



The WHO Member State Mechanism on **Substandard and Falsified Medical Products**

How WHO Member States work together to safeguard access to safe and effective medicines, vaccines and other medical products

The WHO Member State Mechanism

Working together for **safer medical products**

Access to quality medical products is a crucial element of universal health coverage. Yet, every day, substandard and falsified medical products enter the global supply chain resulting in socioeconomic cost and damage to health. Substandard and falsified medicines, vaccines and other medical products, such as in vitro diagnostics, not only increase disease prevalence, exacerbate antimicrobial resistance and produce adverse health effects, they also waste resources, result in economic loss and increase out-of-pocket spending on medical treatment.

Substandard and falsified medicines are produced, distributed and sold all over the world. Preventing, detecting and responding to them is a persistent public health challenge for WHO Member States.

Since its creation in 2012, the Member State Mechanism on Substandard and Falsified Medical Products has become the global forum at which Member States convene, coordinate, decide and organize activities to address substandard and falsified medical products. Since that time, it has provided a collaborative, inclusive, transparent means for countries to work together to face this persistent and pervasive problem.

The work of the Member State Mechanism on Substandard and Falsified Medical Products remains as relevant as ever; low- and middle-income countries spend an estimated \$30.5 billion on substandard and falsified medicines, accounting for 10.5% of medicines samples in the supply chain in these countries (Figure 1).

Figure 1.

Public health and socioeconomic impact of substandard and falsified medicines

1 in 10

observed failure rate
of medicines samples in low- and
middle-income countries



This costs

\$30.5

billion

**estimated spending on substandard and
falsified medicines in low- and middle-
income countries, based on wholesale
level sales**



Child deaths

**estimated 72,430-169,271 deaths
caused by substandard and
falsified antibiotics in children under
5 suffering from pneumonia***



Malaria

**estimated 31,000 -116,000 deaths
caused by substandard and falsified
antimalarials in sub-Saharan Africa***

\$ 38.5 million

**estimated spending on substandard and
falsified antimalarials in sub-Saharan Africa****

Source:

Public health and socioeconomic impact study 2017
[https://www.who.int/medicines/regulation/ssffc/
publications/se-study-sf/en/](https://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/)

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Background

In 2012, the World Health Assembly passed Resolution WHA65.19, to establish a Member State Mechanism to address substandard and falsified medical products (at that time known as substandard/spurious/false-labelled/falsified/counterfeit medical products.)¹ The resolution was passed against a backdrop of increasing concern about such products and the health and socioeconomic harms they cause.

The Member State Mechanism heralded a new approach to the pervasive and persistent problem of substandard and falsified medical products. It enabled Member States to coordinate their efforts with individual countries taking the lead on activities where they were best able to contribute.

¹https://www.who.int/medicines/regulation/ssffc/mechanism/WHA65.19_English.pdf?ua=1

“The goal of the Member State Mechanism is to protect public health and promote access to affordable, safe, efficacious, and quality medical products, and to promote through effective collaboration among Member States and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities.”

Objectives of the Member State Mechanism

- 1.** Identify major needs and challenges, make policy recommendations and develop tools in the areas of prevention, detection methodologies, and control of substandard and falsified medical products in order to strengthen national and regional capacities.
- 2.** Strengthen national and regional capacities in order to ensure the integrity of the supply chain.
- 3.** Exchange experiences, lessons learnt, best practices and information on ongoing activities at national, regional and global levels.
- 4.** Identify actions, activities and behaviours that result in substandard and falsified medical products and make recommendations, including for improving the quality, safety and efficacy of medical products.
- 5.** Strengthen regulatory capacity and quality control laboratories at national and regional levels, in particular for developing countries and least developed countries.
- 6.** Collaborate with, and contribute to, the work of other areas of WHO that address access to quality, safe, efficacious and affordable medical products. This work includes, but is not limited to, the supply and use of generics which could complement measures for the prevention and control of substandard and falsified medical products.
- 7.** Facilitate transparent and coordinated consultation, cooperation and collaboration, from a public health perspective, with relevant stakeholders both regionally and globally.
- 8.** Promote cooperation and collaboration on surveillance and monitoring of substandard and falsified medical products.
- 9.** Further develop definitions of substandard and falsified medical products that focus on the protection of public health.

Structure and governance of the Member State Mechanism

The Member State Mechanism is chaired and run by Member States with the Secretariat supported by WHO (Figure 2). The terms of reference of the Member State Mechanism are framed from a public health perspective and expressly exclude the protection of intellectual property rights from their mandate.

Through regular meetings and a knowledge bank of tools and resources, the Member State Mechanism enables Member States to share experiences and ideas, and to support one another in shaping the best policies and programmes to combat substandard and falsified medical products. It ensures that no country has to face the problem of substandard and falsified medicines alone, and promotes global best practices that benefit all.

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Figure 2. Structure and governance of the Member State Mechanism



Substandard and Falsified Medical Products

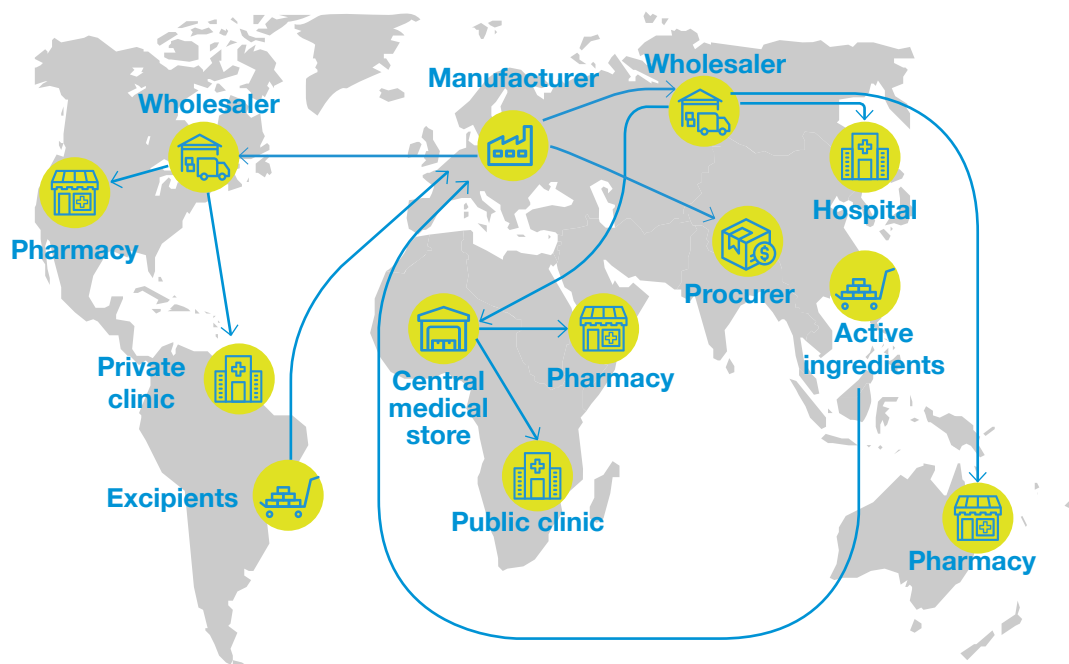
The key to a safer supply chain: **prevention, detection and response**

The work of the Member State Mechanism is aligned with the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. Member States use this system to report occurrences of substandard and falsified medicines in their supply chain. When a report is received by WHO, it is automatically uploaded to a secure database and is immediately compared against all other existing reports. Any matches are identified and details are shared with the reporting Member State.

Although the problem of substandard and falsified medical products is a global concern, solutions often lie at the national level (Figure 3). Data from the Global Surveillance and Monitoring System is analysed by experts at WHO. The analysis is then fed into the Member State Mechanism so that individual countries can determine what actions they can take on the ground. This analysis also informs policy on prevention, detection and response.

A unified terminology common to all Member States and other stakeholders is crucial to the success of the Member State Mechanism and the broader global effort to ensure safe supply chains for medical products. For example, clear, standardized definitions enable better data collection and analysis. Resolving the definition issue was a major achievement of the Mechanism. The terminology now in use (Box 1) both unifies and simplifies description of the issue from a public health perspective.

Figure 3.
A medicine's journey



Source: WHO

Box 1.
WHO and Member States agreed definitions



SUBSTANDARD

Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.



FALSIFIED

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.



**UNREGISTERED/
UNLICENSED**

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

Source: <https://www.who.int/medicines/regulation/ssffc/mechanism/en/>

2020-2021 priorities:

The Member State Mechanism has a two-year workplan that lays out the agreed prioritized activities.

- 1. Develop and promote** training material and guidance documents to strengthen the capacity of national/regional regulatory authorities for the prevention and detection of, and response to, substandard and falsified medical products.
- 2. Expand and maintain** the global focal point network among national medicines regulatory authorities to facilitate cooperation and collaboration.
- 3. Improve** Member States' understanding of detection technologies, methodologies and 'track and trace' models.
- 4. Increase** Member States' knowledge of the links between substandard and falsified medicines and access to quality, safe, efficacious and affordable medical products.
- 5. Develop and leverage** existing activity for effective risk communication and make recommendations for awareness campaigns on substandard and falsified medical products.
- 6. Enhance** Member States' capacity to expand awareness, effectiveness, impact and outreach in their work on substandard and falsified medical products.
- 7. Promote** shared understanding, from a public health perspective, among Member States, regarding medical products in transit.
- 8. Identify and develop** appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.

Getting the job done

Once the list of prioritized activities is agreed, work in that area is then led, either by a Member State, or by the Secretariat. In 2018 and 2019, for example, Brazil maintained the working group on developing and promoting training materials and guidance for regulatory bodies in prevention, detection and response to substandard and falsified medical products. Similarly, the United Kingdom led work on risk communication, while Colombia is leading on developing strategies to address distribution and supply via the internet. Some Member States including Brazil, India and USA make financial contributions whilst others including Argentina and the United Kingdom make significant contributions in kind. In this way, Member States contribute according to their strengths for the benefit of all.

Sharing knowledge through key publications

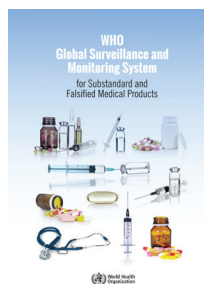
Sharing knowledge is a key function of the Member State Mechanism. A plethora of knowledge products, including guidelines, tools and reports produced by the Member State Mechanism and WHO, are all publicly available online. Two key publications to note are: A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products; and the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products Report.



A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products

This comprehensive study of the public health and socioeconomic impact of substandard and falsified medical products explores the examples of childhood pneumonia and malaria in sub-Saharan Africa. The study discusses the excess morbidity and mortality and disease prevalence associated with substandard and falsified medical products, as well as their contribution to antimicrobial resistance and loss of confidence in the health system. From a socioeconomic perspective, it examines individual and household health systems and socioeconomic costs.

<https://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en/>



WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products Report

Based on data from the WHO Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in vitro diagnostics, this report outlines the impact that substandard and falsified medical products can have on individuals, families, national health systems and the economy. It also describes the forces that drive the trade in these dangerous products, showing how they reach patients and consumers. Finally, the report discusses the systems and actions needed to prevent, detect and respond to the threat posed by substandard and falsified medical products, and describes action being taken by WHO, and by Member States in conjunction with other key partners.

<https://www.who.int/medicines/regulation/ssffc/publications/gsms-report-sf/en/>

Other selected knowledge products

Definitions of Substandard, Unregistered/Unlicensed, and Falsified Medical Products

Provides a simplified global understanding of what constitutes a substandard, falsified and unregistered medical product.

Terms of reference for the Global Focal Point Network for substandard and falsified medical products

Sets out the responsibilities of the regulatory focal points on substandard and falsified medical products and states that each should have access to the WHO substandard and falsified database in order to search for and report products.

Available authentication technologies for the prevention and detection of SF medical products

A technical document explaining existing authentication technologies.

Terms of reference for the working group to identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet

Ongoing work to assist regulatory authorities in addressing the distribution of substandard and falsified medical products through websites, social media and e-commerce platforms.

Guidance on developing a national plan for preventing, detecting and responding to actions, activities and behaviours that result in substandard and falsified medical products

Guidance on putting the prevention, detection and response strategy into practice.

Recommendations for health authorities to detect and deal with actions, activities and behaviours that result in substandard and falsified medical products

Guidance for regulators on responding to substandard and falsified medical products.

Guidance for health authorities on criteria for risk assessment and prioritization of cases

Guidance on how to risk assess and prioritize cases involving substandard and falsified medical products.

“IDEAs”: A global communications framework to help combat the threat from substandard and falsified medical products

Guidance on the design, implementation and monitoring of awareness campaigns.

Existing technologies and “track and trace” models in use and to be developed by Member States

Sets out what track and trace systems do and which countries have implemented systems.

All the documents are available in the six UN languages at the following link:

<https://www.who.int/medicines/regulation/ssffc/mechanism/en/>



Check out online resources

<https://www.who.int/medicines/regulation/ssffc/mechanism/en/>



WHO Member State Mechanism: **making the supply of medical products safer together**

The supply of substandard and falsified medicines is undeterred by national borders and affects countries regardless of their size, location and stage of economic development. International collaboration and cooperation is critical if the issue is to be effectively addressed. All countries are affected to some extent, either in the physical market or through the internet. Only a concerted effort that is inclusive, collaborative and mutually supportive can successfully combat the supply of substandard and falsified medical products.

The Member State Mechanism is a voluntary body open to all Member States' National Medicine Regulatory Authorities and ministries of health. All Member States are encouraged to actively engage with the Member State Mechanism and to make use of the dedicated and proven tools that it has developed over the years. As the size of the pharmaceutical market grows and demand increases, the issue of substandard and falsified medical products is expected to increase unless action is taken. It is recommended that Member States develop their own implementation plans for the prevention, detection and response to substandard and falsified medical products using the outputs of the Member State Mechanism.



Every day, substandard and falsified medical products enter the global supply chain resulting in socioeconomic cost and damage to health.

Since its creation in 2012, the Member State Mechanism on Substandard and Falsified Medical Products has become the global forum at which Member States convene, coordinate, decide and organize activities to address substandard and falsified medical products.



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