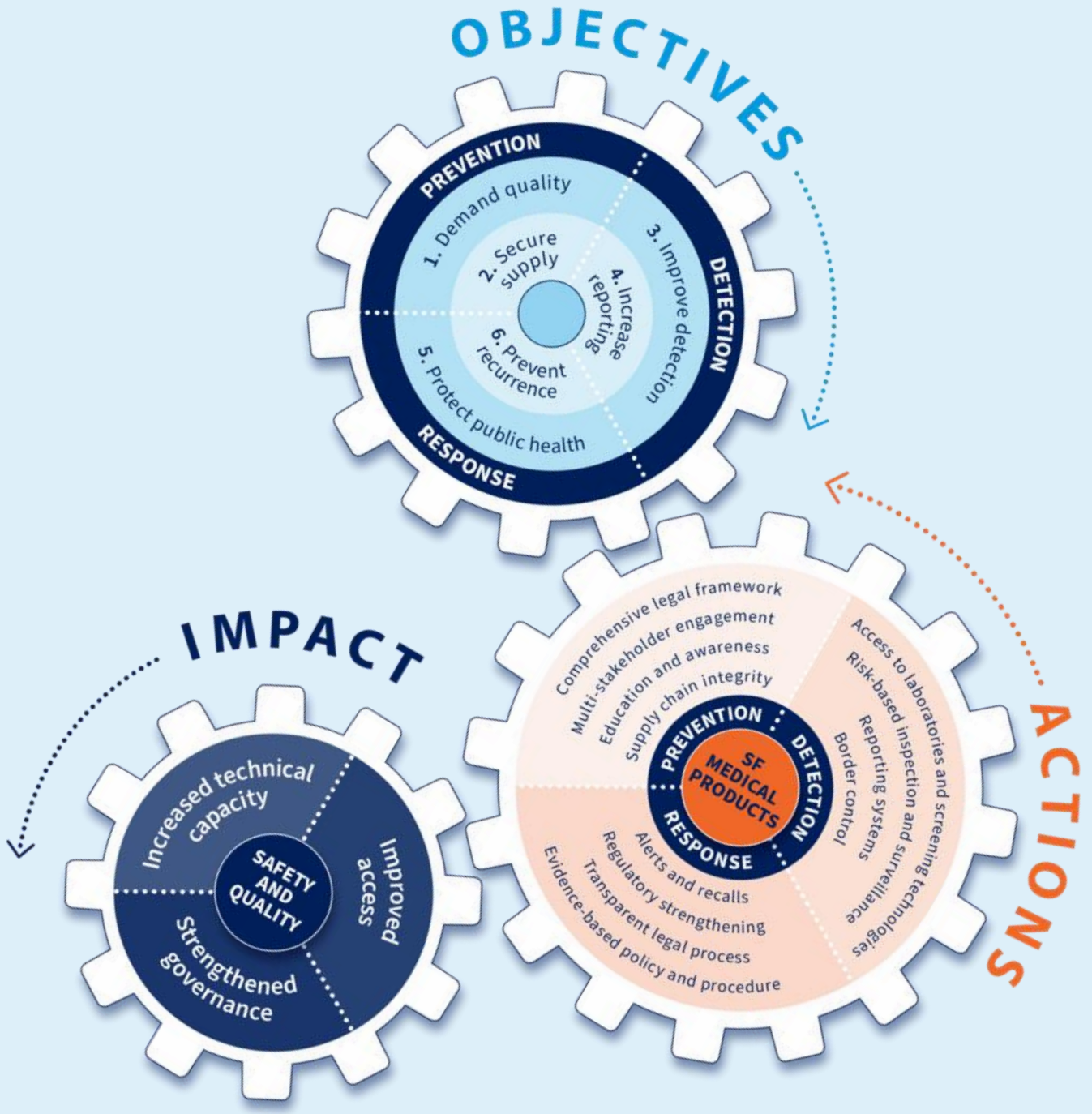
World Health Organization

Driving forces

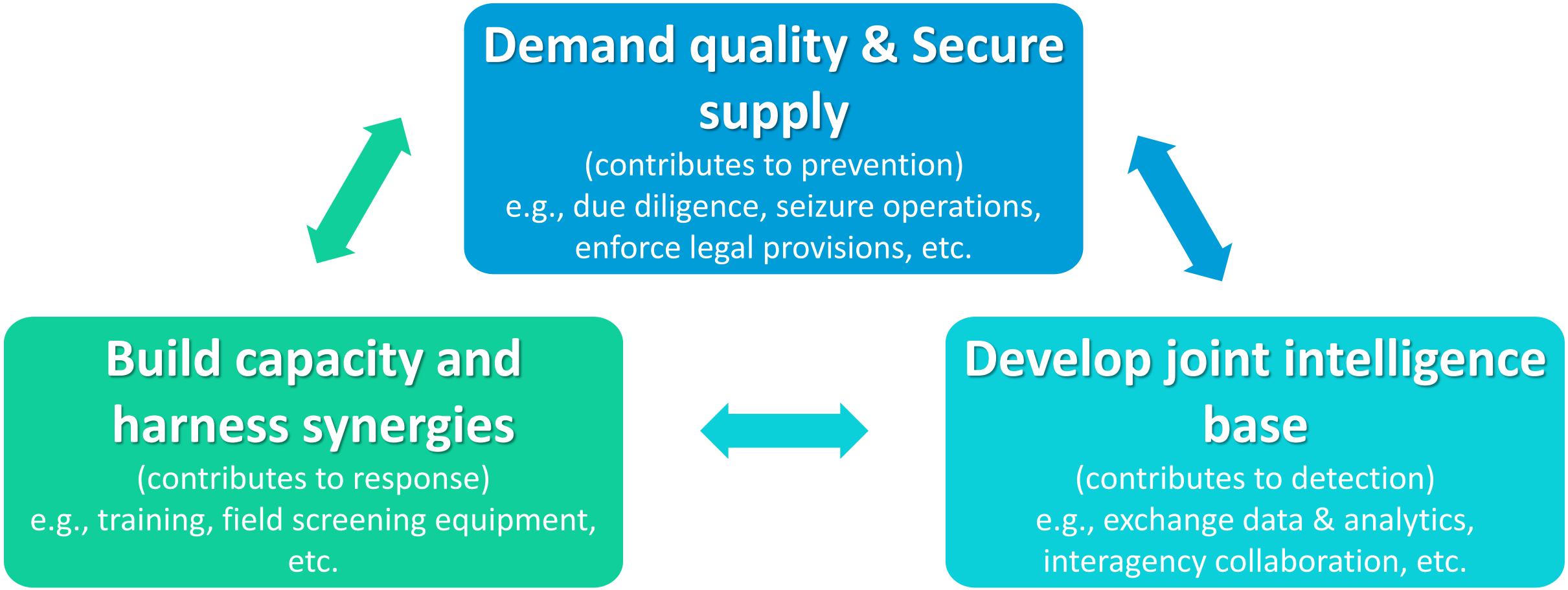


World Health Organization

Framework of action for SF medical Products



World Health Organization



World Health Organization

Prevent-detect-respond strategy

PREVENTION

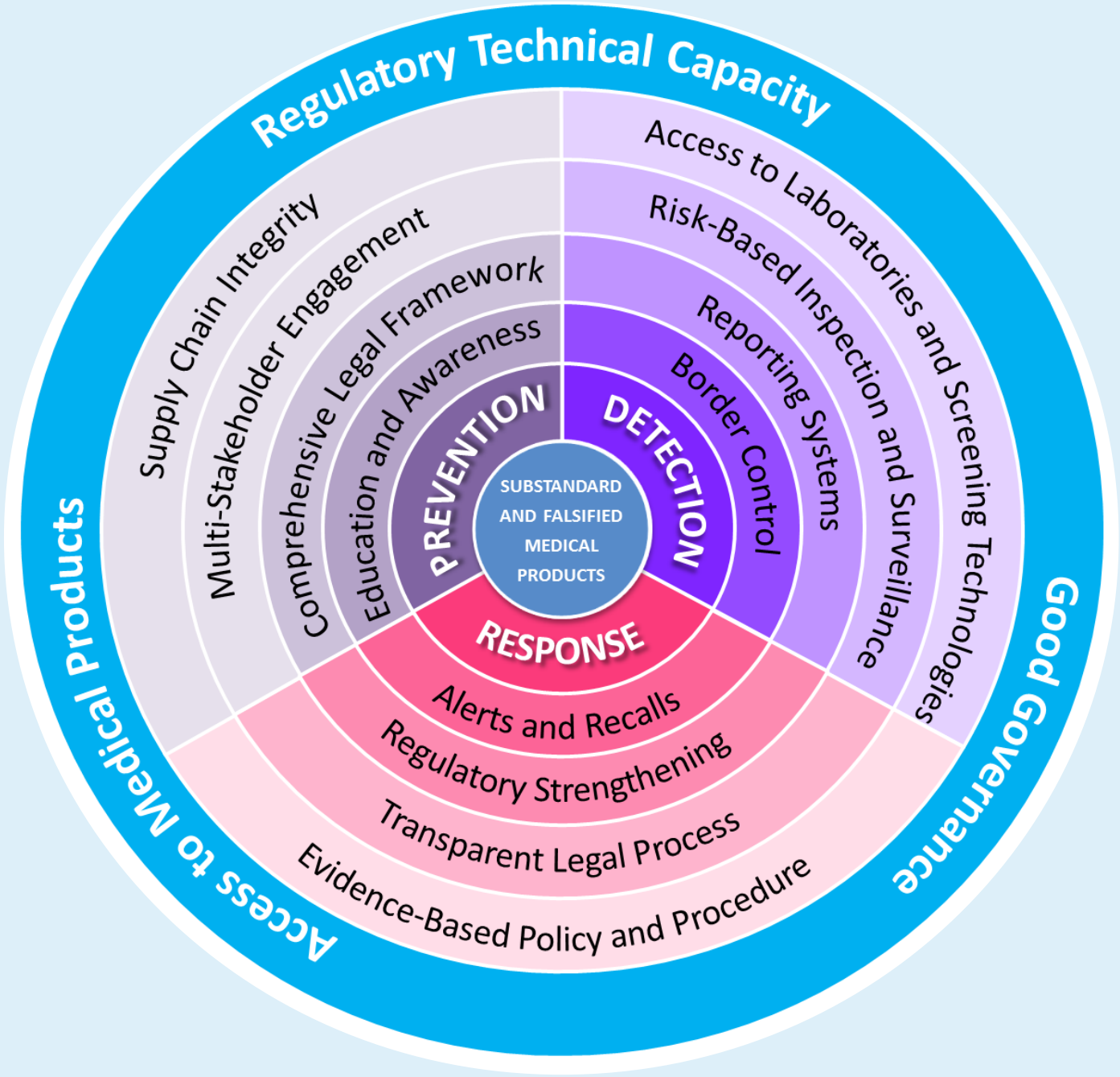
- Demand and require quality at all supply chain levels
- Ensure the safety and security of the supply chain

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)

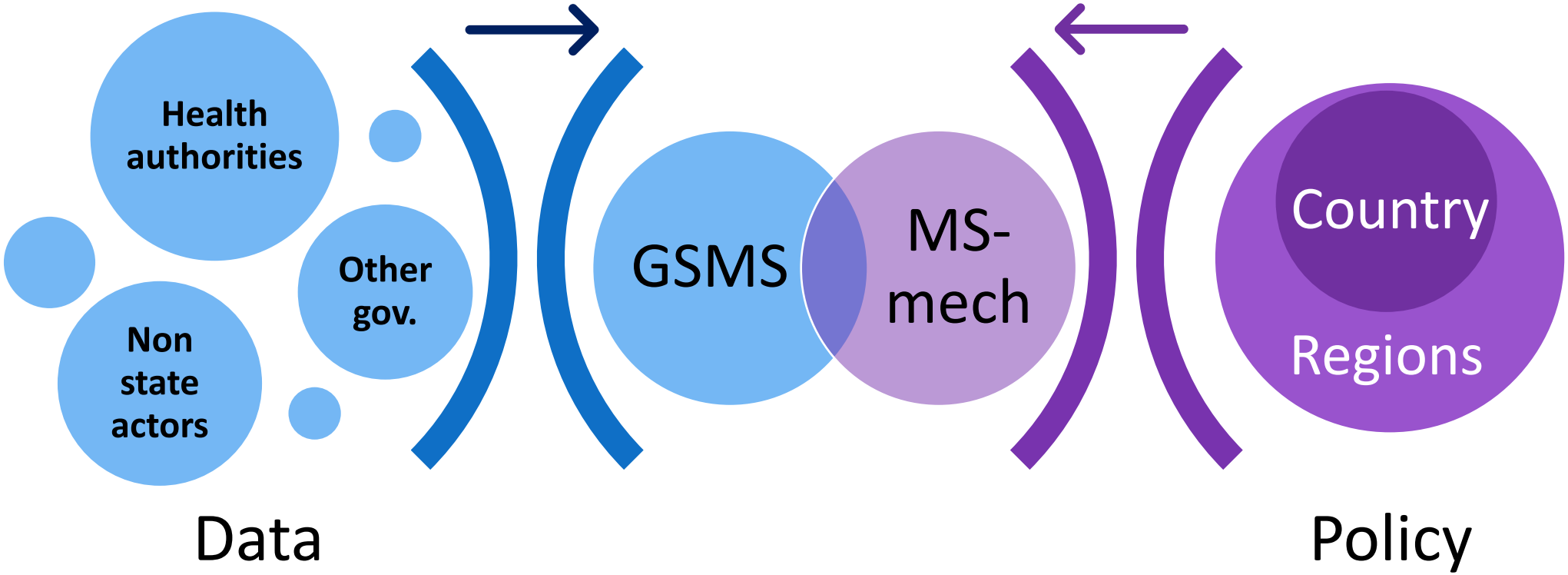


World Health Organization

World Health Organization

WHO dual approach

How WHO addresses SFMP



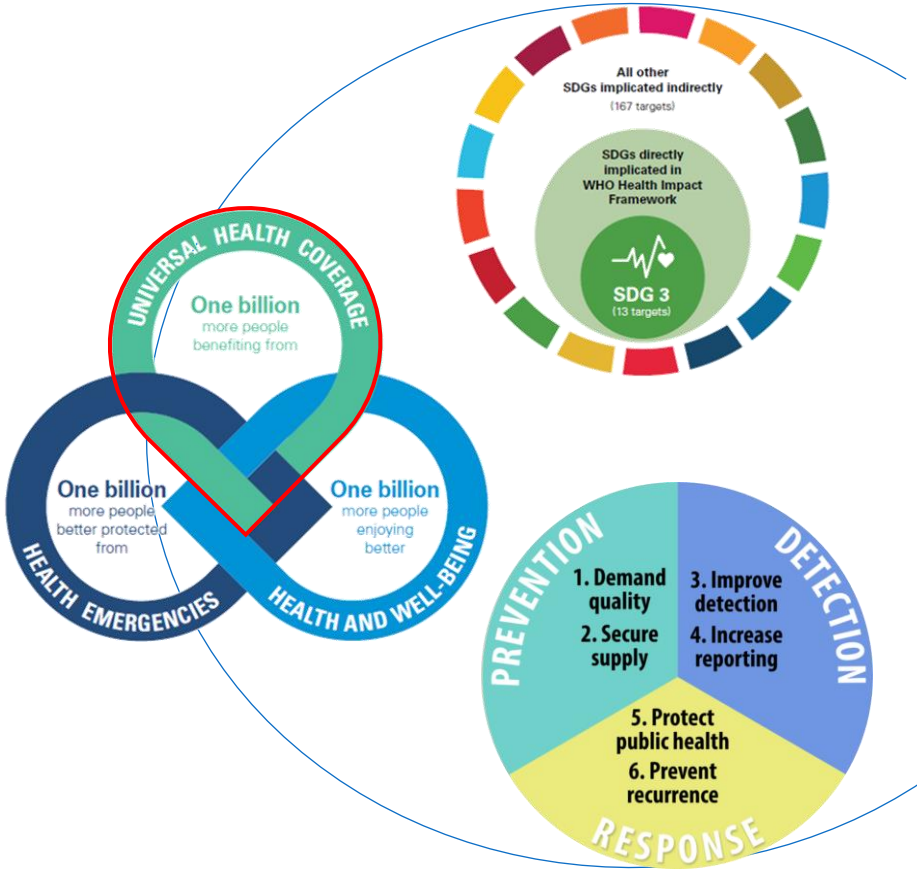
Global Surveillance and Monitoring System (GSMS)
Technical initiative to gather evidence, understand the scope, scale and harm, and support regulatory systems. Countries collaborate with GSMS through designated focal points, supplying data and receiving support. Launched in 2010.

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.

World Health Organization

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

- Public health focus by collaborative leverage of evidence



MISSION

- Protect public health and promote access* to medical products
- Promote prevention and control of SF medical products

OBJECTIVE

- Identify major needs and challenges
- Consultation and cooperation
- Strengthening of national and regional capacities

STRATEGY

- Contribute to / coordinate with other areas of WHO on access
- Support use of evidence-based guidance and public health approaches

World Health Organization

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

World Health Organization

New Portal

- Focus group discussions Jan-Feb 2024
- Design rounds Q1-Q3 2024
- Migration to new platform

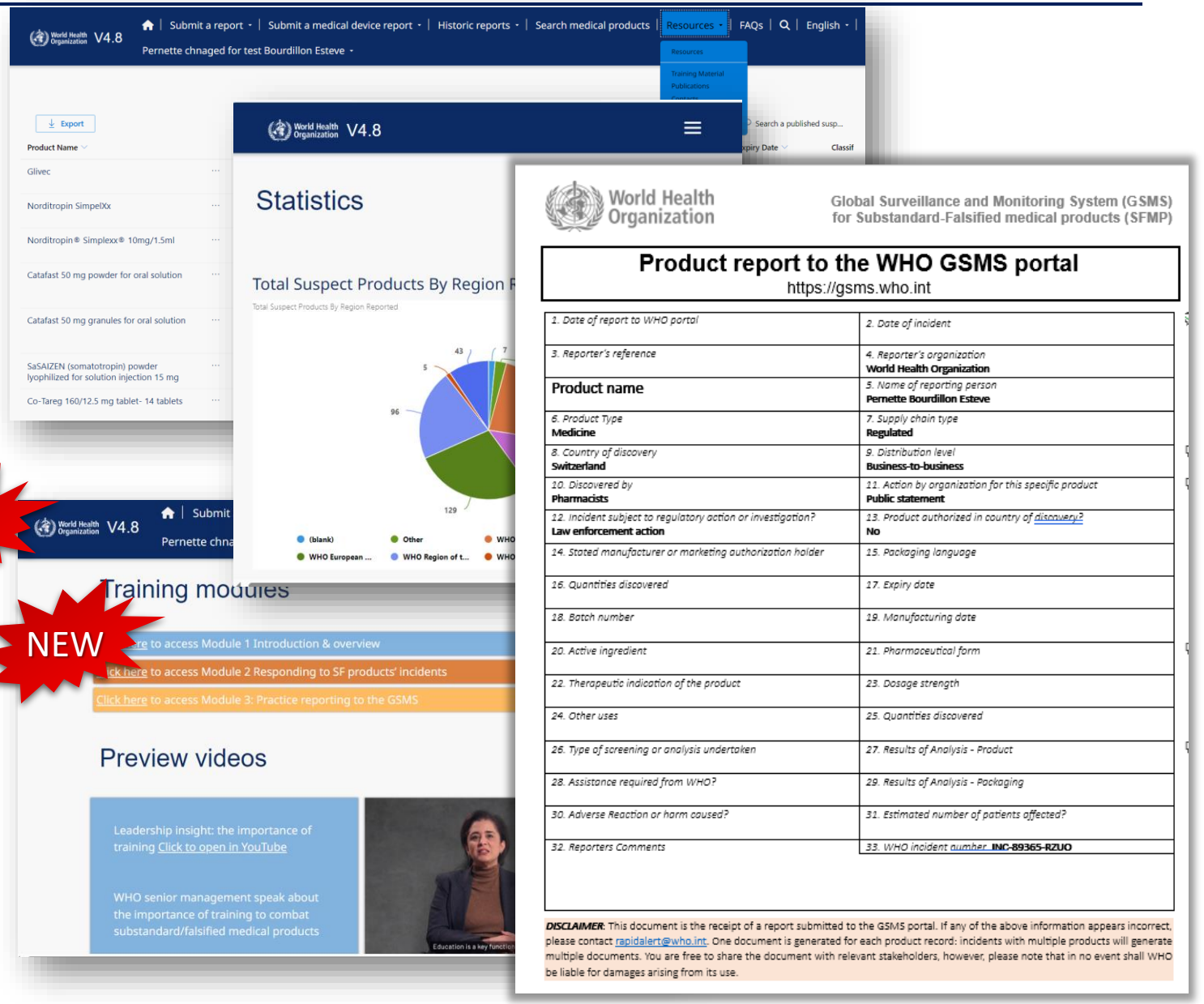
Key improvements:

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

NEW

NEW

NEW



GSMS services (some)

Training toolkit (normative WHO guidance)

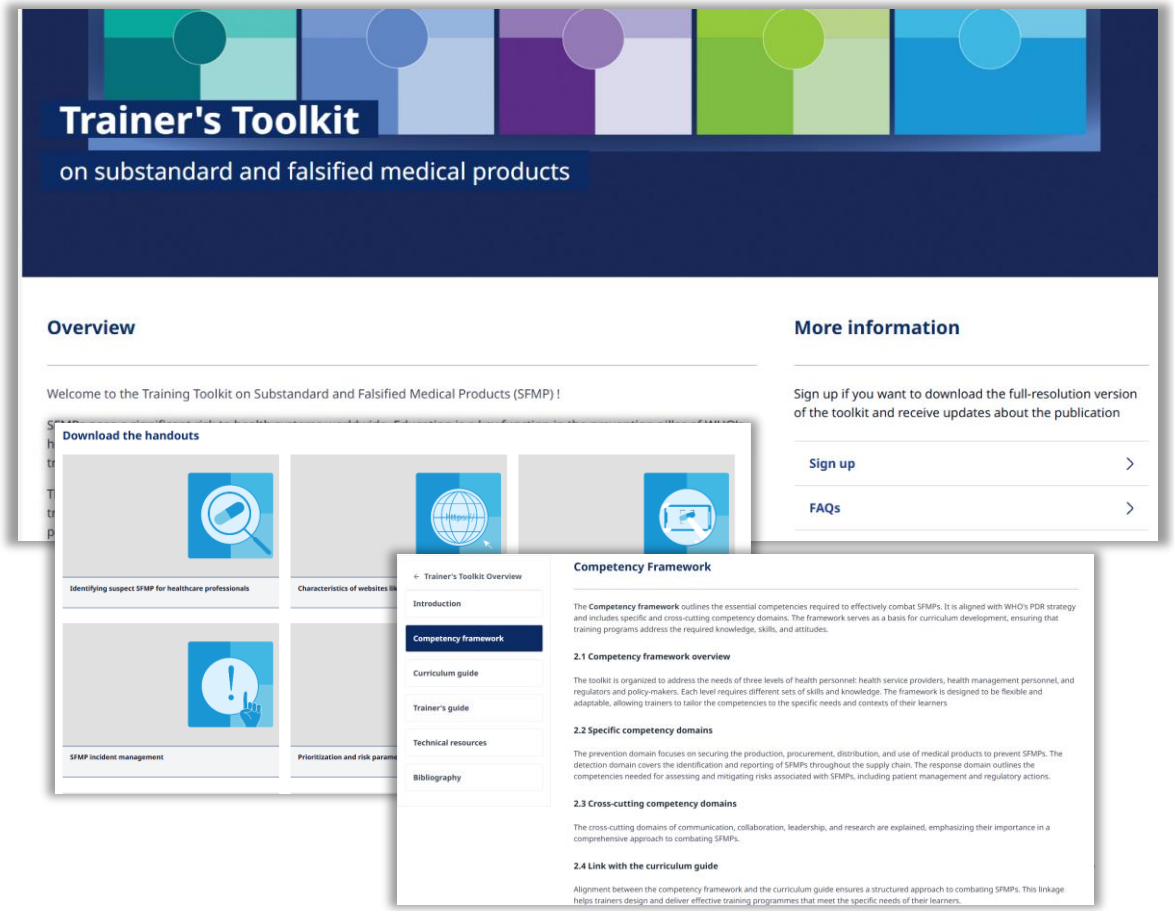
Content

- ✓ 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



World Health Organization

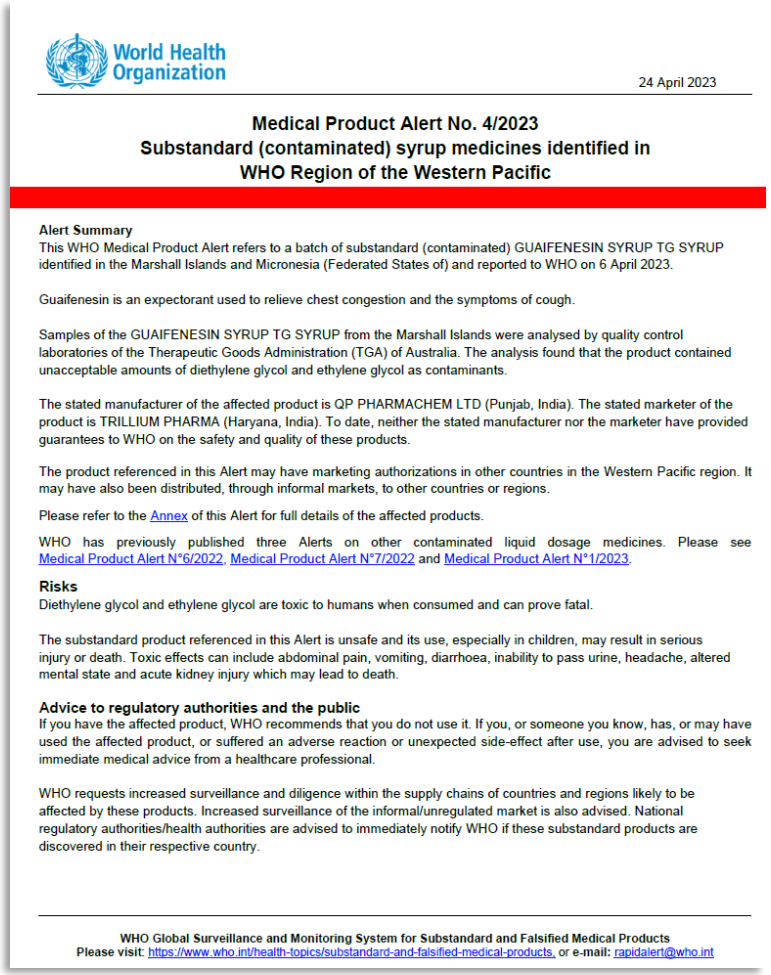
WHO Global Medical Product Alerts

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.



World Health Organization

24 April 2023

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.

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
Please visit: https://www.who.int/health-topics/substandard-and-falsified-medical-products, or **e-mail:** rapidalert@who.int

World Health Organization

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.

World Health Organization

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.).

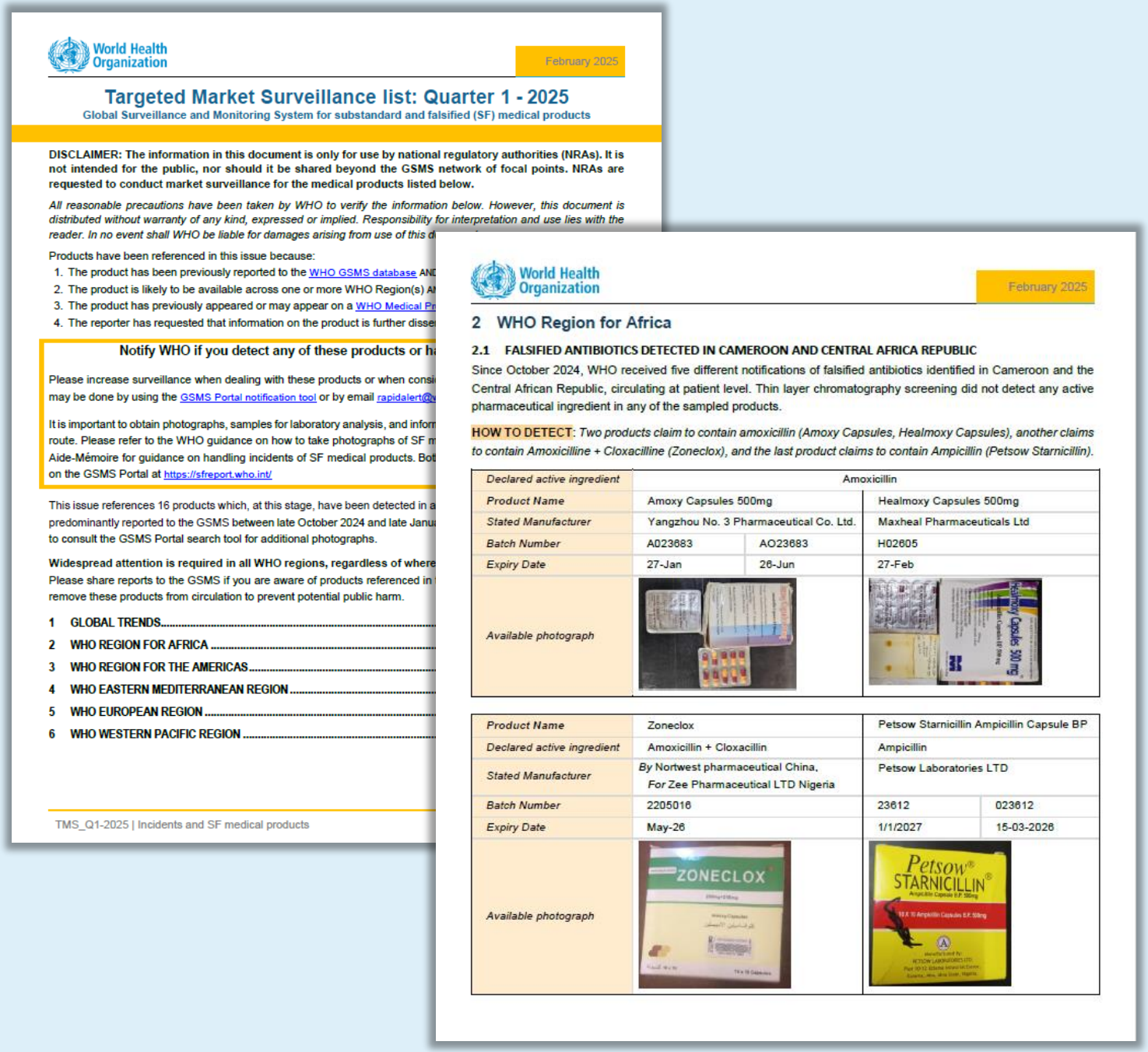
Intention: Nitazenes intentionally added to falsified medicines to increase their potency.

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 d

Products have been referenced in this issue because:

1. The product has been previously reported to the WHO GSMS database AN
2. The product is likely to be available across one or more WHO Region(s) A
3. The product has previously appeared or may appear on a WHO Medical Pr
4. The reporter has requested that information on the product is further disse

Notify WHO if you detect any of these products or h

Please increase surveillance when dealing with these products or when consi may be done by using the GSMS Portal notification tool or by email rapidalert@

It is important to obtain photographs, samples for laboratory analysis, and inform route. Please refer to the WHO guidance on how to take photographs of SF m Aide-Mémoire for guidance on handling incidents of SF medical products. Bot 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 Janu to consult the GSMS Portal search tool for additional photographs.

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

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	H02605
Expiry Date	27-Jan	26-Jun	27-Feb
Available photograph			

Product Name	Zoneclox	Petsow Starnicillin Ampicillin Capsule BP	
Declared active ingredient	Amoxicillin + Cloxacillin	Ampicillin	
Stated Manufacturer	*By* Nortwest pharmaceutical China, *For* Zee Pharmaceutical LTD Nigeria	Petsow Laboratories LTD	
Batch Number	2205016	23612	023612
Expiry Date	May-26	1/1/2027	15-03-2026
Available photograph			

World Health Organization

International cooperation against SF medical products

PREVENT ↔ **DETECT** ↔ **RESPOND**

WHO does WHAT :
Examples of different stakeholders playing different roles when managing incidents of SF medical products

	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.)
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	HMA Heads of Medicines Agencies; EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH; EUROPOL; Organisation mondiale de la Santé Région africaine; asean; ECOWAS;		
GLOBAL systems	World Health Organization; INTERPOL; THE WORLD BANK; World Customs Organization Organisation mondiale des douanes; unicef; UNODC United Nations Office on Drugs and Crime; UNOPS		

Thank you

Rasmus GJESING

Regional Adviser, Access to Medicnes and Health Products (AMP)

Division of Health Systems

WHO Regional Office for Europe

GjesingR@who.int

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

Regulation and Safety – WHO - rapidalert@who.int

World Health Organization