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WHO Member State Mechanism for Substandard/Falsified Medical Products (Mech)

Working Group (H) on Informal Markets

A Framework to Develop a Research Methodology Toolkit to Generate Evidence on Substandard and Falsified Medical Products in Informal Markets

NOTE: Informal Markets Workgroup reached consensus on this framework on November 8, 2024. The framework was adopted by the Member State Mechanism at its plenary on November 21, 2024.

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Executive Summary

Premise: This report describes a framework that supports the WHO Member State Mechanism on Substandard and Falsified Medical Products' (Mech) Informal Market Working Group's (IMWG) efforts to develop technical, research-based activities to better understand the distribution and impacts of substandard and falsified medical products[a] (SFMPs) in physical, virtual, and hybrid informal markets.

To advance this mission, Member States of the IMWG are requested to provide their feedback on the framework presented in this report. Following IMWG input and consensus on this framework, the next step will be to present it to the Mech for adoption.

Issue: Poor quality and/or falsified medicines threaten public health, ranging from insufficient effectiveness to adverse events, including death. Informal (unregulated) markets for medical products, both physical and virtual, may serve as a source of SFMPs. However, there is insufficient evidence about informal markets for medical products globally and the SFMPs distributed therein. Consequently, the scarcity of evidence on informal markets and distribution of medical products therein limits national regulatory agencies from undertaking effective interventions for minimizing the risks of SFMPs from informal markets.

Progress to Date: The IMWG has a four-phase roadmap to address informal market SFMPs. As part of Phase 3 of this roadmap (gathering evidence to address knowledge gaps and to help develop long-term strategies), a WHO workshop of independent experts was held to obtain their insights on informal markets and SFMPs around the world. Workshop discussions concluded that it is imperative to address the current lack of evidence through a standardized methodology toolkit to research, understand, and respond to SFMPs in informal markets for medical products.

Proposal for a Methodology Toolkit: A standardized research methodology toolkit will allow Member States to fill knowledge gaps by analyzing informal markets in their respective jurisdictions, and then respond according to the individual needs of the Member States. Thus, the IMWG, with the support of the WHO Mech and Secretariat, could develop a research methodology toolkit that can be tailored to specific Member State contexts so that evidence on informal markets can be generated at the national level. The framework presented in this report aims to guide the development of this toolkit for studying informal markets for medical products and the SFMPs therein, and synthesizes insights obtained through consultations with global experts from the WHO workshop.

Long-Term Strategy: Following consolidation of IMWG input for the framework in this report, the framework will be presented to the Mech before implementation. To execute this framework, the IMWG, with the help of the WHO Secretariat, should establish an independent technical expert committee to create the toolkit based on the framework (see Figure 1 and Appendix B). The resulting toolkit can then be implemented by the Member States and their research partners. The toolkit will provide guidelines for researchers to define and adapt country-specific research questions, thus empowering Member States to develop their own approaches for minimizing public health risk and harm.

Conclusion: The development of a globally standardized research methodology toolkit, to study SFMPs in physical, virtual, and hybrid informal markets for medical products, is necessary to generate empirical evidence to comprehend and respond to the SFMP crisis.

[a] WHO official definitions: **Substandard (**also called "out of specification") –authorized medical products that fail to meet either their quality standards or specifications, or both. **Falsified** – medical products that deliberately/fraudulently misrepresent their identity, composition, or source.

1. Status of the Informal Markets Workgroup

A. Background

In 2021, the WHO Member State Mechanism on Substandard and Falsified Medical Products (Mech) established the informal markets workgroup (IMWG) to develop strategies for National Regulatory Authorities to mitigate public health risks posed by the distribution of substandard and falsified medical products (SFMPs) through informal markets. To accomplish this task, the Member States of the workgroup adopted a roadmap with four high-level phases, under which the workgroup continues to develop specific activities. The four phases were to: 1) Define informal markets as it relates to medical products; 2) Understand the current knowledge base and knowledge gaps; 3) Gather evidence to address knowledge gaps and to help develop long term strategies; and 4) Develop strategies and policy recommendations for Member States to address the distribution of SFMPs in informal markets.

B. IMWG Roadmap Phases

The IMWG has completed the first two phases of the roadmap; this framework addresses the third phase. In Phase 1, the IMWG developed a consensus definition of *informal market* (as it relates to medical products). The working definition is: "A sector of national or local economy where:

1. the manufacture, import or export, distribution, sale, supply, or purchase of medical products takes place outside of the legal, regulatory, or administrative oversight of relevant public health or regulatory authorities;
2. the medical products have or have not been assessed for safety, efficacy, or quality by public health and regulatory authorities*; and
3. the aforementioned activities may be conducted by persons or entities with or without appropriate qualifications, and may take place in a physical, virtual, or a hybrid environment."

*Authorized products found on the informal market are not considered SF products per se.

In Phase 2, a comprehensive literature review[b] from 2003 to 2023 on the current knowledge base of informal markets around the globe and the SFMPs distributed therein was finalized. The review identified that currently, no holistic or systematic approach exists in researching informal markets and SFMPs. Specifically, it showed that although a disparate set of studies had attempted to document the status of the distribution of SFMPs through informal markets in low-, middle- and high-income countries, categorical research gaps persist. Similarly, a pilot survey that aimed to landscape the existing knowledge and intelligence gaps of informal markets for medical products was disseminated to regulators of Member States in the IMWG and identified a scarcity of evidence.

C. Roadmap Phase 3 Activity: WHO Expert Workshop

Phase 3 (gathering evidence to address knowledge gaps and to help develop long term strategies) is currently underway and is the subject of this document.[c] Due to the complexity of Phase 3, a WHO workshop of subject matter experts was held in December 2023 to gather insights from multiple disciplines, including: medicine regulation; methodological development; anthropology, sociology, and ethnology; analytical chemistry and toxicology; criminology, cybercrime, and organized crime; pharmacy; epidemiology, public health, health policy, and global health. At the end of the workshop discussions, it was concluded that the evidence base on informal markets and SFMPs is lacking, so a methodology toolkit to study this topic would be crucial to address persisting knowledge gaps. Thus, this framework synthesizes insights from the workshop experts to

[b] See WHO Executive Summary of this literature review on substandard and falsified medical products and informal markets.
[c] This framework does not discuss Phase 4 of the IMWG roadmap because the output of Phase 3 will provide the evidence base required to develop appropriate mitigation strategies tailored to Member States.

propose technical, research-based activities that Member States should undertake to gather evidence on informal markets and the SFMPs distributed therein.

2. Framework for Developing the Methodology Toolkit

A. Overview

This framework for the development of a research methodology toolkit has been informed by previous IMWG activities. Firstly, the literature review and pilot survey (IMWG Roadmap Phase 2) on this topic have identified knowledge gaps that this framework deems important to better understand. Secondly, experts from the WHO workshop consolidated their insights on filling knowledge gaps to guide the creation of this framework. This framework considers successes of two existing methodologies applied on national and global levels: the WHO/HAI toolkit on studying medicine prices, availability, and affordability, and the STARmeds toolkit that provides guidance on investigating medicine quality in Indonesia (Appendix A).

Both the WHO/HAI and STARmeds toolkits have inspired this framework, as they have indicated how successful methodologies could be developed to sustainably fill knowledge gaps. The most notable components from these toolkits that this framework aims to replicate include: 1) the standardization of research methods to improve data quality and comparability across studies; 2) global applicability to nations of any income-level and context; 3) development of methods to detect medicine quality; and 4) collaboration between government and non-governmental partners.

While WHO/HAI and STARMeds methodologies focus primarily on physical locations, they, nevertheless, provide a guide for the expert panel on how to develop a toolkit that must also apply to virtual and hybrid markets. Further, these methodologies are highlighted here only as examples of successful approaches; the expert panel should also consult other approaches to study physical, virtual, and hybrid markets.

Thus, by building on existing work while applying novel research techniques, this framework proposes addressing informal market SFMPs by developing a standardized research methodology toolkit that adopts best practices from existing approaches (including but not limited to WHO/HAI and STARMeds) for studying medicines. Overall, the resulting toolkit would be tailored to various Member State contexts to generate evidence on physical, virtual, and hybrid informal markets at the national level.

Furthermore, the methodology should prepare nations for responding to SFMPs in a present and future society that is increasingly reliant on online commerce for medical products. This framework acknowledges that jurisdictions around the world can differ widely in how informal markets manifest and the impact of SFMPs. Nations can vary in their populations' internet use, virtual and physical market presence, access to pharmacies in rural areas, and health system structure and regulatory robustness, all of which can influence the availability and utilization of medical products from unregulated sectors. Additionally, the dynamics between virtual and physical informal markets are distinct. Thus, a methodology toolkit will need to account for any differences among these sectors.

B. Methodology Toolkit Modules

The Guiding Pyramid (Figure 1) proposes four modules that may comprise the methodology toolkit to accomplish two overarching objectives: 1) Understand the scope of informal markets (physical and virtual) for medical products; and 2) how the SFMPs distributed therein are currently being addressed. Using the framework guide in Figure 1, a committee of experts should develop a methodology toolkit according to the modules (discussed below) to generate evidence on informal markets by encompassing the following key elements:

1. Modular but comprehensive
2. Scalable (local to national level)
3. Adaptable to country-level contexts

4. Utilizes existing resources and methods where available

The modules, starting with the base of the Guiding Pyramid (Figure 1), aim to guide prioritized research on informal markets for medical products. As the issue of medical products from informal markets is complex, broad, and multifaceted, a stepwise approach is warranted for a methodology toolkit. Therefore, the framework starts broadly, then narrows focus with each successive module. It begins with landscaping to gain baseline knowledge, then studying medical products in informal markets which involves identifying SFMPs. Subsequently, the impacts of these SFMPs can be assessed. Finally, the appropriate and effective mitigation strategies can then be analyzed.

As each module requires distinct research approaches, separate studies on each topic area within modules should be conducted. Informal markets should also be categorized by whether they take place physically or virtually or in hybrid environments, as their dynamics differ and will require targeted efforts (**Appendix B**). Research collaborations among academics, regulators, and other stakeholders are encouraged to develop and execute this methodology. The four modules are:

1. Module 1 – Landscaping Physical and Virtual Informal Markets

   This module is intended to get a baseline understanding of informal markets for medical products in a specified jurisdiction. Hence, a landscape analysis aims to drive research directions by identifying and characterizing the factors that lead to the existence and operation of informal markets. The topic areas suggested to be investigated are necessarily broad to allow for the gathering of key evidence to fill persisting knowledge gaps, including:

   i. Demographics and geography (e.g., who is operating in or using the informal markets, and physical and virtual locations).
   ii. Supply chains, stakeholders, and the factors that enable them (such as financial incentives).
   iii. Structure and function of informal markets (e.g., what could be considered an informal market for medical products in a country, why do the informal markets exist, and how do they operate).

   The landscaping module should allow for research investigations to be as broad or focused as needed, to account for resource availability and research needs. Fundamentally, all landscaping analyses will require a systematic approach to defining the research question, method development, data collection, and analysis.[1]

2. Module 2 – Understanding Medical Products in Informal Markets and Identifying SFMPs

   Module 2 should build on the landscaping module by detailing approaches to investigate the medical products that are distributed, sold, and bought through informal markets. This module should map medical products (including pharmaceutical drugs, medical devices, and biologics) distributed through physical and virtual informal markets with a focus on the types, prices, and quality of medical products, the dynamics of demand and supply for these medical products, and the accessibility of these products relative to their formal market counterparts.

   Other crucial areas of investigation include identifying SFMPs (by studying medical product quality), evaluating patterns in drug quality issues, and estimating the prevalence of medical products that are substandard and/or falsified. As the medicine sampling and detection methods can be resource-intensive, this module should consider approaches that are appropriate for settings with varying resource availability.

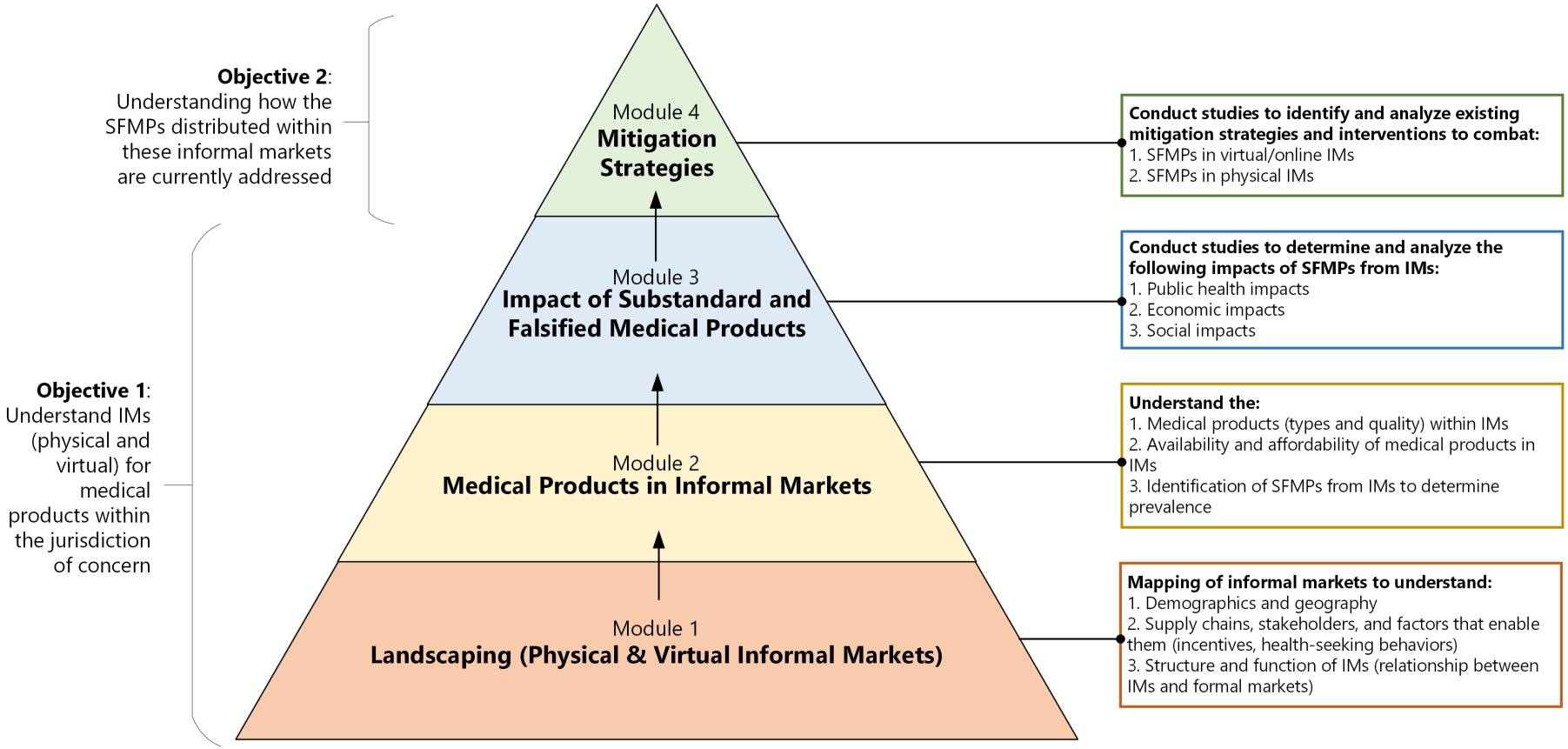

Figure 1: Guiding Pyramid containing proposed modules of a methodology toolkit to generate evidence on Informal Markets for Medical Products.

3. Module 3 – Understanding Health, Economic, and Social Impacts of SFMPs from Informal Markets

   Following the determination of SFMP prevalence rates in informal markets from Module 2, the scope of the issue can be identified. Thus, this module focuses on the consequences of informal market SFMPs and should develop methods to measure the health, economic, and social impacts of these SFMPs.

   Studying the impacts of informal market SFMPs is crucial to filling knowledge gaps, as the current evidence base on these impacts is lacking and does not differentiate between SFMPs that emerge from formal or informal markets. Furthermore, it is helpful to understand how SFMPs impact population health to effectively design future actions that respond to informal market SFMPs.

   Some of the ways that these impacts can be measured include:

   i. Assessing clinical outcomes (e.g., treatment failure, death, and adverse events) in patients using medical products from informal markets compared to those using products from formal markets.
   ii. Determining costs to patients and healthcare systems due to ineffective treatment from SFMPs.

   As measuring the impacts of SFMPs is complex, capturing clinical outcomes will require close cooperation with regulators, health care professionals, and pharmacovigilance teams.

4. Module 4 – Researching Effective Prevention and Mitigation Strategies

   The final module covers the research agenda for identifying and evaluating existing mitigation strategies and interventions to address informal market commerce for medical products and the associated SFMPs. To prevent SFMPs, the effective and ineffective methods that are currently being used to tackle them need to be understood. This knowledge should be harnessed to develop methods that are most likely to be successful for Member States by avoiding limitations in approaches while maintaining best practices.

   Thus, Module 4 should develop methods to identify and assess the relative effectiveness of the various interventions currently being used by Member States to address virtual and physical informal market activity and SFMPs. The types of interventions that can be assessed include:

   i. Formalization of informal vendors, e.g., through licensing and certification programs.
   ii. Enforcement mechanisms.
   iii. Regulatory strategies.
   iv. Track and trace systems.
   v. Communication and consumer-awareness strategies.

   At the conclusion of Module 4, after individual country-level assessments of current mitigation strategies have been conducted, these findings should be synthesized in a global analysis. This global overview should highlight the strategies that have been the most successful and the most limiting across the world, while accounting for the different contexts in which they are applied.

3. Conclusion and Next Steps

The development of a global, standardized methodology toolkit to study informal markets for medical products is required to generate sufficient evidence to empirically understand the issue, and to ultimately develop strategies to protect public health. The toolkit will allow Member States and non-governmental stakeholders to apply focused efforts to their local jurisdictions to learn more about informal markets and SFMPs. Further, the results of these efforts can also foster international collaboration as research findings across countries and regions can help inform solutions to combat the SFMP crisis.

To accomplish this, the Member States of the IMWG are requested to provide their review and consultation on this framework draft before presentation to the Mech and the Steering Committee.

The high-level next steps and outcomes for this framework are as follows:

A. Adoption of Framework to Create a Methodology Toolkit:

1. IMWG consultation and consensus on the framework.
2. Presenting the framework to WHO Mech and its Steering Committee.

B. To Execute the Development of a Methodology:

1. Establish a panel of independent, external technical experts.
2. Secure funding to facilitate the work of the panel to develop, pilot, and finalize a methodology toolkit, with regular updates to the WHO Mech Steering Committee and the IMWG.

C. Desirable Outcomes of Methodology Toolkit:

1. The WHO Mech to review and adopt the methodology toolkit generated by the expert panel.
2. Member States and other stakeholders implement studies based on the methodology toolkit to generate national-level evidence on informal markets.
3. Use the evidence generated to address the distribution of SFMPs via informal markets by communicating research findings to the public, regulators, and policy makers.

Appendix A: Previous Methodology Successes

This framework strongly supports learning from and adopting successful elements from other similar methodologies, and to adopt best practices from two successes listed here as examples. Additional methodologies, particularly those focusing on virtual or hybrid markets, should also be consulted by the expert panel.

1. World Health Organization (WHO) and Health Action International (HAI) Methodology for Medicine Availability and Pricing

   The WHO/HAI methodology on measuring medicine prices, availability, affordability and price components was an innovative, standardized survey methodology project supported by a resolution of WHO Member States at the 54th World Health Assembly in 2001.[2] Since its development in 2003, this methodology that provides guidance to national policymakers and other stakeholders for the measurement of medicine price components has enabled more than 100 surveys in over 50 countries in all regions of the world to have conducted the recommended, standard method. These medicine price surveys have contributed to greater price transparency, helping to expose numerous issues around poor access to medicines due to high prices and low availability.[3] Ultimately, the surveys contribute to the overarching goal of encouraging Member States to action such evidence by making medicines more available and affordable, thereby improving population health.[3]

   Although the WHO/HAI methodology has been primarily deployed in low and middle-income countries to collect medicine price and availability information, the surveys have been conducted in high-income countries as well, including Saudi Arabia and the United States.[3] Thus, the methodology has demonstrated universal applicability across countries of varying country contexts.

2. STARmeds Methodology for Tracking Substandard and Falsified Medicines

   Systematic Tracking of At-Risk Medicines (STARmeds) is a 3-year investigation of medicine quality in Indonesia that started in 2020, with the primary goal of protecting society from the dangers of SFMPs.[4] The research collaboration brings together experts from academic institutions in Indonesia, the United Kingdom, and The Netherlands, and has led to the generation of a toolkit that helps countries to understand and measure the problem of SFMPs, including approaches to estimating SFMP prevalence.

   As STARmeds has demonstrated success on a national level in developing methods for measuring SFMP impacts to better understand medicine quality in Indonesia, applying numerous components of this study to a global methodology could be highly beneficial in standardizing robust, existing approaches.

   Overall, the desirable methodology components present in the WHO/HAI and STARmeds methodologies that this framework encourages for an Informal Markets for Medical Products Methodology to replicate and build upon include:

   - WHO/HAI (Drug Availability, Affordability, and Pricing)
     - Global applicability to nations of any income-level and context.
     - Standardization.
     - Collaboration with nongovernmental organizations and other stakeholders to develop a methodology that aims to support Member States.
   - STARmeds (Drug Quality)
     - Methods to understanding SFMP prevalence.
     - Development of fieldwork and medicine sampling methods to assess medicine quality.

Appendix B: Methodological Considerations for Toolkit

Supplement Table 1 below summarizes subject matter expert input on methodological considerations for the four proposed modules of the methodology toolkit. Since each module comprises of research needs for all types of informal markets, the table entails the appropriate considerations for both virtual and physical locations.

Supplemental Table 1: Methodological considerations for each research module within a framework for generating national-level evidence on informal markets for medical products, and the SFMPs within them.

Module #	Module Name	Importance	Method Considerations for Virtual and Physical Markets		
			Physical & Virtual Markets	**Physical Markets**	**Virtual Markets**
1	**Landscaping of Informal Markets for Medical Products**	It is crucial to fundamentally understand the structure and function of the informal markets for medical products in a jurisdiction before actions can be taken to address them.	Develop methods to understand the scope, structure, and function of informal markets. For instance, determine the: • Demography of stakeholders (i.e., buyers, sellers, distributors) • Drivers of informal markets, including economic incentives for selling/buying medical products • Patients' health-seeking behaviors • Examination of the options available to patients/consumers • Size of the informal market • Sources of medical products and supply chains • Intersection of informal and formal markets (e.g., accessibility of products in informal vs. formal markets)	Map geography of vendor locations at the city, regional, or national level, using geo-coding, and physical verification. *Identifying Stakeholders* • Social network analysis • Develop social biographies for mobile vendors • Key informant interviews • Working group discussions • Qualitative studies (using focus groups) *Identifying Market Size* • Stratified sample analysis (e.g., urban vs. rural) *Identifying Supply Chain Movement* • Track medical products in traditional supply chains *Estimate % of Population Using Physical Markets* • Stratified cluster sampling • Surveying	*Identify Virtual Actors and Digital Supply Chains* • Comprehensively map online ecosystems, using: 1. Data mining (Automated methods for structured and unstructured data) 2. Web forensics *Estimate % of Population Using Virtual Markets* • Web forensics (search engine optimization) • Google trends analysis *Identify Market Activities* • Analyze the Terms & Conditions of licenses for online services • Analyze available legal documentation *Identify Sources of Medicines* • Test buys • Straw buys

Module #	Module Name	Importance	Method Considerations for Virtual and Physical Markets		
			Physical & Virtual Markets	**Physical Markets**	**Virtual Markets**
				Identify Market Activities • Key informant interviews to gather in-depth information from vendors • Observational studies in physical markets	
2	**Types and Quality of Medical Products in Informal Markets**	Determining the types of medical products distributed in informal markets and their accessibility may be vital to understanding what products are in most demand and supply. It is also necessary to understand the quality of these products, so that SFMPs can be detected.	Develop methods to determine: • Types of medical products (drugs, medical devices, vaccines and other biologics, etc.) in informal markets • Availability of these products • Affordability – assess prices of medical products in informal markets compared to formal/regulated markets Develop methods to determine the quality of medical products circulating in informal markets to: • Identify SFMPs • Measure the prevalence of SFMPs • Identify and analyze patterns in drug quality issues When deciding on quality detection approaches, consider approaches adaptable for varying resource levels: • Methods for collecting medical product samples from informal market settings; and • Use of appropriate techniques (e.g., visual inspection, NMR, TLC, etc.) to assess product quality	*Identifying Medical Product Prices* • Mystery shopping • Observational studies *Identifying Medical Product Types* • Surveying (in-person) *Identifying and Engaging with Actors* • Identify local contacts and consumers (Conduct randomized field surveys using mystery shoppers) • Working-group discussions • Key informant interviews • Invite local organization members to be co-researchers *Obtaining Medicine Samples to Quality Test* • Mystery shopping	*Identifying Medical Product Types, Prices, and Availability* • Online browsing • Web data extraction • Google search (structured search queries) • Data-mining methodologies *Identifying Actors* • Working-group discussions (Including with technology companies that serve as platforms for online informal market activity, civil society, researchers, law enforcement) *Obtaining Medicine Samples to Quality Test* • Test buy from virtual platform

Module #	Module Name	Importance	Method Considerations for Virtual and Physical Markets		
			Physical & Virtual Markets	**Physical Markets**	**Virtual Markets**
3	**Impact of SFMPs in Informal Markets**	To design appropriate actions to address SFMPs, it is necessary to identify SFMPs and understand their public health, economic, and social consequences first.	Following determination of SFMP prevalence which indicates the scope of the issue, develop methods to assess the impacts of SFMPs for a Member State. Specifically, identify public health, economic, and social impacts for patients consuming medical products from formal vs. informal markets by: • Comparing clinical outcomes (e.g., treatment failure, mortality, morbidity), *adverse events, and other relevant measures • Determining costs to the patient and healthcare systems resulting from potentially substandard treatment due to SFMPs *Capturing adverse events arising from products sourced through informal markets will likely require close cooperation with regulators, pharmacovigilance teams, and health care professionals, due to the complexity of establishing SFMP impacts.		
4	**Interventions and Mitigation Strategies to Limit Harm of SFMPs from Informal Markets**	Combating SFMP distribution in informal markets requires an assessment of both effective and ineffective methods that are currently employed to tackle them. This knowledge should then be harnessed to develop methods that are most likely to be successful for Member States.	Determine current interventions, including: • Formalization, e.g., through licensing and certification programs • *Enforcement mechanisms • *Regulatory strategies • Track and trace systems • Communication approaches • Consumer-awareness strategies Identify other mitigation strategies by meeting with multiple stakeholders, including: 1. †Regulators 2. †Law enforcement 3. Patient organizations 4. Community leaders 5. Informal market actors * While enforcement and regulatory actions will be necessary to understand, the unintended consequences of such actions on the general population (particularly in underserved communities) merits further, careful examination. † An enhanced and more structured exchange of intelligence between regulatory authorities and law enforcement is vital to understanding current strategies and focusing effort where risk is greatest. These exchanges should involve gathering insights on the informal marketplace and consumer behaviors.		

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