

Global Surveillance and Monitoring System for substandard and falsified medical products

| **Activity report**
| **August 2017–December 2021**



Global Surveillance and Monitoring System

for substandard and
falsified medical products

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Global Surveillance and Monitoring System for substandard and falsified medical products: activity report, August 2017-December 2021

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Foreword

It is with a sincere sense of responsibility that we present the 5-year report on the Global Surveillance and Monitoring System (GSMS) for substandard and falsified (SF) medical products, covering the period August 2017–December 2021. This report marks a milestone in our efforts to address the impact of SF medical products and lays the foundation for annual reports that will continue to guide our actions.

The findings presented in this report underscore the indispensable collective role of Member States and World Health Organization (WHO) in ensuring the quality, safety and accessibility of medical products, particularly in low- and middle-income countries (LMIC). The rise in the number of recorded incidents of SF medical products, including essential medicines such as antimicrobials, oncology medicines and vaccines, highlights the urgent need for coordinated action. Access to good-quality, safe, effective medical products is fundamental to achieving global health objectives.

An average annual increase of 36.3% was recorded during the reporting period (August 2017–December 2021), with 877 recorded incidents. Member States face numerous challenges in recording incidents, including limited technical capacity, weak governance, deficient national reporting systems and inadequate international information exchange. Collaboration among governments, international organizations, the pharmaceutical industry, health-care professionals and civil society is essential to effectively combat this growing threat.

The report presents an overview of the global scale and scope of the problem, emphasizing that no country or region is spared from the scourge of SF medical products. The GSMS has been instrumental in coordinating centralized global recording of structured, systematic data on incidents of SF medical products. With its multidimensional approach, early warning capability and collaborative network, it is uniquely effectiveness in addressing this global issue.

The COVID-19 pandemic significantly affected access to medical products for various patient groups, pharmaceutical supply chains were disrupted, and there was an increased demand for medical products all of which created an environment conducive to the proliferation of SF products. The report highlights the various types of SF medical products that emerged during the pandemic, indicating a need for heightened vigilance and response during health emergencies.

The report also addresses the risks of SF in-vitro diagnostic medical devices (IVDs) and emphasizes the importance of effective regulatory systems, legal frameworks, international cooperation and public awareness. Assessment of the driving forces and facilitators reveals persistent challenges.

In view of these challenges, the report provides several assessments and recommendations. I commit WHO's support to continued strengthening of national regulatory systems, of international cooperation, of coordination among regulators and law enforcement, of public awareness and of national and international recording systems. The findings and recommendations presented in this report show that addressing the issue of SF medical products is a shared responsibility that transcends borders and sectors. By maintaining a collective commitment to this cause, all stakeholders can ensure that patients receive safe, effective medical products, safeguarding public health and patient safety for generations to come.



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Mr Naseem Hudroge, Ms Anita Sands and Ms Pernette Bourdillon Esteve (ISF) collated and analysed the data.

WHO extends its sincere gratitude to all those who contributed to the development and completion of this report. We acknowledge the invaluable support provided by national regulatory authorities, whose dedication to global health and patient safety is the basis of this report.

WHO also thanks the many national focal points whose continued commitment to reporting has been crucial to collection of data on the issue of substandard and falsified medical products.

WHO is also appreciative of contributions from governments, pharmaceutical companies, health-care providers, advocacy groups and other stakeholders who have shared their insights, data and perspectives.

WHO thanks the individuals and organizations involved in establishment and maintenance of the Global Surveillance and Monitoring System for substandard and falsified medical products, whose commitment to transparency and data-driven analysis has been indispensable.

Abbreviations

COVID-19	coronavirus disease 2019
GBT	Global Benchmarking Tool
GSMS	Global Surveillance and Monitoring System
IVDs	in-vitro diagnostic medical devices
LMIC	low- and middle-income countries
MPA	medical product alert
SF	substandard and falsified

Executive summary

This report on the Global Surveillance and Monitoring System (GSMS) for SF medical products in the period 2017–2021 provides insights, describes challenges and offers strategies and actions for preventing, detecting and responding. Access to safe, effective medical products is paramount for global health. This report describes a critical role of WHO in ensuring the quality and safety of medical products, particularly in LMIC. The report signals the alarming rise in the number of reported incidents of SF medical products, including a wide range of essential medicines, such as antimicrobials, oncology medicines and vaccines. During the period covered, 877 incidents were recorded, with an average annual increase of 36.3%. The potential impact on increase in antimicrobial resistance cannot be understated.

The report highlights the challenges faced by Member States, including limited technical capacity, weak governance, deficient national reporting systems and inadequate international information exchange. It emphasizes the importance of cooperation among governments, international organizations, the pharmaceutical industry, health-care professionals and civil society to combat this grave threat.

As the outlook is for a continual increase in the numbers of SF medical products, the report calls for concerted action. The recommendations include strengthening regulatory systems, enhancing national legal frameworks, developing sustainable reporting systems, improving coordination between regulators and law enforcement, raising public awareness and promoting international cooperation.

This report complements work in other areas in WHO and by national governments to improve access to effective, safe, quality-assured medical products. By aligning efforts and leveraging existing initiatives, the global community can maximize its response to the multifaceted challenge of SF medical products and the initiatives and strategies for prevention, detection and response.

1 Global scale and scope of the problem, August 2017–December 2021

1.1 The threat

SF medical products continue to pose a serious risk to global public health. While there is a general perception that the risk of SF products is greater in LMIC, no country or region has avoided the problem of these products, and they have been identified in both well-resourced and poorly resourced regulatory systems.

Substandard medical products deny patients access to safe, effective, high-quality products. While their substandard quality may not have been intentional, they can have inadequate therapeutic effectiveness and, in some cases, pose serious risks to patient safety, particularly in vulnerable patient populations.

Falsified medical products have been deliberately designed, manufactured and/or supplied in such a way as to fraudulently misrepresent their identity, composition or source. Genuine, authorized medicines can be falsified, such as by use of fraudulent packaging to disguise out-of-date products. In other cases, batch details and expiry dates are physically altered on packaging to extend the shelf life of a product. Fraudulent documentation of the origin and source of genuine products may falsify them, as their safety and efficacy are no longer guaranteed. Such products are therefore particularly difficult to detect. Falsified medical products may contain no active ingredient, the wrong active ingredient or the wrong amount of active ingredient. They may also contain contaminated excipients or starting materials.

The Global Surveillance and Monitoring System (GSMS) is key to WHO's work to combat SF medical products. Since its inception in 2013, the GSMS has been used to coordinate centralized global recording of structured, systematic data on incidents of SF medical products, allowing comprehensive, accurate assessment of the extent and impact of the issue. The terms of reference of the GSMS for SF medical products include significant improvement of the quantity, quality and

analysis of data¹. The system uses data to identify not only SF medical products but also the populations at greatest risk and vulnerabilities in supply chains and health systems. The results can assist Member States in developing policies and procedures and guide investment and capacity-building for the prevention, detection and response to SF medical products.

The GSMS is unique in its global scope, multidimensional approach, integrated systems, early warning capability, collaborative network and emphasis on data-sharing and transparency. These features enable the system to effectively monitor, detect and respond to the threat of SF medical products globally, as part of WHO's mission to promote health and well-being worldwide.

The GSMS employs several methods to collect and analyse information on incidents of SF medical products. These methods include:

- **Focal points:** National Medicines Regulatory Authorities (NMRAs) and industry have designated personnel who act as focal points for the GSMS. These individuals are responsible for identifying and reporting suspected or validated SF products.
- **Health-care providers:** may also report suspicious products or incidents directly to the WHO
- **Public reporting:** the GSMS encourages public reporting of suspected SF medical products. This can be done through various channels, including online reporting forms and hotlines at country level, allowing patients and consumers to report incidents directly.

¹ Global Surveillance Monitoring System for substandard and falsified (SF) medical products. Geneva: World Health Organization; 2022 (https://cdn.who.int/media/docs/default-source/substandard-and-falsified/gsms_terms-of-reference160517.pdf?sfvrsn=e2ff0ccf_3&ua=1).

- **Media monitoring:** Regular real-time intelligence gathering is conducted with specialized software to search for relevant keywords on online news outlets, social media platforms, and online forums, reporting negative experiences, adverse effects, or suspicious product characteristics.
- **Electronic reporting:** WHO provides an electronic online portal for focal points to submit reports on suspected SF products. This online system facilitates standardized data collection and ensures secure information storage.
- **Field investigations and inspections:** National regulatory authorities with or without support from WHO may conduct on-the-ground investigations and inspections to verify reports and gather detailed information about suspected SF products. These inspections help in identifying and documenting the nature and extent of the problem.
- **Data analysis and risk assessment:** The GSMS collects data from the various sources, including laboratory testing results, and market surveillance data are analysed by the ISF team. This information is used by the ISF team to use established criteria to assess the risk posed by SF medical products and to identify trends and patterns.
- **Collaboration with other organizations:** The GSMS collaborates with other international

organizations, such as Interpol, the World Customs Organization, and non-governmental organizations (NGOs), to share information and coordinate efforts to combat SF medical products.

- **Limitations:** The GSMS primarily relies on reports submitted by trained focal points as well as following up on information reported by the public. This means the data collected may not always have the same level of validity and would not reflect the absolute prevalence of SF medical products in circulation. It however provides crucial insights into potential issues and is facilitates targeted interventions.

1.2 The scale

WHO provides information on incidents of SF medical products for each WHO region; individual Member States are not identified, as recording is uneven and may be inconsistent during a defined period. Furthermore, the WHO regions do not comprise equal numbers of Member State, and the population size and regulatory capacity of each Member State varies widely. Despite these limitations, the GSMS holds perhaps the most comprehensive global record of incidents of SF medical products. Between 2013 (its inception) and 2022, the GSMS recorded a total of 1462 Incidents. In the period covered by this report, the third quarter of 2017 to the fourth quarter of 2021, 877 Incidents were recorded, providing information on 1630 confirmed or suspected

Fig. 1. Numbers of recorded incidents of SF products, August 2017–December 2021

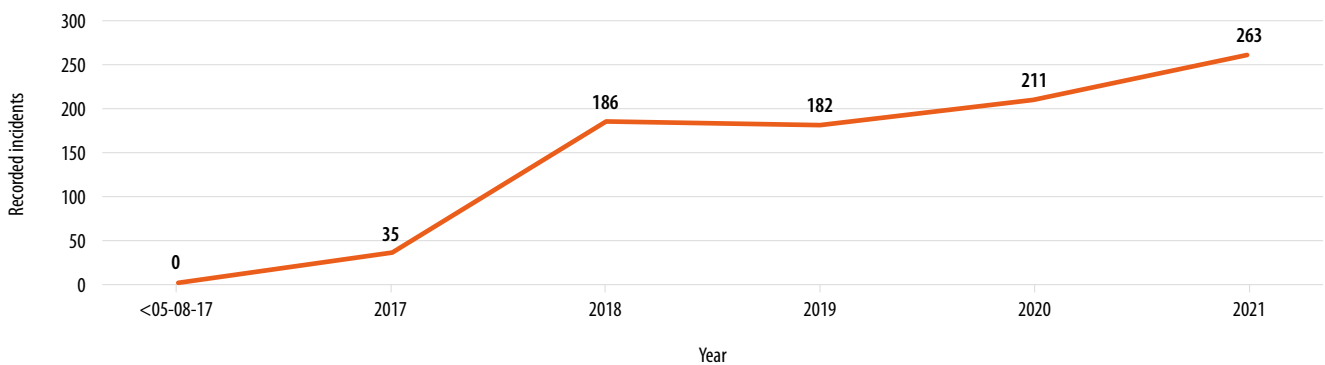
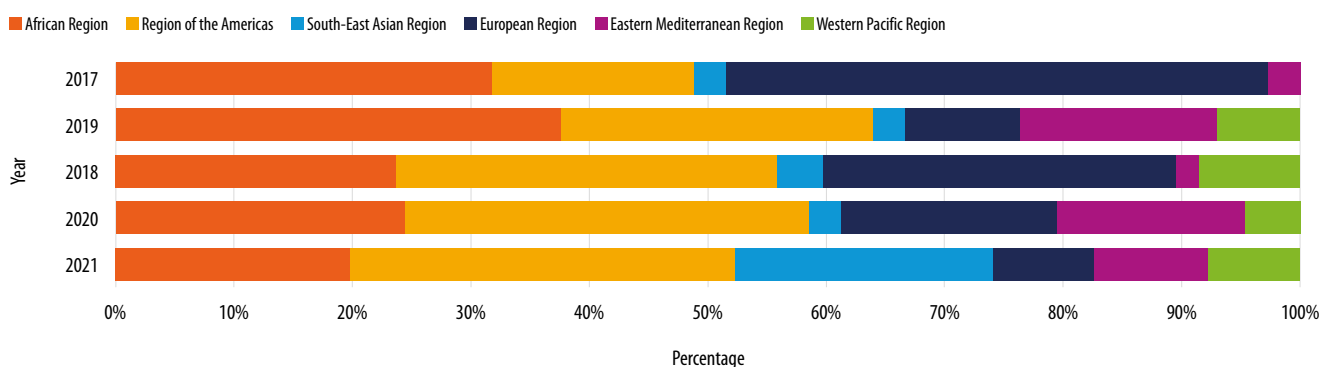


Fig. 2. Incidents recorded by WHO region, by decreasing order of the total number of recorded incidents



SF products. The number of records increased on average by 36.3% annually (Fig. 1). For SF medicines and vaccines, one incident can include one or more product at one time and place, and a “product” includes the product name, product code(s), a regulatory version and a manufacturing site(s). More than one lot number can be recorded for a suspected product in the GSMS database.

The WHO report *A study on the public health and socioeconomic impact of substandard and falsified medical products in 2017*² noted that 10% of medical products in LMIC were substandard or falsified, indicating substantial under-recording and a much larger problem. High incidence rates, however, may indicate that the occurrence of SF in a supply chain is due to ineffective control measures; alternatively, high rates might reflect better case detection. High rates are a good indicator of the load on the system and hence useful for planning strategies to combat SFs.

All WHO regions are affected by SF medical products, and the total number of recorded incidents across all WHO regions increased during the reporting period (Fig. 2).

There were 226 incidents recorded from the WHO African Region, indicating challenges in ensuring the

safety and quality of medical products in the Region, including the difficulty of regulators in exercising effective market control and surveillance. Detection of imported SF products, before they are placed on the market, may be hampered by lack of detection technologies and ineffective coordination with national customs authorities.

The Region of the Americas recorded the highest number of SF incidents in all years during the reporting period, a continual annual increase, except for a small decrease in 2021.

In the reporting period, 151 incidents were recorded in the WHO European Region, even though many countries in the Region have considerably more mature regulatory systems than elsewhere. Unique challenges faced by the Region include complex supply chains and significant proliferation of illicit websites that supply SF and unauthorized medical products.

The numbers of incidents recorded in the South-East Asian, Eastern Mediterranean and Western Pacific regions have historically been significantly lower than those in the other regions. After 2020, however, notable increases were seen in the South-East Asian and Eastern Mediterranean regions.

² A study on the public health and socioeconomic impact of substandard and falsified medical products. Geneva: World Health Organization; 2017 (<https://www.who.int/publications/i/item/9789241513432>).

2 WHO Medical Product Alerts

In its terms of reference, the WHO GSMS issues medical product alerts (MPAs) on SF medical products that represent a significant threat to public health. Alerts are issued only when an SF product poses a genuine, significant threat to public health and when enhanced international risk communication is appropriate to help detect and remove the products from the market.³

MPAs may apply to SF products detected in more than one country or WHO region. Of the 32 MPA published during the reporting period, 10 were for SF products detected in more than one country and 5 were for SF products detected in more than one region. All the MPAs concerned falsified rather than substandard products.

During the reporting period, 32 MPAs were issued by the GSMS for 63 SF medical products (Fig. 3).

Fig. 3. Number of medical product alerts issued per reporting year

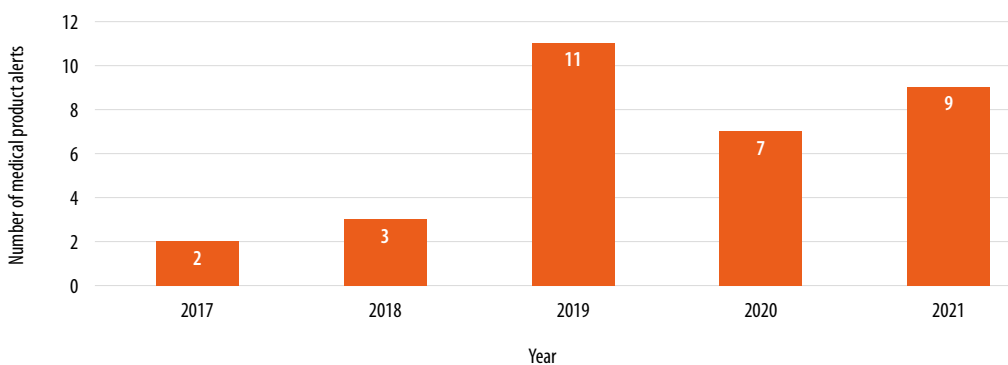
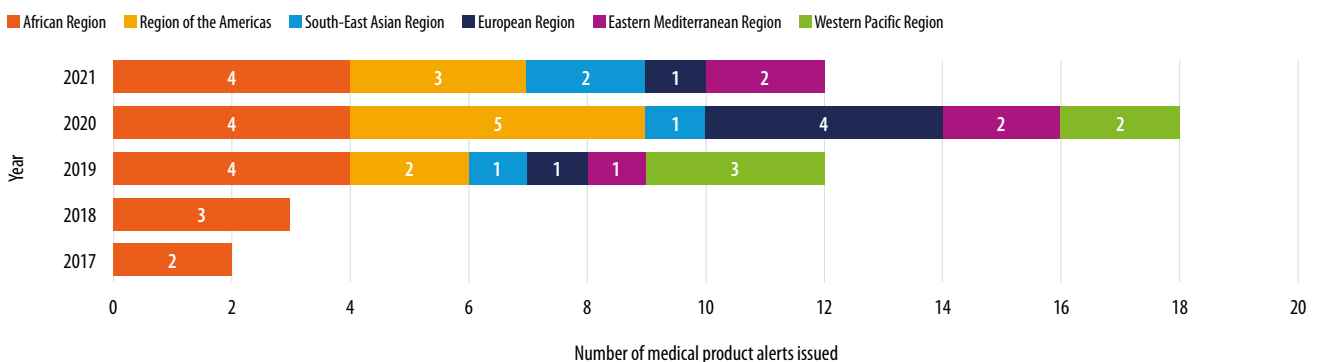


Fig. 4. Numbers of medical product alerts issued per reporting year, by WHO region



³ Regulation and prequalification. WHO Medical Product Alerts – background. Geneva: World Health Organization; 2023 (<https://www.who.int/teams/regulation-prequalification/incidents-and-SF/medical-product-alerts-background>).

3 Significance and impact of the COVID-19 pandemic

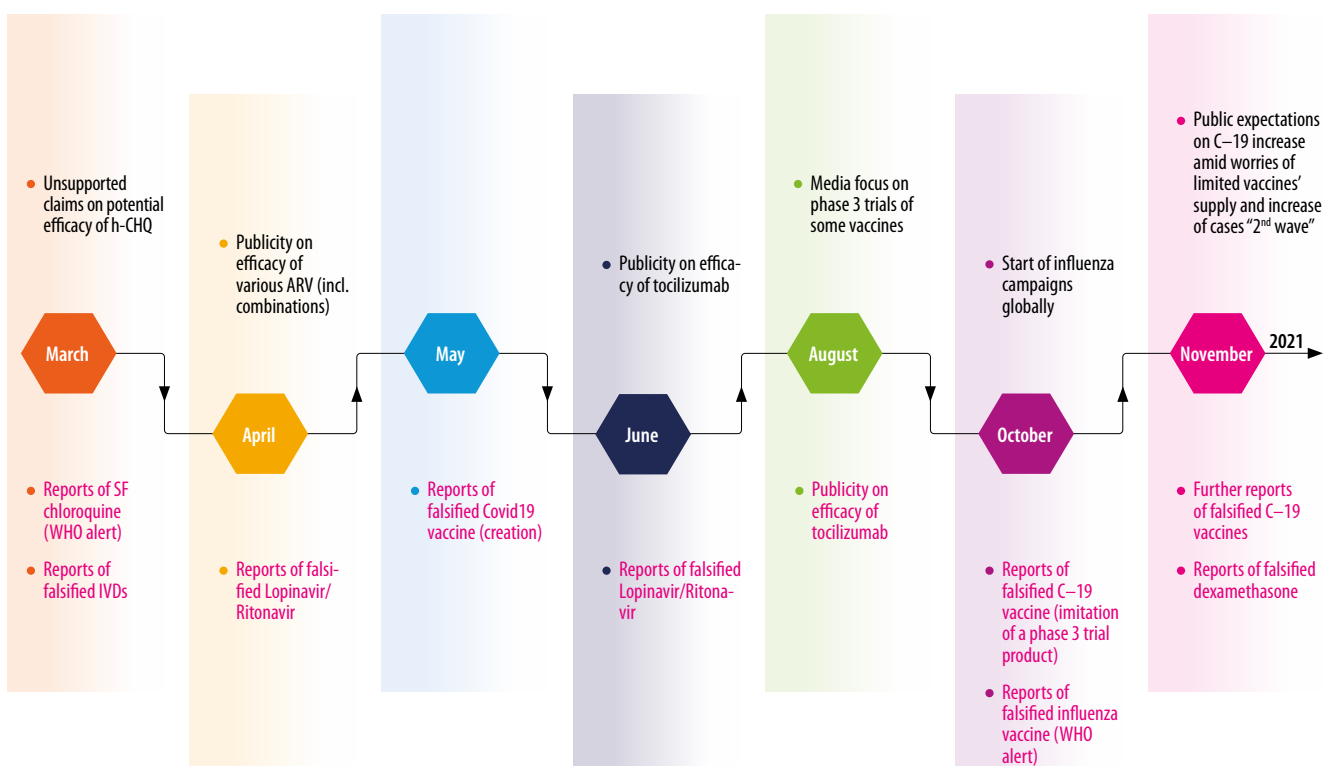
The COVID-19 pandemic had a significant impact on access to medical products for various patient groups. Patients with cancer, heart disease, chronic respiratory diseases, diabetes or other noncommunicable diseases were particularly affected by disruptions in pharmaceutical supply chains and limited physical access to health-care providers and pharmacies during nationwide lockdowns.⁴

The pandemic also generated a large demand for medical products for the diagnosis, prevention and treatment of COVID-19, including provision of medical products at a distance. Manufacturing and distribution

networks were disrupted by transport restrictions and lockdowns, leading to shortages of some medical products, which fuelled demand that was sometimes met by provision of unauthorized, substandard or falsified medical products.

The infodemic⁵ and misinformation that accompanied the pandemic caused confusion among both health-care professionals and the public, and this situation was exploited by illicit groups involved in the manufacture and distribution of SF medical products and products claimed to be effective against COVID-19. The lockdowns and social distancing measures also resulted in a rise

Fig. 5. Records of SF medical products recorded in the GSMS at the time of declaration of COVID-19 as a public health emergency of international concern in 2020



IVD, in-vitro diagnostics; h-CHQ, hydroxychloroquine; ARV, antiretroviral; C-19, COVID-19.
Source: WHO GSMS database and media monitoring.

⁴ COVID-19 pandemic significantly impacted access to medicines for noncommunicable diseases. Geneva: World Health Organization; 2023 (<https://www.who.int/news/item/22-03-2023-covid-19-pandemic-significantly-impacted-access-to-medicines-for-noncommunicable-diseases>).

⁵ Infodemic. Geneva: World Health Organization; 2023 (https://www.who.int/health-topics/infodemic#tab=tab_1).

in e-commerce and online shopping, which led to a flourishing supply of falsified medical products on illicit online marketplaces.⁶ The GSMS identified three types of SF medical products during the pandemic:

- repurposed products claimed to be effective against COVID-19;
- repurposed products claimed to be effective against COVID-19; and
- SF versions of novel products with fraudulent claims of treating or curing COVID-19.

After the Director-General of WHO declared COVID-19 to be a public health emergency of international concern, on 30 January 2020, a notable increase was observed in the GSMS of links between perceived efficacy, demand and increased numbers of records of SF versions of medical products of interest (Fig. 5). During the reporting period, the GSMS recorded 38 Incidents of SF products detected in 17 countries, either because the products fall in the above categories or because of altered market dynamics.

⁶ COVID-19 boost to e-commerce sustained into 2021, new UNCTAD figures show. Geneva: United Nations Conference on Trade and Development; 2022 (<https://unctad.org/news/covid-19-boost-e-commerce-sustained-2021-new-unctad-figures-show>).

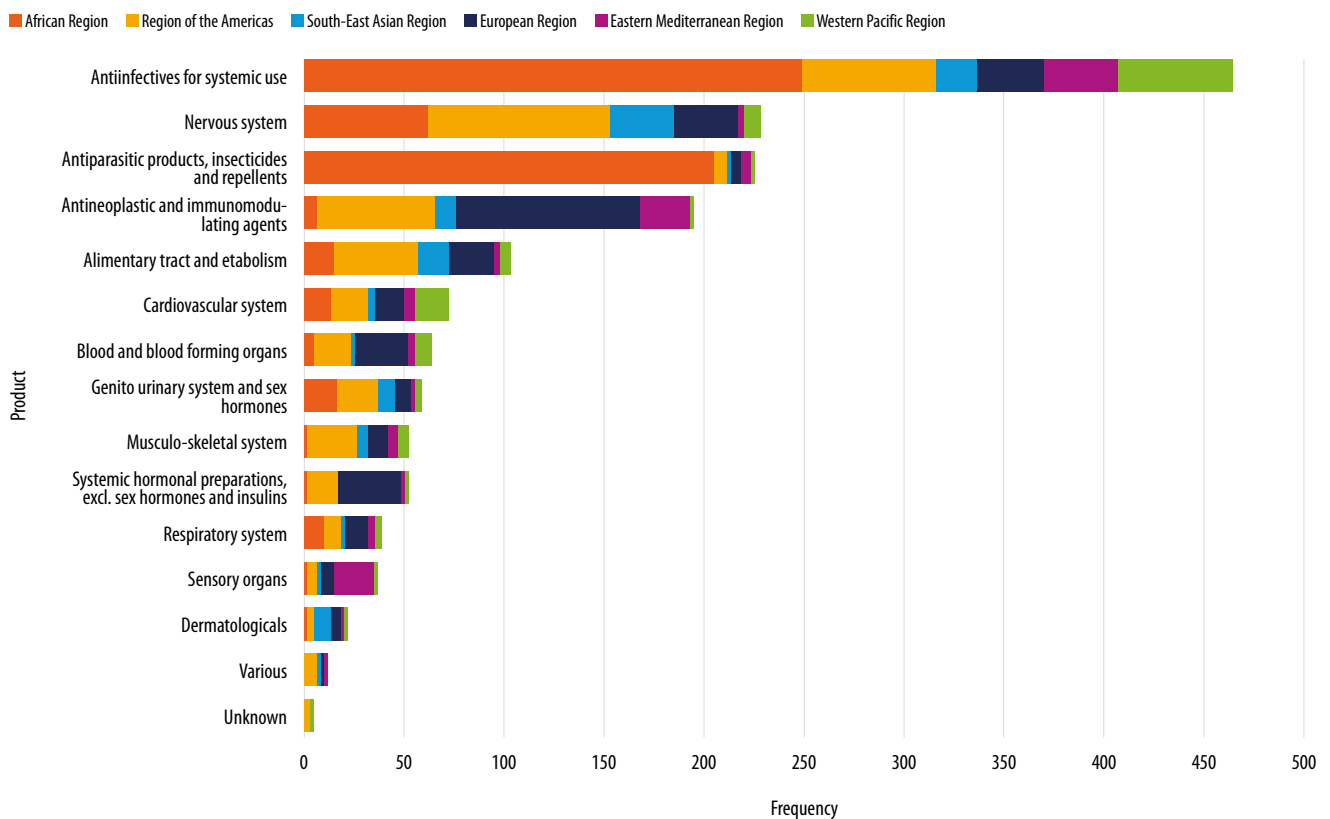
4 Medical products at risk

The GSMS recorded SF products in seven therapeutic categories during the reporting period, anti-infective agents being the most frequently recorded. All regions of the world are at risk of SF medical products, although there is significant regional variation in the categories of SF products (Fig. 6). The SF therapeutic categories for which there were the most records in the WHO African Region were anti-infective agents for systemic use,

antiparasitic products, insecticides and repellents, and products for nervous system disorders.

The continued trend in the increasing number of records of anti-infective agents over those in previous periods and the potential impact on tackling antimicrobial resistance are notable.

Fig. 6. Frequency of products at risk of being substandard or falsified, August 2017–December 2021, by WHO region



5 Substandard and falsified in-vitro diagnostic medical devices (IVDs)

SF medical products in the GSMS database include in-vitro diagnostic medical devices (IVDs). An incident with regards to a medical device is any malfunction or deterioration in the safety, quality or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any undesirable side-effect,⁷ including any instance in which death or serious deterioration in health occurred to a patient, user or other person. An IVD incident relates to only one product, unlike SF medicines and vaccines, for which one incident may refer to one or more products.

During the reporting period (1 January 2020 to 31 December 2021), 124 incidents were recorded for IVDs that were prequalified, listed for emergency use or otherwise recommended by WHO. Of the 124 IVD incidents, all but one was recorded as potentially substandard. The one incident referred to a falsified HIV rapid diagnostic test. The data analysis period differs from the rest of this report because IVD incidents were initially collected in a separate database for WHO Prequalification of In Vitro Diagnostics. All IVD incidents were transferred to GSMS by the end of 2019.

5.1 Sources of records

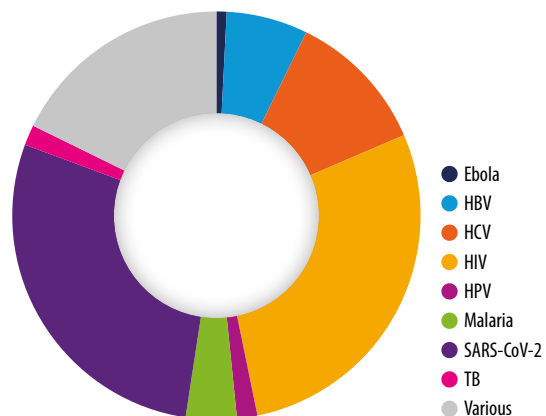
During the 2-year reporting period, significant differences were seen in the numbers of records from national regulatory authorities, IVD manufacturers and IVD users: 71% of the SF IVD incidents were recorded by the manufacturer, 24.2% by IVD users and only 4.8% by IVD regulators. These proportions are not unexpected, as recording of incidents and corrective actions for safety to WHO is a post-listing requirement

for manufacturers of products prequalified by WHO and listed for emergency use.⁸

5.2 Types of SF IVDs recorded

Of the 124 incidents, the most commonly recorded products were IVDs for HIV and SARS-CoV-2 (35 incidents each, 28.2%), followed by dedicated analysers for nucleic acid techniques for various pathogens (17.7%) (Fig. 7).

Fig. 7. IVD incidents by type of pathogen, 2020–2021



Ebola: Ebola virus; HBV, hepatitis B virus; HCV, hepatitis C virus; HPV, human papillomavirus; Malaria, *Plasmodium* spp.; TB, *Mycobacterium tuberculosis*

There was significant under-recording of rapid diagnostic tests for malaria, given the high sales volume, which was 419 million tests in 2020. By comparison, 190 million HIV rapid diagnostic tests were sold during the same period.⁹ Reporting of incidents of SF IVDs used in malaria diagnosis should therefore be strengthened, as legal provisions for post-marketing and market surveillance of medical devices may be

⁷ Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. Geneva: World Health Organization; 2020 (<https://iris.who.int/handle/10665/337551>).

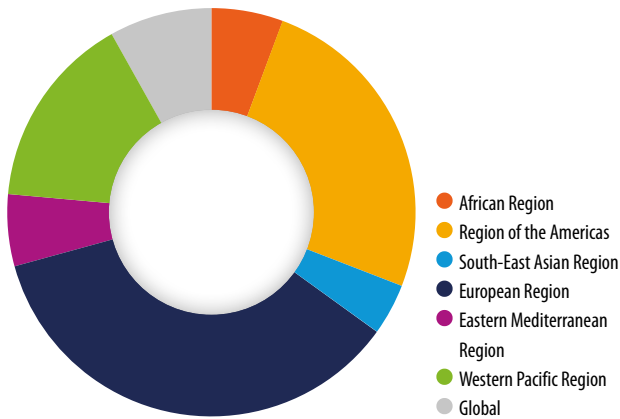
⁸ Overview of the WHO prequalification of in vitro diagnostics assessment: prequalification of in vitro diagnostics. Version 9. Geneva: World Health Organization; 2021 (https://extranet.who.int/prequal/sites/default/files/document_files/21-01-27-Overview-DX-Prequalification-Requirements-PQDx_007-v9.pdf#:~:text=Introduction,-World%20Health%20Organization&text=WHO%20prequalification%20of%20IVDs%20is,product%20meets%20WHO%20prequalification%20requirements.).

⁹ World malaria report 2021. Geneva: World Health Organization; 2021 (<https://www.who.int/publications/i/item/9789240040496>).

weak or inexistent in many countries, particularly those in which malaria is prevalent.

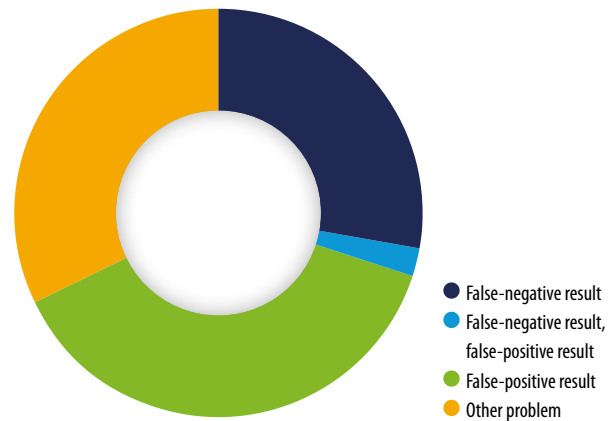
Incidents related to HIV IVDs were recorded mainly in the Region of the Americas and in the European Region (Fig. 8), possibly because of the greater maturity of regulatory systems in those regions.

Fig. 8. Numbers of IVD Incidents recorded, by WHO region, 2020–2021



The terms used by the International Medical Device Regulators Forum for recording adverse events were used to classify incidents. The most common were output problems, specifically false positive test results (38%) and false negative test results (28%) (Fig. 9). Other problems were manufacturing, packaging or shipping problems and failure to obtain readings, leading to invalid results. Manufacturers undertook 34 corrective actions to ensure safety.

Fig. 9. Type of problem recorded for IVDs, 2020–2021



6 Driving forces and facilitators

The persistent main reasons for SF medical products remain significantly unaltered. These are:

- limited access to affordable, safe, effective, high-quality medical products;
- weak technical capacity of national regulatory systems; and
- poor governance of manufacturing networks, supply chains and health delivery systems, including corruption and unethical practices.

Several factors increase the likelihood of SF medical products and the potential risks they pose and thus limit an effective response to the threat:

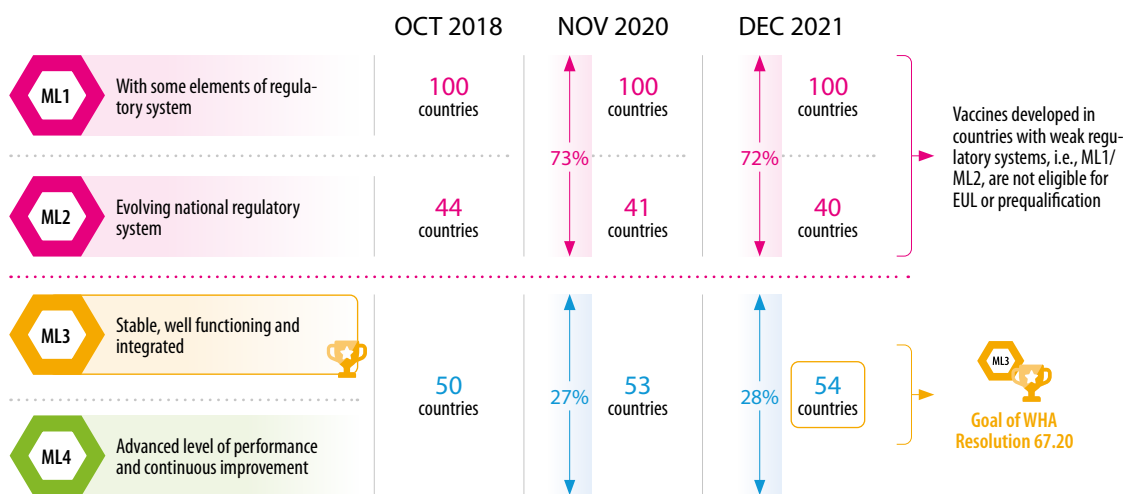
- weak regulatory systems;
- inadequate legal frameworks for market control;
- limited international cooperation and information-sharing;

- inadequate or inexistent national recording systems;
- ineffective coordination among national regulatory authorities, law enforcement and customs agencies;
- little public awareness of the risks;
- limited use of technology for product authentication or tracking; and
- rapidly evolving scientific and medical developments.

Understanding of these factors could allow countries to develop targeted strategies to address the threat effectively.

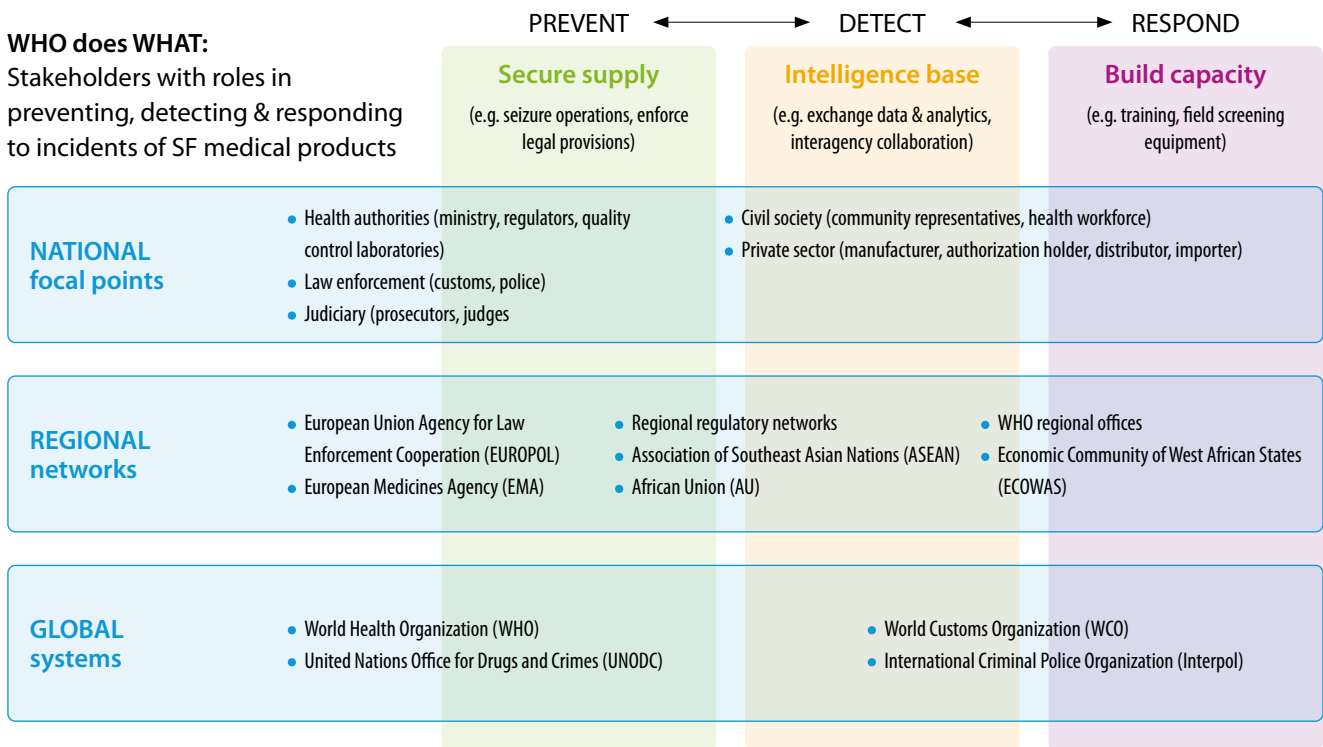
Weak regulatory systems: Regulatory systems must be strengthened to address the challenges posed by SF medical products. Inadequate regulatory frameworks in some Member States may facilitate the entry of SF

Fig. 10. Maturity of national regulatory systems for medicines and vaccines as of December 2021



ML: (regulatory system) maturity level; EUL: emergency use listing; WHA, World Health Assembly
 Source: WHO Regulation Systems Strengthening team.

Fig. 11. International cooperation to prevent SF medical products



products onto the market. The risk from substandard products may be particularly high in Member States in which the regulatory system cannot oversee the life cycle of medical products and in which some sectors have no regulatory presence (e.g. importation through ports and informal markets).

The WHO Global Benchmarking Tool¹⁰ (GBT) is the means by which WHO and Member States evaluate regulatory systems. The tool can be used by regulatory authorities to evaluate their strengths in core functions and identify areas for improvement. Four levels of the maturity of a regulatory system have been defined to reflect the extent to which it is stable, functioning and integrated. Maturity level 3 represents the minimum target for a well-functioning system. During the reporting period, only 28% of WHO Member States had a stable, well-functioning, integrated regulatory system. Most countries had only some elements or were evolving their regulatory system.

A mature regulatory system is important, as market surveillance and control are critical in preventing,

detecting and responding to SF medical products and ensuring the quality and safety of the products.

Inadequate legal frameworks for market control: A regulatory system may be well resourced and function well but may be based on an insufficiently robust legal framework for controlling and monitoring medical products on the market. This situation can lead to the proliferation of SF medical products, particularly in an unregulated or illicit market. During the period 2016–2021, 84 Member States (representing 71% of the global population) had either self-benchmarked or had been formally benchmarked with the GBT tool. Of the 27 countries that had been formally benchmarked, 22 (81%) categorized at up to maturity level 3 were not fully implementing 11 indicators in the tool that are directly linked to SF medical products. Effective market control is essential to curtail the availability and circulation of such products.

Limited international cooperation and information-sharing: Collaboration and information-sharing among Member States and with WHO are crucial for detecting and responding to incidents of SF medical products. Cooperation is necessary to establish cohesive, effective approaches to the global problem, while inadequate information-sharing can impede the detection, removal

¹⁰ WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems. Geneva: World Health Organization; 2021 (<https://www.who.int/tools/global-benchmarking-tools#:~:text=The%20GBT%20is%20designed%20to,quality%20and%20risk%20management%20system>).

and analysis of SF medical products, thereby increasing the chances for patient harm. Transparent information-sharing on SF medical products is critical for informed decision-making and effective interventions. International cooperation to prevent SF products is illustrated in Fig. 11.

Inadequate or inexistent national recording systems:

Two of the GBT indicators address documented procedures to enable the public to record suspected SF medical products for national regulatory authorities and to share findings and regulatory decisions with other countries. An effective, sustainable national recording system is necessary to detect and respond to SF medical products, for a national assessment of the extent of the problem and to design timely, sustained interventions. The lack of such systems severely limits the role of national regulatory authorities in tackling SF medical products.

Ineffective coordination among national regulatory authorities, law enforcement and customs agencies:

One of the most prevalent challenges is lack of strategic cooperation and coordination among authorities. The lack of defined legal relations and agreements on information-sharing in many regulatory systems has created opportunities for illicit organized crime to produce and distribute SF medical products. Enhanced coordination is vital to strengthen market control and prevent illegal activities in the medicines supply chain.

Little public awareness of the risks: In 2020–2021, WHO conducted a study of the level of awareness of SF products in Ghana, Nigeria, Sierra Leone and Uganda

and then supported nationwide risk communication campaigns to educate the public on the prevalence and dangers of SF medical products. The initial results show inadequate public awareness about the risks associated with SF medical products, which can result in unintentional consumption or use of these products. Awareness campaigns are essential to empower individuals to make informed decisions about their health.

Limited use of technology for product authentication or tracking: Technology is essential for verifying the authenticity and origin of medical products, to enhance product traceability and improve patient safety.

Rapidly evolving scientific and medical developments:

The fast pace of advances in science and medicine may outpace regulatory capability for adequate evaluation and approval of new products. Global media coverage may also amplify such developments and may focus on use of unauthorized therapies, clinical trials and novel products. The coverage may include false or misleading information about unproven treatments, thereby leading individuals to seek unregulated, potentially unsafe products. Such an “infodemic” was observed during the COVID-19 pandemic and led to the demand and the supply of both falsified and unauthorized medical products claimed to prevent or treat COVID-19. Lack of global regulatory alignment and inconsistent or inadequate regulatory frameworks allow illicit actors to exploit the demand to introduce falsified medical products masquerading as the latest medical innovations.

7 Assessment and recommendations

Assessment of trends up to 2021 indicates that the threat of SF medical products remains a significant risk to patient health and safety in all regions. SF medical products are likely to continue to proliferate beyond the next 12 months.

While recording of incidents generally increased during the reporting period, the regional breakdown is uneven, with particularly limited recording of SF IVDs by national regulatory authorities. The results also show that IVD users should actively record incidents to facilitate investigation by manufacturers, and manufacturers must meet their responsibility for prompt recording of incidents for regulators or ministries of health. Poor-quality IVDs can often be identified visually, including defective components or misleading labelling, which were recorded more frequently in settings with limited resources. Safety issues were recorded predominantly in countries with well-established regulations and consistent data analysis. The assessment shows, however, inconsistent recording by users of the probability of harm, indicating an area for improvement in data consistency and clarity.

The larger number of records of SF antimicrobials relative to other therapeutic categories identified in targeted market surveys in Africa remains of concern, as it has a potential impact on the global fight against antimicrobial resistance. Antimicrobial resistance is a growing global health threat where bacteria, viruses, and other microorganisms become resistant to the drugs that were once effective in treating infections. Potential consequences or effects of the rise of antimicrobial resistance are significant and should not be minimized or downplayed. The implications or any correlation will require increased generation of scientific evidence.

The high levels of recording should not be interpreted as an indication of prevalence but as differences in the capacity of regions and Member State for detection, effective national recording and willingness to share information with the WHO GSMS. The constant increase

in recording may also reflect the initiatives of regional and national regulatory authorities for effective detection. It is notable that, even with better detection, there has been no decrease in the number of recorded incidents.

Under-recording has not only immediate implications for patients' health but provides a distorted perception of the scale of the problem, which complicates effective allocation of resources by policy-makers and health organizations and implementation of targeted interventions. The true penetration of SF products into supply chains and their use are still not fully known, complicating mitigation of risks and protection of vulnerable populations. Acknowledgement of the under-recording of SF medical products, use of a science-based approach and a collective commitment to combating SF medical products would have a significant effect in the long term. The impact of inaction is far-reaching, as globalization, technological advancements and the accessibility of online marketplaces will continue to provide the means to distribute SF medical products on a global scale. Other driving forces, such as media reporting and lack of policy alignment, will also continue to facilitate the promotion and distribution of these potentially dangerous products.

While new technologies and innovations could enhance detection, their availability and timely delivery remain significant challenges to deployment at scale, especially in low-resource settings. The focus should remain on strengthening regulatory systems, which is one of the most important means of addressing SF products globally and strategically. Lack of regulatory alignment, weak oversight and poor enforcement of regulatory standards complicate effective mitigation of the threat. The most urgent need is for improved national recording systems and for Member States to share information on SF incidents and products in a timely, transparent manner. Market surveillance and access to up-to-date data are essential to assess the current state of the threat and to adapt strategies to tackle this persistent challenge.

Global surveillance of SF medical products in the period 2017–2021 further stresses the importance of the following:

- continued strengthening of national regulatory systems;
- enhanced international cooperation and timely information-sharing;
- better coordination among regulators, law enforcement and customs authorities;
- increased public awareness of the risks of SF medical products;
- strengthened national and international recording systems;
- greater incident recording of SF rapid diagnostic tests for malaria;
- stronger post-market surveillance of rapid diagnostic tests, especially in regions with high rates of HIV and malaria, to ensure early identification and resolution of safety concerns; and
- provision of support to countries with weak or inexistent regulatory systems for IVDs to establish robust regulatory frameworks and to prioritize incident recording and patient safety.

These actions will require sustained cooperation among governments, international organizations, the pharmaceutical industry, health-care professionals and civil society. Measures such as strengthening regulatory systems, improving supply chain management, enhancing surveillance and raising public awareness are integral to a comprehensive approach. The WHO Member State Mechanism for SF medical products¹¹ provides an inclusive, collaborative, mutually supportive platform to address some of these issues.

¹¹ WHO Member State Mechanism. Geneva: World Health Organization; 2023 (<https://www.who.int/teams/regulation-prequalification/incidents-and-SF/mechanism>).

8 Conclusions

This report underscores the critical importance of ensuring safe, effective, good-quality medical products. Establishment of the GSMS for SF medical products by WHO has played a pivotal role in addressing this need, providing a central platform for global recording and risk assessment of incidents involving such products, managing incidents and supporting Member States. During the period 2017–2021, the number of incidents associated with a broad spectrum of essential medicines and IVDs increased. Despite some regional disparities in recording, the results indicate that the threat of SF medical products will persist and potentially worsen.

Identification of the drivers of this proliferation and the challenges faced by Member States in responding effectively demand sustained cooperation among the various stakeholders, as no one entity could fully mitigate the risks posed by these products. This report therefore calls for united, concerted action to eliminate the threat. The main recommendations are for evidence-based policies, strengthened regulatory systems and legal frameworks, sustainable recording systems, better coordination, heightened public awareness and increased international cooperation.

The report emphasizes the importance of aligning with existing WHO initiatives that aim to improve access to safe and quality-assured medical products, while also strengthening the ability of Member States to address SF medical products. These initiatives include, but are not limited to, the WHO Global Benchmarking Tool (GBT) which evaluates national regulatory systems, and the framework for WHO Listed Authorities (WLA).

Understanding of the public health and socio-economic impact of SF medical products has increased among various stakeholders who are actively collaborating to address the challenges. Progress in understanding the threat must be matched by sustainable, outcome-oriented actions, including strengthening regulatory frameworks, increasing the security of supply chains and investing in advanced technology for detection and verification. Campaigns to raise awareness in the public and among stakeholders are essential to inform patients, health-care professionals, government officials and the pharmaceutical industry. The campaigns should empower individuals to make informed decisions and facilitate the detection and recording of SF products.

While significant progress has been made, the report indicates that SF medical products will remain a risk, especially in LMIC. Commitment to addressing the issue must therefore be unwavering. The consequences of allowing such products to persist extend beyond individual patients to health-care systems, economies and global health security.

Tackling SF medical products is a shared responsibility that transcends borders and sectors. By maintaining a collective commitment to this cause, all stakeholders can ensure that patients receive safe, effective medical products, thereby safeguarding public health and patient safety for generations to come.



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