World Health Organization

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/

* University of Edinburgh
** London School of Hygiene and Tropical Medicine

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/falsely-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.

[1]https://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

Governance

The Member State Mechanism has a chair supported by 11 vice chairs, representing the six regions of WHO.

The terms of office of the chairperson and vice-chairpersons start at the end of a regular session of the Mechanism and expire at the end of every second regular session. The chair rotates amongst the regions on an alphabetical basis.

Chairs

2012-2014
African Region
Dr Paul Orhii, Nigeria

2014-2015
Region of the Americas
Ambassador A.P. D'Alotto, Argentina

2015-2016
Eastern Mediterranean Region
Deputy Minister Dr. R. Dinarvand, Islamic Republic of Iran

2017-2018
European Region
Dr Belén Escribano Romero, Spain

2019-2020
South-East Asian Region
Dr V.G. Somani, India

Current Vice Chairs

African Region
Benin
Kenya

Region of the Americas
Brazil
United States of America

Eastern Mediterranean Region
Islamic Republic of Iran
Iraq

European Region
Russian Federation
Spain

South-East Asian Region
India
Indonesia

Western Pacific Region
People's Republic of China
Malaysia

Substandard and Falsified Medical Products

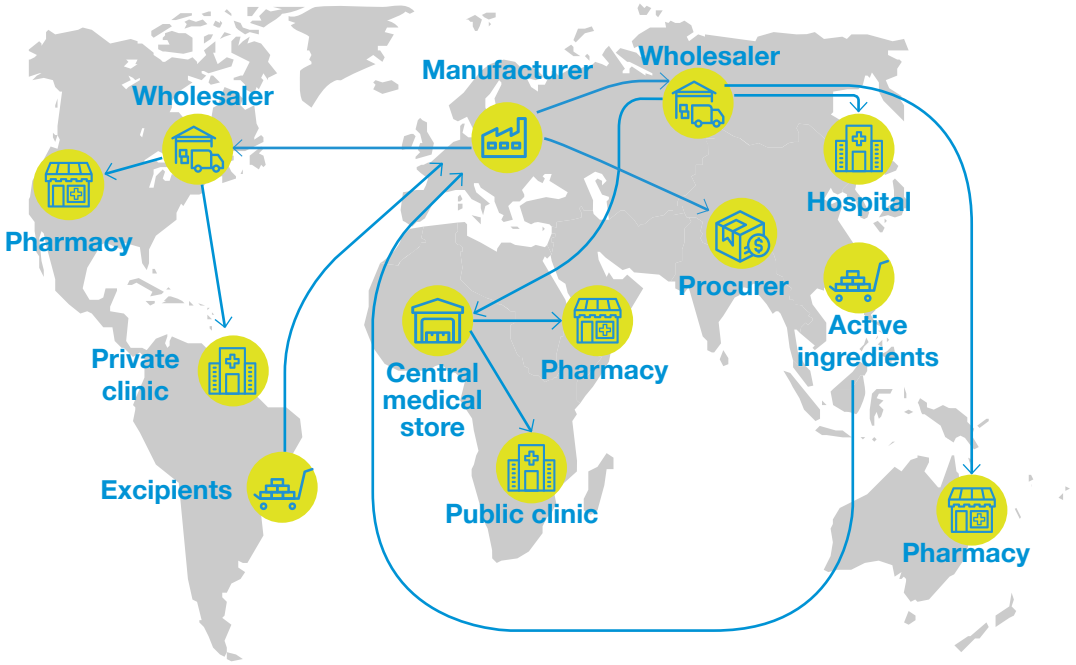
The key to a safer supply chain: **prevention, detection and response**

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